State of Iowa

Iowa Administrative Code Supplement

Biweekly
April 2, 2014

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ADMINISTRATIVE CODE EDITOR

Published by the
STATE OF IOWA
UNDER AUTHORITY OF IOWA CODE SECTION 17A.6

The Iowa Administrative Code Supplement is published biweekly pursuant to Iowa Code section 17A.6. The Supplement contains replacement chapters to be inserted in the loose-leaf Iowa Administrative Code (IAC) according to instructions included with each Supplement. The replacement chapters incorporate rule changes which have been adopted by the agencies and filed with the Administrative Rules Coordinator as provided in Iowa Code sections 7.17 and 17A.4 to 17A.6. To determine the specific changes in the rules, refer to the Iowa Administrative Bulletin bearing the same publication date.

In addition to the changes adopted by agencies, the replacement chapters may reflect objection to a rule or a portion of a rule filed by the Administrative Rules Review Committee (ARRC), the Governor, or the Attorney General pursuant to Iowa Code section 17A.4(6); an effective date delay imposed by the ARRC pursuant to section 17A.4(7) or 17A.8(9); rescission of a rule by the Governor pursuant to section 17A.4(8); or nullification of a rule by the General Assembly pursuant to Article III, section 40, of the Constitution of the State of Iowa.

The Supplement may also contain replacement pages for the IAC Index or the Uniform Rules on Agency Procedure.

INSTRUCTIONS

FOR UPDATING THE

IOWA ADMINISTRATIVE CODE

Agency names and numbers in bold below correspond to the divider tabs in the IAC binders. New and replacement chapters included in this Supplement are listed below. Carefully remove and insert chapters accordingly.

Editor's telephone (515)281-3355 or (515)242-6873

Iowa Finance Authority[265]

Replace Chapter 44

Ethics and Campaign Disclosure Board, Iowa[351]

Replace Chapter 4
Replace Chapter 9

Inspections and Appeals Department[481]

Replace Chapter 58

Public Health Department[641]

Replace Analysis
Replace Chapter 41
Replace Chapter 95
Replace Chapter 127
Replace Chapters 131 and 132
Insert Reserved Chapter 205 and Chapter 206

Professional Licensure Division[645]

Replace Chapter 300
Replace Chapter 303

Pharmacy Board[657]

Replace Chapter 4
Replace Chapter 10

Transportation Department[761]

Replace Analysis
Replace Chapter 162 with Reserved Chapter 162

CHAPTER 44
IOWA AGRICULTURAL DEVELOPMENT DIVISION

265—44.1(175) General.

44.1(1) *Description of Iowa agricultural development division (IADD) board.* The IADD board consists of five members appointed by the governor. The executive director of the Iowa finance authority or the executive director's designee shall serve as an ex officio nonvoting member. Members are appointed for staggered six-year terms. The appointed members shall elect a chairperson and vice chairperson annually, and other officers as the appointed members determine. The executive director of the authority may organize the division and employ necessary qualified personnel.

44.1(2) *General course and method of operations.* The IADD board generally meets on a monthly basis or at the call of the chairperson or whenever two appointed members so request. The purpose of the meetings shall be to review progress in implementation and administration of programs, to consider and act upon proposals for assistance, and take other actions as necessary and appropriate.

44.1(3) *Location where public may submit requests for assistance or obtain information.* Requests for assistance or information should be directed to the Iowa Finance Authority, 2015 Grand Avenue, Des Moines, Iowa 50312; telephone (515)725-4900. Requests may be made personally, by telephone, U.S. mail or any other medium available, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Special arrangements for accessibility to the authority at other times will be provided as needed.

[**ARC 1112C**, IAB 10/16/13, effective 9/26/13; **ARC 1400C**, IAB 4/2/14, effective 5/7/14]

265—44.2(175) Definitions. For any terms not defined in this rule, refer to Iowa Code section 175.2.

"Act" means Iowa Code chapters 16 and 175.

"Agricultural asset" means agricultural land, agricultural improvements, depreciable agricultural property, crops or livestock used for farming purposes.

"Agricultural asset transfer agreement" means any commonly accepted written agreement which specifies the terms of the transfer of operation of the agricultural asset. The agreement may be made on a cash basis or a commodity share basis.

"Agricultural improvements" means any improvements, buildings, structures or fixtures suitable for use in farming which are located on agricultural land. "Agricultural improvements" includes a single-family dwelling located on agricultural land which is or will be occupied by the beginning farmer and structures attached to or incidental to the use of the dwelling.

"Agricultural land" means land suitable for use in farming and which is or will be operated as a farm.

"Application" means a completed instrument on a form approved by IADD.

"BFCF" means beginning farmer custom farming tax credit program.

"BFCF eligible applicant" means an individual, partnership, family farm corporation or family farm limited liability company that has a net worth of not more than the maximum allowable net worth. The applicant must also satisfy all of the criteria contained in Iowa Code sections 175.36A and 175.38 and the provisions of these rules relating to recipient eligibility as they relate to who operates or will operate a farm.

"BFLP" means beginning farmer loan program.

"BFLP eligible applicant" means an individual who has a net worth of not more than the maximum allowable net worth. The applicant must also be a beginning farmer, as defined in Iowa Code section 175.12, who satisfies all of the criteria contained in the Act and provisions of these rules relating to recipient eligibility as they relate to who operates or will operate a farm.

"BFTC" means beginning farmer tax credit program.

"BFTC eligible applicant" means an individual, partnership, family farm corporation or family farm limited liability company that has a net worth of not more than the maximum allowable net worth. The applicant must also satisfy all of the criteria contained in Iowa Code sections 175.36A and 175.37 and the provisions of these rules relating to recipient eligibility as they relate to who operates or will operate a farm.

"Bond purchaser" means any lender or any person, as defined in Iowa Code section 4.1(20), who purchases an authority bond under the individual agricultural development bond program.

"Cash basis agreement" means an agreement whereby operation of the agricultural asset is transferred via a fixed cash payment per annum.

"Commodity share basis" means an agreement whereby operation of the agricultural asset is transferred via a risk-sharing mechanism, whereby the agricultural asset owner receives a portion of the production and payment for use of the agricultural asset.

"Custom farming contract" means any commonly accepted written contract which specifies the terms of the work to be performed by the beginning farmer for an Iowa landowner or tenant or livestock owner. The contract must provide for the production of crops or livestock located on agricultural land. The taxpayer will pay the BFCF eligible applicant on a cash basis, and the total amount paid must equal at least $1,000. The contract must be in writing for a term of not more than 12 months. A contract is not allowed if the taxpayer and BFCF eligible applicant are: persons who hold a legal or equitable interest in the same agricultural land or livestock; related family members, such as spouse, child, stepchild, brother, or sister; or partners in the same partnership which holds a legal or equitable interest.

"Farm" means a farming enterprise which is generally recognized as a farm rather than a rural residence.

"Farming" means the cultivation of land for the production of agricultural crops, the raising of poultry, the production of eggs, the production of milk, the production of fruit or other horticultural crops, grazing, the production of livestock, aquaculture, hydroponics, the production of forest products, or other activities designated by the authority.

"IADD" means the Iowa agricultural development division of the Iowa finance authority.

"Lender" means any regulated bank, trust company, bank holding company, mortgage company, national banking association, savings and loan association, life insurance company, state or federal governmental agency or instrumentality, or other financial institution or entity authorized and able to make mortgage loans or secured loans in this state.

"Low-income farmer" means a farmer who cannot obtain financing to purchase agricultural property without the assistance of an LPP loan with the authority.

"LPP" means loan participation program.

"LPP eligible applicant" means an individual who has a net worth of not more than the maximum allowable net worth. The applicant must be a low-income farmer who satisfies all of the criteria contained in the Act and the provisions of these rules relating to recipient eligibility as they relate to who operates or will operate a farm.

"LPP loan" means the "last-in/last-out" loan participation requested by the lender from the authority.

"Maximum allowable net worth" for calendar year 2013 is $691,172. The maximum allowable net worth for each calendar year shall be increased or decreased as of January 1 of such calendar year by an amount equal to the percentage increase or decrease (September to September) in the United States Department of Agriculture "Index of Prices Paid for Commodities and Services, Interest, Taxes, and Farm Wage Rates" reported as of October 1 of the immediately preceding calendar year.

"Net worth" means total assets minus total liabilities as determined in accordance with generally accepted accounting principles with appropriate exceptions and exemptions reasonably related to an equitable determination of the net worth of the individual, partnership, limited liability company or corporation. Assets shall be valued at fair market value.

"Participated loan" means a loan, any portion of which is participated to the authority by the lender.

"Projected gross income" means the total of all nonfarm income plus gross farm revenues which include revenue from cash sales, inventory and receivable charges, crops, livestock products, government program payments, and other farm income received by the borrower during the next calendar year.

"Term debt coverage ratio" means the total of net farm income from operations plus total nonfarm income plus depreciation/amortization expense plus interest on term debt plus interest on capital leases minus total income tax expense minus withdrawals for family living multiplied by 100 and divided by the sum of annual scheduled principal and interest payments on term debt and the annual scheduled principal and interest payments on capital leases. The ratio provides a measure of the ability of the borrower to

cover all term debt and capital lease payments. The greater the ratio over 100 percent, the greater the margin to cover the payments.

"Total assets" means all assets including but not limited to cash, crops or feed on hand, livestock held for sale, breeding stock, marketable bonds and securities, securities not readily marketable, accounts receivable, notes receivable, cash invested in growing crops, net cash value of life insurance, machinery, equipment, cars, trucks, farm and other real estate including life estates and personal residence, value of beneficial interest in a trust, government payments or grants, and any other assets.

"Total assets" shall not include items used for personal, family or household purposes by the applicant; but in no event shall any property be excluded, to the extent a deduction for depreciation is allowable for federal income tax purposes. All assets shall be valued at fair market value by the lender. The value shall be what a willing buyer would pay a willing seller in the locality. A deduction of 10 percent may be made from fair market value of farm and other real estate.

"Total liabilities" means all liabilities including but not limited to accounts payable, notes or other indebtedness owed, taxes, rent, amount owed on any real estate contract or real estate mortgage, judgments, accrued interest payable, and any other liabilities. Liabilities shall be determined on the basis of generally accepted accounting principles.

In only those cases where the liabilities include an amount for deferred tax liability that causes the applicant's net worth to change from exceeding the maximum allowable net worth to an amount no greater than the maximum allowable net worth, the applicant is required to have a certified public accountant prepare the financial statement and provide supporting calculations and documentation acceptable to the board.

"Veteran" means the same as defined in Iowa Code section 35.1.

[**ARC 1112C**, IAB 10/16/13, effective 9/26/13; **ARC 1400C**, IAB 4/2/14, effective 5/7/14]

265—44.3(175) General recipient eligibility.

44.3(1) *Residence.* The eligible applicant must be a resident of Iowa. The project must be located in Iowa.

44.3(2) *Training and experience.* The eligible applicant must have documented to the satisfaction of the authority sufficient education, training, and experience for the anticipated farm operations.

44.3(3) *Access to capital.* The eligible applicant must demonstrate to the satisfaction of the authority access to the following as may be needed: adequate working capital, farm machinery, livestock, and agricultural land.

[**ARC 1112C**, IAB 10/16/13, effective 9/26/13; **ARC 1400C**, IAB 4/2/14, effective 5/7/14]

265—44.4(175) Beginning farmer loan program.

44.4(1) *Individual agricultural development bond program description.* This program is intended to allow BFLP eligible applicants to obtain lower interest rate loans for qualified purposes by obtaining loan funds from the proceeds of a tax-exempt bond issued by the authority and purchased by the bond purchaser. The authority will enter into a loan agreement with the BFLP eligible applicant and assign that BFLP loan to the bond purchaser. At the same time, the authority will issue a tax-exempt bond in the amount of the BFLP loan, and the bond purchaser will purchase that bond, which is used to fund the BFLP loan assigned to the bond purchaser. The bond which is issued by the authority and purchased by the bond purchaser is a nonrecourse obligation. The only security for the bond purchaser is the underlying security on the assigned BFLP loan.

44.4(2) *Application procedures.* The BFLP eligible applicant may apply for a BFLP loan with any bond purchaser. Any BFLP loan approved will be assigned to that bond purchaser. BFLP loan eligibility is determined by the requirements of the Act and the rules of the authority.

a. If a BFLP eligible applicant meets the BFLP loan eligibility requirements, the decision on whether to enter into the loan agreement is between the BFLP eligible applicant and the bond purchaser. The BFLP eligible applicant and bond purchaser must agree on the terms of the loan, such as interest rates, length of loan, down payment, service fees, origination charges and repayment schedule. The terms may not be more onerous than terms charged to similar customers for similar loans, taking into account the tax-exempt nature of interest on the BFLP loan.

b. Following completion of the BFLP loan application by the BFLP eligible applicant and approval by the bond purchaser, the BFLP loan application must be submitted to the authority for its review and approval.

c. The authority's review will include, but not be limited to, whether:

(1) The BFLP loan applicant is a BFLP eligible applicant;

(2) The BFLP loan proceeds will be used for a qualified purpose under the Act, rules of the authority, and the Internal Revenue Code and IRS regulations relating to private activity bonds;

(3) The terms of the BFLP loan comply with these rules; and

(4) The bond purchaser meets the definition of a lender or bond purchaser.

d. The authority may require that the bond purchaser furnish any information which the authority deems necessary to determine whether the bond purchaser qualifies as either a lender or bond purchaser. If the authority determines that the bond purchaser does not qualify as either a lender or bond purchaser, it may deny the application.

e. Following approval and issuance of the bond, the authority will enter into a loan agreement with the BFLP eligible applicant and then assign the BFLP loan without recourse to the bond purchaser. The authority may charge fees as needed to defray its costs for processing the BFLP loan and bond.

44.4(3) *Issuance of bond.* All bonds issued by the authority will conform to all applicable requirements of the United States Internal Revenue Code of 1986 as amended, and its regulations.

a. Public hearings may be held by a staff member, board member of the IADD, an appointee or employee of the authority, or other qualified hearing officer.

b. Following approval of the BFLP loan by the authority, and upon completion of a public hearing and approval of the bond issuance by the governor or another elected state official designated by the governor, the authority will issue a bond, to be purchased by the bond purchaser, in the amount and fitting the terms of the BFLP loan to the BFLP eligible applicant. The principal and interest on the bond are a limited obligation payable solely out of the revenues derived from the BFLP loan to the BFLP eligible applicant and the underlying collateral or other security furnished by or on behalf of the BFLP eligible applicant. The bond purchaser shall have no other recourse against the authority. The principal and interest on the bond do not constitute an indebtedness of the authority or a charge against its general credit or general fund.

44.4(4) *Priority of applications.* Applications shall be processed by the authority on a first-come, first-served basis, based upon the receipt of all completed documents by the authority.

44.4(5) *Procedures following bond issuance.* No bond proceeds may be used for a nonqualified purpose or by a nonqualified user. Following disbursement of the bond proceeds, the bond purchaser and BFLP eligible applicant may be required to certify to the authority that the proceeds were used by the BFLP eligible applicant for a qualified purpose.

44.4(6) *Assignment of BFLP loans by bond purchasers.* A bond purchaser may assign a BFLP loan in whole or in part to any person, as defined in Iowa Code section 4.1(20). Serving of the BFLP loan may also be assigned. The authority must be notified in writing prior to assignment of the BFLP loan.

44.4(7) *Assumption of BFLP loans, substitution of collateral and transfer of property.* BFLP loans may not be assumed without the prior approval of the authority, and then only if the purchaser of the property is a BFLP eligible applicant for a BFLP loan. Equipment and other depreciable property may be exchanged or traded for similar property, and other property such as breeding livestock may be added or substituted as collateral at the discretion of the bond purchaser without the prior approval of the authority.

44.4(8) *Right to audit.* The authority shall have at any time the right to audit the records of the bond purchaser and the BFLP eligible applicant relating to the BFLP loan and bond to ensure that bond proceeds were used for a qualified purpose by a qualified user.

[**ARC 1112C**, IAB 10/16/13, effective 9/26/13; **ARC 1400C**, IAB 4/2/14, effective 5/7/14]

265—44.5(175) Loan participation program.

44.5(1) *Program summary.* The loan participation program is intended to assist lenders and LPP eligible applicants (hereinafter referred to as "borrower(s)") by purchasing a portion of a loan made by a lender to a borrower for the purchase of agricultural property.

a. Supplement to borrower's down payment. The LPP loan can be used to supplement the borrower's down payment so that the borrower can more readily secure a loan (the "participated loan") from a lender.

b. Last-in/last-out collateral position. The program enables lenders to request a "last-in/last-out" LPP loan from the authority. The lender, on behalf of the borrower, shall apply for the LPP loan on application forms provided by the authority.

c. Lender's certification. The lender and the borrower shall certify that the information included in the application and any other documents submitted for consideration is true and correct to the best of their knowledge.

d. LPP loan in conjunction with BFLP loan. The loan participation program may be used in conjunction with the authority's beginning farmer loan program, provided the borrower meets the criteria for both programs.

44.5(2) *Underwriting criteria.* Commercial underwriting criteria will be used as determined by the authority.

44.5(3) *Eligible projects and activities.*

a. Use of project. LPP loans must be for new purchases or new construction. Assets purchased or constructed with LPP loan funds must be used for agricultural purposes.

b. Agricultural land. The participated loan can be used for the purchase of agricultural land, which may include small acreages on which sufficient agricultural improvements are located to conduct a livestock operation. If a house is located on land for which an LPP loan is requested, an appraisal of the house will be made. If the appraised value of the house exceeds 50 percent of the appraised value of the property or total collateral, then the property will not be eligible for an LPP loan.

c. Agricultural improvements. The participated loan can be used for the construction or purchase of improvements located on agricultural land (which is suitable for use in farming). Examples of such improvements include, but are not limited to, the following: confinement systems for swine, cattle, or poultry; barns or other outbuildings; and grain storage facilities and silos.

d. Livestock used for breeding purposes. The participated loan can be used for the purchase of livestock for which an income tax deduction for depreciation is allowed in computing state and federal income taxes.

e. Machinery and equipment. The participated loan can be used for the purchase of agricultural machinery and equipment for which an income tax deduction for depreciation is allowed in computing state and federal income taxes. This machinery and equipment must be used in the borrower's farming operation.

f. Interim financing by lender. Interim financing by the lender may be done.

44.5(4) *Ineligible projects and activities.* The following program activities are ineligible:

a. Refinancing of existing debt. Refinancing of existing debt or new purchases which have been incurred by the borrower more than 60 days prior to approval of the LPP loan by the authority.

b. Financing personal expenses. Financing personal or living expenses and working capital to purchase such items as feed, seed, fertilizer, fuel, and feeder livestock.

c. Down payment funds for contract sale. Down payment for a contract sale, or in connection with a loan from a nonregulated lender.

44.5(5) *Program parameters.*

a. Purchase price impact. Maximum LPP loan amount is the lesser of:

(1) Thirty percent of the purchase price; or

(2) $150,000.

b. LPP loan terms. The authority has established the following with respect to LPP loan terms:

(1) The maximum amortization period for the LPP loan is 7 years for depreciable agricultural property. When a participated loan is made for livestock, the length of the LPP loan is restricted to the expected useful life of the animal being purchased.

(2) LPP loan payments on participated real estate loans will be equally amortized for the term of the LPP loan, but shall not exceed a 20-year amortization, including a 10-year term with balloon payment

and the balance of the LPP loan paid in full by the end of the tenth year. If utilized in conjunction with federal programs, the amortization will be consistent with federal rules.

(3) The IADD board will set the interest rate on the LPP loan.

c. LPP loans outstanding. Loans under the program may be issued more than once, provided that the outstanding LPP loan totals do not exceed $150,000 to any single borrower.

44.5(6) *LPP loan application procedures.*

a. Financial statement. Lenders may use their own form of financial statement and other forms deemed necessary and appropriate to document the eligibility of the borrower and the borrower's ability to make principal and interest payments. A copy of the borrower's most current financial statement (generally prepared one month preceding application submission), the prior two years' financial statements, and a projected after-closing financial statement must be submitted with the application.

If the borrower or the borrower's spouse is involved in a business, partnership, limited liability company, or corporation, either related or unrelated to the borrower's farming operation, a financial statement from this entity must also be submitted with the application.

b. Income statement. A copy of the borrower's prior three years' federal income tax returns (if available) shall be submitted.

c. Background letter. The application will also include a background letter on the borrower, documenting to the satisfaction of the authority sufficient training, experience and access to capital.

d. Credit evaluation. The lender will submit a credit evaluation of the project for which an LPP loan is sought. The lender will evaluate the borrower's net worth and ability to pay principal and interest and certify the sufficiency of security for the participated loan. The authority will review the application and make its own credit evaluation prior to issuance of an LPP loan. Such evaluation will center on whether:

(1) The borrower adequately demonstrates the ability to service the debt requirements of the participated loan based on cash flow, net worth, down payment, and collateral pledged for the participated loan.

(2) The borrower provides sufficient collateral to adequately secure the participated loan and keep the participated loan collateralized throughout its term.

(3) The lender certifies that all of the borrower's debts will be current at the time the participated loan is closed.

(4) The applicant is a low-income farmer who cannot obtain financing to purchase agricultural property without the assistance of an LPP loan with the authority.

(5) The lender certifies that no other private or state credit is available or can be obtained in a timely manner.

e. Processing LPP loan applications. Applications for the program will be taken and processed by the authority on a first-come, first-served basis. The authority reserves the right to change the program or terminate the approval of LPP loans under the program at any time. Grounds for termination/suspension of the program would include, but not be limited to, reaching the maximum allowable limit for total outstanding LPP loans as established by the authority or changing the program by order of the Iowa general assembly or by rules promulgated by the authority.

f. Security for participated loans and use of security documents. The lender shall take any security, cosignatures, guarantees or sureties that are deemed necessary for any participated loan. Any guarantee of repayment or pledge of additional collateral required by the lender to secure the participated loan shall secure the entire participated loan.

g. Recording documents and fees. Any recording or filing fees or transfer taxes associated with the participated loan will be paid by the borrower or lender and not the authority. Also, the authority will have no responsibility with respect to the preparation, execution, or filing of any declaration of value or groundwater hazard statements.

44.5(7) *Loan administration procedures.*

a. Lender's responsibilities. The lender is responsible for servicing the participated loan following accepted standards of loan servicing and for transferring LPP loan payments to the authority.

(1) At the request of IADD, the lender shall:

1. On an annual basis, provide the authority with copies of a current financial statement or a current tax return, or both.

2. Provide copies of insurance to the authority with the lender named as loss payee. The lender will apply payments to the participated loan on a pro-rata basis.

(2) The lender shall not, without prior consent of the authority:

1. Make or consent to any substantial alterations in the terms of any participated loan instrument;

2. Make or consent to releases of security or collateral unless replaced with collateral of equal value on the participated loan;

3. Use the collateral purchased with funds from the participated loan as security for any other loan without prior written consent of the authority;

4. Accelerate the maturity of the participated loan;

5. Sue upon any participated loan instrument;

6. Waive any claim against any borrower, cosignor, guarantor, obligor, or standby creditor arising out of any instruments.

b. Payment due dates. Payment due dates for the LPP loan will be the same as for the lender's share of the loan.

c. Prepayment penalty. There is no penalty for early repayment of principal or interest.

d. Repayment proceeds and collateral. Without limitation, the repayment of proceeds and collateral shall include rights of setoff and counterclaim, which the lender or the authority jointly or severally may at any time recover on any participated loan.

e. Subsequent loans. Any loan or advance made by a lender to a borrower subsequent to obtaining an LPP loan under the program and secured by collateral or security pledged for the participated loan will be subordinate to the participated loan.

f. Events of loan default.

(1) Default will occur when the participated loan payment is 30 days past due. Notice to cure will be sent to the borrower with a copy sent to the authority; and the lender will take appropriate steps to cure the default through mediation, liquidation, or foreclosure if needed.

(2) After a participated loan is in default for a period of 30 days, the lender shall file with the authority monthly reports regarding the status of the participated loan.

(3) The authority may, anytime a participated loan is in default, purchase the unpaid portion of the participated loan from the lender including the note, security agreements, additional guarantees, and other documents. The authority would become the servicer of the participated loan in such case.

g. Applying principal and interest payments. Lenders shall receive all payments of principal and interest. All payments made prior to liquidation or foreclosure shall be made on a pro-rata basis. All accrued interest must be paid to zero at least annually on the anniversary date of the note.

h. Application of proceeds of loan liquidation. Application of proceeds of loan liquidation will be determined after a written liquidation plan is approved by the authority or the authority's loan committee. All amounts recovered upon liquidation or foreclosure will be applied first to the unpaid balance of the lender's portion and then to the unpaid portion of the LPP loan's portion. All funds received from liquidation or foreclosure procedures shall be applied in the following order of priority:

First Priority: To the payment of the outstanding principal of and accrued interest on the lender's portion of the participated loan;

Second Priority: To the payment of the outstanding principal of and accrued interest on the authority's LPP loan;

Third Priority: To the payment on a pro-rata basis of all reasonable and necessary expenses incurred by the lender or the authority in connection with such liquidation or foreclosure procedures.

44.5(8) *Right to audit.* The authority shall have, at any time, the right to audit records of the lender and the borrower relating to any participated loan made under the program.

[**ARC 1112C**, IAB 10/16/13, effective 9/26/13; **ARC 1400C**, IAB 4/2/14, effective 5/7/14]

265—44.6(175) Beginning farmer tax credit program.

44.6(1) *General provisions.*

a. *Term.* The term of the credit shall be equal to the term of the agricultural assets transfer agreement, except that any unused credit may be carried forward for a period of five years if unused in the tax year the credits are earned. Credits may not be carried back to past tax years.

b. *Fees.* The authority may charge reasonable and necessary fees to defray the costs of this program.

c. *Expiration of lease.* The BFTC eligible applicant will continue to be eligible for the term of the lease. Upon expiration of the lease, both the taxpayer and BFTC eligible applicant must reapply to continue the tax credit.

44.6(2) *Application procedures.*

a. The authority shall prepare and make available appropriate forms to be used in making application for the tax credit, including forms for both the taxpayer and the BFTC eligible applicant.

b. Each application shall include, but not be limited to, the following:

(1) Taxpayer information: name and address, e-mail address if available, social security number, length of the lease, type of lease, and location of the agricultural asset to be leased. In addition, the application shall have attached to it a copy of the lease agreement between the parties.

(2) BFTC eligible applicant information: name and address, e-mail address if available, social security number, and location of the asset to be leased. In addition, the application shall have attached to it a copy of the BFTC eligible applicant's most recent financial statement (generally prepared one month preceding application submission). The application will also include a background letter on the BFTC eligible applicant documenting to the satisfaction of the authority sufficient training, experience and access to capital. This letter may be submitted by one or more of the following: the BFTC eligible applicant, the taxpayer or another third party.

c. Complete applications shall be processed in the order they are received by the authority.

44.6(3) *Execution of an agricultural assets transfer agreement.* In addition to the requirements of rule 265—44.6(175), both the taxpayer and the BFTC eligible applicant shall execute an agricultural assets transfer agreement. This form shall be in a format used by the Iowa State Bar Association or other commonly accepted form and signed by all parties.

44.6(4) *Procedures following tax credit approval.* Either the BFTC eligible applicant or the taxpayer shall immediately notify the authority of any material changes in the agricultural assets transfer agreement. The authority shall act upon these changes pursuant to Iowa Code section 175.37. Material changes cannot result in an increase in the original tax credit amount approved.

[**ARC 1112C**, IAB 10/16/13, effective 9/26/13; **ARC 1400C**, IAB 4/2/14, effective 5/7/14]

265—44.7(16) Beginning farmer custom farming tax credit program.

44.7(1) *General provisions.*

a. *Term.* The term of the credit shall not exceed one year, except that any unused credit may be carried forward for a period of five years if unused in the tax year the credits are earned. Credits may not be carried back to past tax years.

b. *Fees.* The authority may charge reasonable and necessary fees to defray the costs of this program.

c. *Expiration of custom hire contract.* The BFCF eligible applicant will continue to be eligible during the year of the custom farming contract. Upon expiration of the contract, both the taxpayer and BFCF eligible applicant must reapply to qualify for subsequent tax credits.

44.7(2) *Application procedures.*

a. The authority shall prepare and make available appropriate forms to be used in making application for the tax credit, including forms for both the taxpayer and the BFCF eligible applicant.

b. Each application shall include, but not be limited to, the following:

(1) Taxpayer information: name and address, e-mail address if available, social security number, and description and location of the custom hire work completed. In addition, the application shall have attached to it a copy of the custom hire contract between the parties.

(2) BFCF eligible applicant information: name and address, e-mail address if available, social security number, and location of where custom hire work was completed. In addition, the application shall have attached to it a copy of the BFCF eligible applicant's most recent financial statement (generally prepared one month preceding application submission). The application will also include a background letter on the BFCF eligible applicant documenting to the satisfaction of the authority sufficient training, experience and access to capital. This letter may be submitted by one or more of the following: the BFCF eligible applicant, the taxpayer or another third party.

c. Complete applications shall be processed in the order they are received by the authority.

44.7(3) *Execution of custom farming contract.* In addition to the requirements set forth in rule 265—44.7(16), both the taxpayer and the BFCF eligible applicant shall execute a custom farming contract. This form shall be in a format provided by the authority or other commonly accepted forms and signed by all parties.

44.7(4) *Calculation of custom hire tax credit.* The taxpayer and BFCF eligible applicant will submit a completed application to the authority, including a list of all custom work completed by the BFCF eligible applicant. The application will also include verification of all payments made to the BFCF eligible applicant for work completed.

44.7(5) *Procedures following tax credit approval.* Either the BFCF eligible applicant or the taxpayer shall immediately notify the authority of any material changes in the custom hire contract. The authority shall act upon these changes pursuant to Iowa Code section 175.38. Material changes cannot result in an increase in the original tax credit amount approved. Death of a party to the contract, divorce, or sale of the property will be considered eligible material changes.

[**ARC 1112C**, IAB 10/16/13, effective 9/26/13; **ARC 1400C**, IAB 4/2/14, effective 5/7/14]

These rules are intended to implement Iowa Code chapters 16 and 175 and 2013 Iowa Acts, chapter 100.

[Filed Emergency ARC 1112C, IAB 10/16/13, effective 9/26/13]

[Filed ARC 1400C (Notice ARC 1113C, IAB 10/16/13), IAB 4/2/14, effective 5/7/14]

CHAPTER 4
CAMPAIGN DISCLOSURE PROCEDURES

[Prior to 9/9/87, Campaign Finance Disclosure[190] Ch 4]
[Prior to 3/30/94, Campaign Finance Disclosure Commission[121] Ch 4]

DIVISION I
ORGANIZATIONAL REQUIREMENTS

351—4.1(68A,68B) Requirement to file statement of organization (DR-1)—persons subject to requirements; financial thresholds; where to file; when due.

4.1(1) *Persons subject to requirement.* Every committee shall file a statement of organization (Form DR-1) within ten days from the date of its organization. The forms shall be either typewritten or printed legibly in black ink.

a. "Committee" defined. "Committee" includes the following:

(1) A "candidate's committee" that is the committee, even if the committee consists only of the candidate, designated by a candidate for a state or local office to receive contributions, make expenditures, or incur debts in excess of $750.

(2) A "political committee" (PAC) that is a committee exceeding the $750 organizational threshold to expressly advocate the nomination, election, or defeat of candidates or to expressly advocate the passage or defeat of a ballot issue. The board shall automatically classify as a political committee any political organization that loses its status as a political party because it fails to meet the requirements of Iowa Code section 43.2. The board shall automatically classify as a political committee any county central committee that operated under the former political party.

(3) A "state statutory political committee" (state party), "county statutory political party" (county central committee), or "city statutory political committee" (city central committee).

(4) A person that wishes to register a committee for purposes of using the short form "paid for by" attribution statement shall file Form DR-SFA pursuant to rule 351—4.11(68A).

b. When organization occurs; financial thresholds. At the latest, organization is construed to have occurred as of the date that the committee first exceeded $750 of financial activity in a calendar year in any of the following categories: contributions received (aggregate of monetary and in-kind contributions); expenditures made; or indebtedness incurred.

c. Permanent organizations temporarily engaging in political activity. The requirement to file the statement of organization applies to an entity that comes under the definition of a "political committee" (PAC) in Iowa Code Supplement section 68A.102(18) by receiving contributions, making expenditures, or incurring debts in excess of $750 in any one calendar year for the purpose of expressly advocating the election or defeat of a candidate for public office, or for the purpose of expressly advocating the passage or defeat of a ballot issue. A permanent organization that makes a one-time contribution in excess of $750 may in lieu of filing a statement of organization follow the procedure in rule 351—4.35(68A). A permanent organization that makes loans to a candidate or committee or that is owed debts from a candidate or committee is not deemed to be engaging in political activity requiring registration.

d. Independent expenditure committee. A person that is required to file campaign disclosure reports pursuant to 2009 Iowa Code Supplement section 68A.404(3)*"a"* as amended by 2010 Iowa Acts, Senate File 2354, section 3, due to the filing of an independent expenditure statement (Form Ind-Exp-O) shall be referred to as an "independent expenditure committee." An independent expenditure committee, or a sole individual making an independent expenditure by filing Form Ind-Exp-I, is not required to file a statement of organization.

4.1(2) *Place of filing.* Statements of organization mandated by statute to be filed electronically with the board shall be filed through the board's Web site at www.iowagov/ethics. A statement of organization not mandated by statute to be filed electronically may be filed with the board at 510 East 12th Street, Suite 1A, Des Moines, Iowa 50319; by fax at (515)281-4073; or as an E-mail attachment.

4.1(3) *Time of filing.* A statement of organization shall be filed with the board within ten days after the financial filing threshold in subrule 4.1(1) has been exceeded. A statement must be physically received by the board or, if mailed, must bear a United States Postal Service postmark dated on or

before the report due date. Faxed or electronically filed statements must be submitted on or before 11:59 p.m. of the tenth day after the organization of the committee is required. A committee that is mandated by statute to electronically file a statement of organization shall file the statement with the board on or before 4:30 p.m. on the due date. If the tenth day falls on a Saturday, Sunday, or holiday on which the board office is closed, the filing deadline is extended to the next working day when the board office is open.

4.1(4) *Candidate defined.* For purposes of Iowa Code chapters 68A and 68B and the rules of the board, "candidate" means an individual who takes affirmative action to seek nomination or election to a state or local public office. For purposes of Iowa Code chapter 68A and any rules of the board on campaigning for public office, "candidate" includes any judge or judicial employee who is required by law to stand for retention. "Takes affirmative action" includes making a public announcement of intention to seek nomination or election, making any expenditure or accepting any contribution for nomination or election, distributing petitions for signatures for nomination, filing nomination papers or an affidavit of candidacy, or being nominated by any convention process set out by law.

4.1(5) *Ballot issue defined.* "Ballot issue" means a question that has been approved by a political subdivision or the general assembly to be placed before the voters or is otherwise required by law to be placed before the voters. "Ballot issue" does not include the nomination, election, or defeat of a candidate.

4.1(6) *Electronic format or electronic filing defined.* "Electronic format" or "electronic filing" means the board's electronic filing system for submitting a statement of organization via the board's Web site at www.iowa.gov/ethics.

This rule is intended to implement Iowa Code section 68A.201 and section 68A.401 as amended by 2009 Iowa Acts, Senate File 51, section 1.

[**ARC 7995B**, IAB 7/29/09, effective 9/2/09; **ARC 8290B**, IAB 11/18/09, effective 12/23/09; **ARC 8826B**, IAB 6/2/10, effective 5/17/10; **ARC 9031B**, IAB 8/25/10, effective 9/29/10]

351—4.2(68A,68B) Information required: committee name.

4.2(1) *Full name required.* The statement of organization shall include the full name of the committee. A committee using an abbreviation or acronym as part of the committee name shall provide with the statement of organization a written explanation of the full word or words that are abbreviated or that form the acronym.

4.2(2) *Duplication of name prohibited.* The committee name shall not duplicate the name of another committee organized under Iowa Code chapter 68A. The board shall determine whether two committee names are in duplication in violation of Iowa Code section 68A.201(2)*"a."* A committee duplicating the name of another organized committee shall choose a new committee name upon notification from the board. A candidate who files an amended statement of organization to reflect a change in office sought shall not be required to change the name of the candidate's committee unless the committee's name duplicates the name of another organized committee. A committee shall not duplicate the name of a dissolved committee for a period of ten years after the dissolved committee is certified as being dissolved except when the candidate for both committees is the same individual.

4.2(3) *Candidate's surname required in committee name.* A candidate filing a statement of organization on or after July 1, 1995, shall include the candidate's surname within the committee name. This requirement also applies to a new candidate's committee organized by a candidate who has a preexisting candidate's committee but who organizes a new candidate's committee or files an amended statement of organization.

This rule is intended to implement Iowa Code Supplement section 68A.201.

[**ARC 7646B**, IAB 3/25/09, effective 4/29/09]

351—4.3(68A,68B) Information required: committee purpose; party affiliation.

4.3(1) *Committee purpose.* An organized campaign committee shall identify the purpose of the committee on the statement of organization. The purpose shall be indicated in part by designating the committee as one of the following types of committees:

Type 1 - A candidate's committee for a statewide or legislative candidate or a judge standing for retention. This type of committee is referred to as a state candidate's committee.

Type 2 - A political committee that expressly advocates for or against candidates at the state level. This type of committee is referred to as a statewide PAC.

Type 3 - A state statutory political committee. This type of committee is referred to as a state party.

Type 4 - A county statutory political committee. This type of committee is referred to as a county central committee.

Type 5 - A candidate's committee for a candidate seeking county office. This type of committee is referred to as a county candidate's committee.

Type 6 - A candidate's committee for a candidate seeking city office. This type of committee is referred to as a city candidate's committee.

Type 7 - A candidate's committee for a candidate seeking school board or other political subdivision office except for a county or city office. This type of committee is referred to as a school board or other political subdivision candidate's committee.

Type 8 - A political committee that expressly advocates for or against candidates for county office. This type of committee is referred to as a county PAC.

Type 9 - A political committee that expressly advocates for or against candidates for city office. This type of committee is referred to as a city PAC.

Type 10 - A political committee that expressly advocates for or against candidates for school board or other political subdivision except for county or city candidates. This type of committee is referred to as a school board or other political subdivision PAC.

Type 11 - A political committee that expressly advocates for the passage or defeat of a ballot issue, franchise election, or referendum conducted for a county, city, school, or other political subdivision ballot question. This type of committee is referred to as a ballot issue committee. This type of committee also includes a political committee that expressly advocates for or against a statewide ballot issue (constitutional amendment) or a political committee that expressly advocates for or against ballot issue questions in multiple cities or counties.

4.3(2) *Party affiliation.* A candidate's committee is deemed to be established to expressly advocate the election of a candidate for public office. Each candidate's committee shall designate the political affiliation of the candidate. Any other committee shall designate that it is either established to expressly advocate the election or defeat of candidates or the passage or defeat of a ballot issue.

This rule is intended to implement Iowa Code Supplement section 68A.201.

[**ARC 8289B**, IAB 11/18/09, effective 12/23/09]

351—4.4(68A,68B) Information required: officers; committee information; signatures.

4.4(1) *Committee officers.* The committee shall disclose on the statement of organization the name, mailing address, telephone number, and office of each committee officer whom the committee is required by statute to appoint. Each candidate's committee shall appoint a treasurer who shall be an Iowa resident and at least 18 years of age. Every other committee shall appoint a separate treasurer and chairperson, each of whom shall be at least 18 years of age. The committee may appoint other officers not required by statute without restriction on residency or age, and the committee is not required to disclose these officers. Except for a candidate's committee, every committee shall either have an Iowa resident as treasurer or shall maintain all of the committee's funds in bank accounts in a financial institution in Iowa.

4.4(2) *Committee address and telephone number.* The address and telephone number of the candidate as indicated on the statement of organization shall be the official address and telephone number to be used for communication from the board to the candidate's committee. The address and telephone number of the committee chairperson as indicated on the statement of organization shall be the official address and telephone number to be used for communication from the board to every other committee except for a candidate's committee. If an electronic mail address has been provided on the statement of organization, communication from the board to a committee shall be sent by electronic mail.

4.4(3) *Signatures.* The candidate and treasurer shall sign the statement of organization filed by a candidate's committee. The chairperson and treasurer shall sign a statement of organization filed by any other type of committee. A statement of organization filed electronically using the board's Web site is deemed signed when filed.

This rule is intended to implement Iowa Code Supplement section 68A.201.

351—4.5(68A,68B) Segregation and timely deposit of funds; information required: identification of financial institution, account name; notice to treasurer.

4.5(1) *Segregation and deposit of funds.* All committee funds shall be maintained in a financial institution and shall be segregated from any other funds held by a candidate, officer, member, or associate of the committee. The committee treasurer shall deposit all contributions within seven days of receipt by the treasurer in an account maintained by the committee.

4.5(2) *Exception from segregation of committee funds.* A candidate's committee that receives contributions only from the candidate is not required to maintain a separate account. A permanent organization temporarily engaging in activity that qualifies it as a political committee that uses existing general operating funds and does not solicit or receive funds from other sources for campaign purposes is not required to maintain a separate account.

4.5(3) *Identification of financial institution and account.* The committee shall disclose on the committee's statement of organization the name and mailing address of all financial institutions in which committee funds are maintained. The committee shall also disclose the name and type of all accounts in which committee funds are maintained, and the name of any such account shall be the same as the committee name on the statement of organization.

4.5(4) *Notice to treasurer.* Any person who receives contributions for a committee shall render the contributions to the treasurer within 15 days of receipt and provide the committee treasurer with the reporting information required by Iowa Code Supplement section 68A.203(2).

This rule is intended to implement Iowa Code Supplement sections 68A.201 and 68A.203.

351—4.6(68A,68B) Amendments to statement of organization; requirement for new statement of organization for new office sought.

4.6(1) *Amendment within 30 days.* If there is a change in any of the information disclosed on a statement of organization, the committee shall file with the board an amended statement within 30 days of the change. An amended statement shall be filed with the board in a format as required by 2009 Iowa Code Supplement section 68A.401 as amended by 2010 Iowa Acts, Senate File 2128, section 3, and board rule 351—4.1(68A,68B).

4.6(2) *New office sought.* A candidate who filed a statement of organization for one office but eventually seeks another office may file an amended statement of organization to reflect the change in office sought in lieu of dissolving the old committee and organizing a new committee. A candidate filing an amended statement of organization for a new office shall continue to file the required campaign reports regardless of whether the $750 financial filing threshold for the new office has been exceeded. A candidate who has filed a statement of organization for one office and who then exceeds the financial activity threshold as set forth in Iowa Code section 68A.102(5) for a new office shall, within ten days of exceeding the threshold, file either an amended statement of organization disclosing information for the new office sought or organize and register a new committee.

This rule is intended to implement Iowa Code Supplement section 68A.201.

[**ARC 8787B**, IAB 6/2/10, effective 7/7/10]

DIVISION II
REPORTING AND FINANCIAL TRANSACTION REQUIREMENTS

351—4.7(68A,68B) Disclosure reporting required; information on initial report; minimum filing if no activity.

4.7(1) *Disclosure reporting required.* Every committee that has filed a statement of organization under Iowa Code section 68A.201 and rule 351—4.1(68A,68B), has exceeded the financial activity

threshold set out in Iowa Code section 68A.102(5) or (18) prior to the cutoff date for reporting campaign transactions, or has made an independent expenditure shall file a campaign disclosure report pursuant to Iowa Code section 68A.402. Form Ind-Exp-O shall serve as a campaign disclosure report for an independent expenditure committee. Form Ind-Exp-I shall serve as a campaign disclosure report for a sole individual making an independent expenditure.

4.7(2) *Information on initial report.* The first disclosure report filed by a committee shall include the relevant financial information covering the period from the beginning of the committee's financial activity through the end of the current reporting period.

4.7(3) *Funds available from prior committee.* If funds are available to a candidate's committee from a prior candidacy of that candidate, or to a ballot issue committee from a prior effort on a ballot issue, and the prior candidacy or effort had not exceeded the financial reporting threshold, the carryover balance shall be disclosed by the new committee. The disclosure shall be made on Schedule A - Contributions and shall include the amount of the carryover, the date of the prior election, and the name and address of any source that made contributions to the candidacy or ballot effort that totaled more than $750 during the preceding three calendar years.

4.7(4) *Funds available from preballot issue activity.* Funds that are raised for an activity that is not included in the definition of a ballot issue in Iowa Code Supplement section 68A.102(1) and that are made available to a subsequent ballot issue committee shall be disclosed by the committee. The disclosure shall be made on Schedule A - Contributions and shall include the amount of the carryover balance, the date of the preballot issue activity, and the name and address of any source that made contributions to the activity that totaled more than $750 during the previous three calendar years.

4.7(5) *No financial activity during reporting period.* A committee that did not have any financial activity during the relevant reporting period for which a disclosure report is due shall be required to file only Form DR-2. However, if the committee had previously disclosed debts or loans, those obligations shall again be disclosed on either Schedule D - Incurred Indebtedness or Schedule F - Loans Received and Repaid, as appropriate, and the schedule or schedules shall be included with Form DR-2. A candidate's committee that has reportable campaign property under Iowa Code Supplement section 68A.304 shall disclose the property on Schedule H - Campaign Property and the schedule shall be included with Form DR-2.

This rule is intended to implement Iowa Code Supplement section 68A.402.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.8(68A,68B) Disclosure reporting required—where reports filed.

4.8(1) *Place of filing.* Disclosure reports mandated by statute to be filed electronically with the board shall be filed through the board's Web site at www.iowagov/ethics. A disclosure report not mandated by statute to be filed electronically may be filed with the board at 510 East 12th Street, Suite 1A, Des Moines, Iowa 50319; by fax at (515)281-4073; or as an E-mail attachment.

4.8(2) *Reports made available.* The board shall post on its Web site at www.iowa.gov/ethics all statements and reports filed under Iowa Code chapter 68A.

4.8(3) *Records retention.* The board shall maintain and retain all statements and reports filed under Iowa Code chapter 68A under the applicable provisions of Iowa Code chapter 305.

4.8(4) *Electronic format or electronic filing defined.* "Electronic format" or "electronic filing" means the board's electronic filing system for submitting campaign disclosure reports via the board's Web site at www.iowa.gov/ethics.

This rule is intended to implement Iowa Code section 68A.401 as amended by 2009 Iowa Acts, Senate File 51, section 1, and section 68A.402 as amended by 2009 Iowa Acts, Senate File 49, section 4.

[**ARC 7995B**, IAB 7/29/09, effective 9/2/09; **ARC 9031B**, IAB 8/25/10, effective 9/29/10]

351—4.9(68A) Campaign disclosure report due dates.

4.9(1) *Statewide office, general assembly, judge standing for retention.* A candidate's committee of a candidate for statewide office or the general assembly or a judge standing for retention shall file campaign disclosure reports as follows:

a. *Election year.*

Report due	Covering period
May 19	January 1 through May 14
July 19	May 15 or Wednesday preceding primary election* through July 14
October 19	July 15 through October 14
January 19 (next calendar year)	October 15 or Wednesday preceding general election* through December 31 of election year

b. Supplementary report.

Report due	Covering period
Friday preceding primary election*	May 15 through Tuesday preceding primary election*
Friday preceding general election*	October 15 through Tuesday preceding general election*

*If supplementary report required. See subrule 4.9(2).

c. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

d. Special election.

Report due	Covering period
Five days preceding the election*	Date of initial activity through tenth day prior to the special election

This report is in addition to the election year reports required under paragraph 4.9(1)"a."*

4.9(2) *Statewide office or general assembly—supplementary reports.* In addition to reports required under subrule 4.9(1), a supplementary report is required if contributions received during the period beginning on the date of initial financial activity, or the day after the period covered by the last report, as applicable, through the Tuesday preceding the primary or general election equal or exceed the following thresholds:

Office sought	Contribution threshold
Governor	$10,000 or more
Other statewide office	$5,000 or more
General assembly	$1,000 or more

4.9(3) *County candidate.* A candidate's committee of a candidate for county office shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
May 19	January 1 through May 14
July 19	May 15 through July 14
October 19	July 15 through October 14
January 19 (next calendar year)	October 15 through December 31 of election year

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

c. Special election.

Report due	Covering period
Five days preceding the election*	Date of initial activity through tenth day prior to the special election

This report is in addition to the election year reports required under paragraph 4.9(3)"a."*

4.9(4) *City candidate.* A candidate's committee of a candidate for city office shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
Five days before primary election	Date of initial activity through ten days before primary election
Five days before general election	Nine days before primary election through ten days before general election
Five days before runoff election*	Nine days before the general election through ten days before the runoff election
January 19 (next calendar year)	Cutoff date from previously filed report through December 31

*If a runoff election is held.

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

c. Special election.

Report due	Covering period
Five days preceding the election*	Date of initial activity through tenth day prior to the special election

This report is in addition to the election year reports required under paragraph 4.9(4)"a."*

4.9(5) *School board or other political subdivision.* A candidate's committee of a candidate for school board or other political subdivision office, except for county office or city office, shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
Five days before election	Date of initial activity through ten days before election
January 19 (next calendar year)	Nine days before election through December 31

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

c. Special election.

Report due	Covering period
Five days preceding the election*	Date of initial activity through tenth day prior to the special election

This report is in addition to the election year reports required under paragraph 4.9(5)"a."*

4.9(6) *State statutory political committee (state political party).* A committee defined in Iowa Code Supplement section 68A.102(22)as a state statutory political committee shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
May 19	January 1 through May 14
July 19	May 15 through July 14
October 19	July 15 through October 14
January 19 (next calendar year)	October 15 through December 31 of election year

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

4.9(7) *County statutory political committee (county central committee).* A committee defined as a county statutory political committee in Iowa Code Supplement section 68A.102(12) shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
May 19	January 1 through May 14
July 19	May 15 through July 14
October 19	July 15 through October 14
January 19 (next calendar year)	October 15 through December 31 of election year

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

4.9(8) *State political committee (state PAC).* A political committee expressly advocating the nomination, election, or defeat of candidates for statewide office or the general assembly or a judge standing for retention shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
May 19	January 1 through May 14
July 19	May 15 through July 14
October 19	July 15 through October 14
January 19 (next calendar year)	October 15 through December 31 of election year

b. Nonelection year.

Report due	Covering period
July 19	January 1 through June 30
January 19 (next calendar year)	July 1 through December 31

4.9(9) *County political committee (county PAC).* A political committee expressly advocating the nomination, election, or defeat of candidates for county office shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
May 19	January 1 through May 14
July 19	May 15 through July 14
October 19	July 15 through October 14
January 19 (next calendar year)	October 15 through December 31 of election year

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

4.9(10) *City political committee (city PAC).* A political committee expressly advocating the nomination, election, or defeat of candidates for city office shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
Five days before primary election	Date of initial activity through ten days before primary election
Five days before general election	Nine days before primary election through ten days before general election
Five days before runoff election*	Nine days before the general election through ten days before runoff election
January 19 (next calendar year)	Cutoff date from previously filed report through December 31

*If a runoff election is held.

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

4.9(11) *School board or other political subdivision political committee (school board or other local PAC).* A political committee expressly advocating the nomination, election, or defeat of candidates for school board or other political subdivision office, except for county office or city office, shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
Five days before election	Date of initial activity through ten days before election
January 19 (next calendar year)	Nine days before election through December 31

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

4.9(12) *Statewide or local ballot issue committee (ballot issue PAC).* A committee expressly advocating the passage or defeat of a statewide or local ballot issue shall file campaign disclosure reports as follows:

a. Election year.

Report due	Covering period
Five days before election	Date of initial activity or previous report through ten days before election
May 19	Date of initial activity or previous report through May 14
July 19	Date of initial activity or previous report through July 14
October 19	Date of initial activity or previous report through October 14
January 19 (next calendar year)	Cutoff date from previously filed report through December 31

b. Nonelection year.

Report due	Covering period
January 19 (next calendar year)	January 1 through December 31 of nonelection year

4.9(13) *Permanent organizations.* A permanent organization temporarily engaging in political activity as described in Iowa Code Supplement section 68A.102(18) shall organize a political committee and shall keep the funds relating to that political activity segregated from its operating funds. The committee shall file reports on the applicable due dates as required by this rule. The reports shall identify the source of the original funds used for a contribution made to a candidate or a candidate's committee. When the permanent organization ceases to be involved in the political activity, the permanent organization shall dissolve the political committee. "Permanent organization" means an organization that is continuing, stable, and enduring, and was originally organized for purposes other than engaging in election activities.

4.9(14) *Election year defined.* "Election year" means a year in which the name of the candidate or ballot issue appears on a ballot to be voted on by the electors of the state of Iowa. For state and county statutory political committees, "election year" means a year in which primary and general elections are held.

4.9(15) *Independent expenditure reporting.* An independent expenditure committee that is required to file campaign disclosure reports pursuant to 2009 Iowa Code Supplement section 68A.404(3) as amended by 2010 Iowa Acts, Senate File 2354, section 3, shall file an initial report at the same time as the committee files its original independent expenditure statement. The committee shall then continue to file reports according to the same schedule as the office or election to which the independent expenditure was directed until the committee files a notice of dissolution pursuant to Iowa Code section 68A.402B(3) as amended by 2010 Iowa Acts, Senate File 2354, section 2. Form Ind-Exp-O shall serve as a campaign disclosure report for an independent expenditure committee. Form Ind-Exp-I shall serve as a campaign disclosure report for a sole individual making an independent expenditure.

This rule is intended to implement Iowa Code section 68A.402.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.10(68A) Time of filing. A report must be physically received by the board or, if mailed, shall bear a United States Postal Service postmark dated on or before the report due date. Faxed, E-mailed, or electronically filed reports must be submitted on or before 11:59 p.m. of the report due date. However, as provided in Iowa Code section 68A.402 as amended by 2009 Iowa Acts, Senate File 49, section 4, any report that is required to be filed five days or less prior to an election must be physically received by the board prior to 4:30 p.m. on the report due date. A report that is mandated by statute to be electronically filed shall be filed with the board on or before 4:30 p.m. on the due date. If the due date falls on a Saturday, Sunday, or holiday on which the board office is closed, the due date is extended to the first working day when the board office is open.

This rule is intended to implement Iowa Code section 68A.401(1) as amended by 2009 Iowa Acts, Senate File 51, and section 68A.402 as amended by 2009 Iowa Acts, Senate File 49, section 4.

[**ARC 8290B**, IAB 11/18/09, effective 12/23/09]

351—4.11(68A) Voluntary registration—Form DR-SFA.

4.11(1) *Persons voluntarily registering a committee.* A person that has not exceeded the $750 financial filing threshold may file Form DR-SFA for purposes of using the short form "paid for by"

attribution statement under Iowa Code section 68A.405 and rule 351—4.38(68A). A person using the short form "paid for by" attribution statement shall file Form DR-SFA with the board prior to distributing the political material containing the short form "paid for by" attribution statement.

4.11(2) *$750 threshold later exceeded.* A person filing Form DR-SFA shall not be required to file a statement of organization or be required to file disclosure reports unless the $750 threshold is later exceeded. A person that later exceeds the $750 threshold and that fails to timely file a statement of organization or to timely file disclosure reports may be subject to the appropriate board sanctions as set out by statute and board rule.

4.11(3) *Subsequent elections.* A person that filed Form DR-SFA for one election and then becomes involved in a subsequent election and wants to voluntarily register a committee shall file either a new Form DR-SFA or file an amended Form DR-SFA, which provides information concerning the new election.

This rule is intended to implement Iowa Code sections 68A.201 and 68A.405.

[**ARC 7994B**, IAB 7/29/09, effective 9/2/09]

351—4.12(68A,68B) Exception from reporting requirement—reports due within five days of one another. When two disclosure reports are due from the same committee within five days of each other, the activity may be combined into one report. A committee choosing this option shall file a report on or before the second due date that covers the extended reporting period.

This rule is intended to implement Iowa Code Supplement section 68A.402.

351—4.13(68A,68B) Report forms—summary page (DR-2) and supporting schedules. The board may require committees to submit relevant information not specifically delineated in Iowa Code Supplement chapter 68A on their disclosure report where the report form asks for and leaves space for information. All information shall be pertinent to the duties of the board.

4.13(1) *Official reporting forms.* The disclosure reporting forms provided by the board shall be the official forms on which the disclosure reports shall be submitted. Machine copies of original report forms are acceptable. The standard forms for campaign disclosure reports are:

DR-2 — Disclosure Summary Page
Schedule A — Monetary Receipts
Schedule B — Monetary Expenditures
Schedule C — (Reserved)
Schedule D — Incurred Indebtedness
Schedule E — In-kind Contributions
Schedule F — Loans Received and Repaid
Schedule G — Consultant Activity
Schedule H — Campaign Property

4.13(2) *Computer-generated reports.* Committees that are not mandated by statute to file disclosure reports electronically may generate a disclosure report in lieu of using a board-approved paper report or the board's electronic filing system so long as the generated report contains the same information and is in the same basic format as a board-approved paper report. A committee failing to submit a generated report that contains the same information and is in the same basic format as a board-approved paper report shall be required by the board's staff to file an amended report, and the committee may be subject to board sanctions as provided in Iowa Code chapter 68B and rule 351—9.4(68B).

4.13(3) *Typewritten or legible ink reports required.* Information provided on all forms, statements, and reports that are required to be filed under Iowa Code chapter 68A or the board's rules in 351—Chapter 4 and that are not mandated by statute to be filed electronically shall be either typewritten or printed legibly in black ink. Approved computer-generated documents satisfy this requirement. If the board deems that a form, statement, or report is not legible or is otherwise not in compliance with rule 351—4.13(68A,68B), the person shall be required to file an amended form, statement, or report and the person may be subject to board sanctions as provided in Iowa Code chapter 68B and rule 351—9.4(68B).

4.13(4) *Special information required for city, school, or local ballot issue elections.* Committees expressly advocating the election or defeat of a candidate for city or school public office, or expressly advocating the passage or defeat of a local ballot issue, shall indicate in the designated spaces on the report summary page the date that the election is to be held, the period covered by the disclosure report, and the control county responsible for conducting the election.

4.13(5) *Signature on DR-2 Report Summary Page.* A disclosure report shall be signed by the individual filing the report. A disclosure report filed electronically using the board's Web site is deemed signed when filed.

4.13(6) *Independent expenditure disclosures.* An independent expenditure committee that is required to file campaign reports pursuant to 2009 Iowa Code Supplement section 68A.404(3) as amended by 2010 Iowa Acts, Senate File 2354, section 3, shall disclose campaign transaction information as required by Iowa Code section 68A.402A. However, the committee is required to disclose only those monetary receipts as provided in 2009 Iowa Code Supplement section 68A.404(3)*"a"*(2) as amended by 2010 Iowa Acts, Senate File 2354, section 3. Form Ind-Exp-O shall serve as a campaign disclosure report for an independent expenditure committee. Form Ind-Exp-I shall serve as a campaign disclosure report for a sole individual making an independent expenditure.

This rule is intended to implement Iowa Code Supplement sections 68A.402 and 68A.403.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10; **ARC 9031B**, IAB 8/25/10, effective 9/29/10]

351—4.14(68A,68B) Schedule A - Monetary Receipts.

4.14(1) *Reporting of all monetary receipts; chronological listing.* The committee shall report the amounts of all monetary receipts which are accepted by the committee during the reporting period. If a contribution is returned to a contributor prior to the end of the reporting period and is not deposited into the committee's bank account, the contribution is deemed to have been rejected and shall not be reported. A contribution which is physically received and either deposited into the committee's account or not returned by the end of the reporting period is deemed to have been accepted. The schedule entries shall be listed in chronological order by the date on which the contribution is received.

4.14(2) *Date of contribution—date received.* The schedule shall include the complete date (month/day/year) that the contribution was physically received by a person on behalf of the committee. If the contribution is by check, the date of the contribution to be reported is the date the check is physically received by a person on behalf of the committee, even if this date is different from the date shown on the check. For contributions received by mail, the date of the contribution to be reported shall be the date that the recipient physically opens the envelope.

4.14(3) *Name and address of contributor; joint accounts.* The schedule shall include the name and address of each person who has made one or more contributions of money to the committee if the aggregate amount of contributions (either monetary or in-kind) received from that person in the calendar year exceeds $25, except that the itemization threshold is $200 for a state statutory political committee and $50 for a county statutory political committee. In the case of a contribution by check, the contributor name on the disclosure report shall be the name shown as the account name on the account, except that if the check is on a joint account, the contribution shall be presumed to be from the person who signs the check. If the committee chooses to itemize contributions that are less than the required itemization threshold, it may do so, but shall either do so for all contributions or none of the contributions under the threshold.

4.14(4) *Unitemized contributions and freewill donations.* If the committee does not choose to itemize all contributions under the itemization threshold ($25 for most committees, see Iowa Code Supplement section 68A.402(3)*"b"*), it shall aggregate these contributions and report the aggregate amount as "unitemized contributions." No date received is required to be provided for miscellaneous unitemized contributions. Unitemized contributions may be solicited and received through a freewill donation such as a "fish bowl" or "pass the hat" collection if the collection is in compliance with rule 351—4.30(68A,68B). Unitemized contributions collected through freewill donations (the net amount of the collection after the itemization of those persons whose contributions of more than $10 in the freewill collection resulted in exceeding the annual itemization threshold) shall be reported by showing

the net amount as "unitemized contributions—pass the hat (or can collection or fish bowl, for example) collection." The "date received" to be reported for a freewill donation is the date a representative of the committee takes possession of the proceeds of the collection.

4.14(5) *Relationship to candidate.* In the case of contributions to candidates' committees, the schedule shall include information indicating whether the contributor is related to the candidate within the third degree of consanguinity or affinity. "Consanguinity" means a relative through descent from common ancestors (by blood). "Affinity" means a relative through a current marriage. A husband has the same relation, by affinity, to his wife's blood relatives as she has to them by consanguinity and vice versa. "Degree of kinship" is determined by counting upward from one of the persons in question to the nearest common ancestor, and then down to the other person, calling it one degree for each generation in the ascending as well as the descending line. Under this rule, a woman's sister is related to her by consanguinity in the second degree. The sister is thus related to the woman's husband by affinity in the second degree. Other examples of relationships within the third degree between a contributor and a candidate would be the following: children and stepchildren (first degree); siblings and half-siblings (second degree); grandparents (second degree); grandchildren (second degree); aunts and uncles (third degree); nieces and nephews (third degree); great-grandparents (third degree) and great-grandchildren (third degree), all irrespective of whether the blood relationship is to the candidate or to the candidate's spouse.

4.14(6) *ID number and check number.* If a contribution to a statewide or general assembly candidate or a judge standing for retention is from a statewide political committee (PAC) or a state party committee, the candidate receiving the contribution shall include on the candidate's disclosure report the board-assigned identification number of the contributing committee and the check number by which the contribution was made. A list of ID numbers may be obtained from the board and is also available on the board's Web site at www.iowa.gov/ethics.

4.14(7) *Fund-raiser income.* Contributions arising from the sale of goods or services at a fund-raising event shall be designated by marking the indicated space on the schedule.

4.14(8) *Interest and other monetary receipts other than contributions.* If the monetary receipt is not a "contribution," the name and address of the source of the funds shall be identified in the space provided for the name and address of "contributor," with a notation as to the purpose of the payment, such as "bank interest."

4.14(9) *Reverse entries—refunds.* If a committee determines to decline or otherwise return a contribution after it has been received, accepted, and deposited, the committee may issue a refund to the contributor, which shall be reported on Schedule A as a reverse entry, reducing the monetary receipts.

This rule is intended to implement Iowa Code Supplement section 68A.402.

351—4.15(68A,68B) Schedule B - Monetary Expenditures.

4.15(1) *Date expended.* The committee shall report the amounts of all itemized expenditures (expenditures of $5 or more) made by the committee for the reporting period chronologically by the date expended. The date of the expenditure is the date the check is issued. The complete date (month/day/year) shall be provided.

4.15(2) *Name and address of recipient.* The schedule shall include the name and address of each person to whom disbursements, other than loan repayments, were made during the reporting period. (Loan repayments shall be reported on Schedule F.)

4.15(3) *Purpose of expenditure.* The schedule shall include a description of the purpose of each disbursement. The description shall be a clear and concise statement that specifically describes the transaction which has occurred. The following general terms are examples of descriptions which are not acceptable: "expenses," "reimbursement," "candidate expense," "services," "supplies," and "miscellaneous expense." The following are examples of acceptable descriptions: "printing—candidate yard signs," "printing—PAC membership solicitation letter," "mailing—candidate brochures," "reimbursement for candidate lodging to attend campaign event," or "mileage reimbursement—150 miles @ 25¢ per mile." A combined description is not acceptable unless sufficient information is

provided so that the cost of separate purposes can be discerned, for example, "printing and mailing of 1,000 brochures."

4.15(4) *Miscellaneous (unitemized) expenses.* Notwithstanding the other provisions of this rule, disbursements of less than $5 may be shown as miscellaneous disbursements or expenses for the period so long as the aggregate miscellaneous disbursements to any one person during a calendar year do not exceed $100.

4.15(5) *Candidate ID number and committee check number.* If a contribution is made by a statewide political committee (PAC) or a state party committee to a statewide or general assembly candidate or a judge standing for retention, the committee making the contribution shall include on the committee's disclosure report the board-assigned identification number of the recipient candidate's committee and the check number by which the contribution was made. A list of candidate ID numbers may be obtained from the board and is also available on the board's Web site at www.iowa.gov/ethics.

4.15(6) *Check transactions required.* All disbursements, including all expenditures and any other withdrawals from committee funds, shall be by check. Cash withdrawals and "petty cash" accounts are not permitted. Committees' activities which necessitate cash drawers or other cash transactions shall be conducted and reported as provided by rule 351—4.36(68A,68B).

4.15(7) *Reverse entries—refunds.* If a committee receives a refund of all or part of a disbursement previously made, the committee shall report the refund on Schedule B as a reverse entry, reducing the monetary expenditures. The purpose should include an explanation as to why the refund was made.

4.15(8) *Interest paid; bank charges.* Although repayments of loan principal are reported on Schedule F (see rule 351—4.18(68A,68B)), interest payments on loans shall be reported on Schedule B. Bank service charges and fees (e.g., monthly service fees, costs for check printing, returned check charges) shall also be reported and identified on Schedule B.

This rule is intended to implement Iowa Code Supplement section 68A.402.

351—4.16(68A,68B) Schedule D - Incurred Indebtedness.

4.16(1) *Reporting of debts and obligations other than monetary loans.* The committee shall report all debts and obligations owed by the committee which are in excess of the thresholds in subrule 4.14(3). This applies to any unpaid debt or obligations incurred by the committee for the purchase of a good or service, either as a debt or obligation owed to the immediate provider of the good or service, or as a debt or obligation owed to an individual who initially personally paid for the good or service on behalf of the committee with the expectation of ultimately receiving reimbursement from the committee. However, monetary loans to the committee (which are deposited directly into the committee's account) shall be reported on Schedule F, not on Schedule D.

4.16(2) *Date incurred; balance owed.* The committee shall report the amounts of all indebtedness owed by the committee at the end of the reporting period, reported chronologically by the date incurred. The date the debt or obligation is incurred is the date on which the committee committed to obtaining the good or service underlying the obligation. This date may be earlier than the date the provider of the good or service issues a bill to the committee. For example, if the committee places a printing order, but the printer does not issue a bill until some time after the order is placed, the date which shall be reported as the date the debt was incurred is the date the order is placed, not the date the bill was issued. If the precise amount of the final bill is not known by the time the report is due, the committee shall provide its best estimate as to what the obligation will be, with an indication "(e)" that the amount reported is an estimate. The complete date (month/day/year) shall be provided. Debts and obligations incurred and reported in a prior reporting period but which remain unpaid as of the end of the current reporting period shall be included, showing the remaining balance on the obligation, as well as any new obligations incurred in the current reporting period. Payments of all or part of a previously reported obligation shall be reported as expenditures on Schedule B.

4.16(3) *Name and address of person to whom the debt or obligation is owed.* The schedule shall contain the name and address of each person to whom an obligation is owed, including both those obligations which were incurred during the reporting period and those outstanding obligations which are being carried forward from prior reports. If the obligation is owed to an individual who initially

personally paid for the good or service on behalf of the committee with the expectation of ultimately receiving reimbursement from the committee, the original nature of the obligation shall be provided; the name and address of the original provider of the good or service shall also be provided, unless the nature of the obligation indicates that the obligation is for the anticipated reimbursement for mileage or postage stamps.

4.16(4) *Nature of obligation.* The schedule shall include a description of the nature of each obligation. The description shall be a clear and concise statement that specifically describes the transaction which has occurred. The following general terms are examples of descriptions which are not acceptable: "expenses," "reimbursement," "candidate expense," "services," "supplies," and "miscellaneous expense." The following are examples of acceptable descriptions: "printing—candidate yard signs," "printing—PAC membership solicitation letter," "mailing—candidate brochures," "anticipated reimbursement for candidate lodging to attend campaign event," or "anticipated mileage reimbursement—150 miles @ 25¢ per mile." A combined description is not acceptable unless sufficient information is provided so that the cost of separate purposes can be discerned, for example, "printing and mailing of 1,000 brochures."

This rule is intended to implement Iowa Code Supplement section 68A.402.

351—4.17(68A,68B) Schedule E - In-kind Contributions.

4.17(1) *Reporting of all in-kind contributions; chronological listing.* The committee shall report the amounts of all in-kind contributions which are accepted by the committee during the reporting period. The schedule entries shall be listed in chronological order by the date on which the contribution is received.

4.17(2) *Date of contribution—date received.* The schedule shall include the complete date (month/day/year) on which the in-kind contribution was provided to the committee. The actual or fair market value of the in-kind contribution shall be reported regardless of whether or not the person providing the in-kind contribution has been billed for the costs.

4.17(3) *Name and address of contributor.* The schedule shall include the name and address of each person who has made one or more in-kind contributions to the committee if the aggregate amount of contributions (either monetary or in-kind) received from that person in the calendar year exceeds $25, except that the itemization threshold is $200 for a state statutory political committee and $50 for a county statutory political committee.

4.17(4) *Relationship to candidate.* In the case of in-kind contributions to candidates' committees, the schedule shall include information indicating whether the contributor is related to the candidate within the third degree of consanguinity or affinity, as defined in subrule 4.14(5).

4.17(5) *Description of in-kind contribution; loaned equipment as in-kind contribution.*

a. The schedule shall include a description of the good or service contributed to the committee in kind. The description shall be a clear and concise statement that specifically describes the transaction which has occurred.

b. A committee's use of equipment owned by another organization, committee, or individual is reportable as an in-kind contribution. Equipment includes, but is not limited to, typewriters, calculators, copy machines, office furniture, computers and printers.

4.17(6) *Fair market value.* The committee shall provide either the actual (if known) or estimated fair market value of the good or service received.

4.17(7) *Fund-raiser item.* Goods or services contributed in kind for sale at a fund-raising event shall be designated by marking the indicated space on the schedule.

4.17(8) *Unitemized contributions.* Notwithstanding the other provisions of this rule, in-kind contributions with a fair market value less than the itemization threshold noted in subrule 4.17(3) may be reported as "unitemized in-kind contributions."

This rule is intended to implement Iowa Code Supplement section 68A.402.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.18(68A,68B) Schedule F - Loans Received and Repaid.

4.18(1) *Reporting of monetary loans (not debts and obligations for goods and services).* The committee shall report all loan activity made to or repaid by the committee during the reporting period. This applies to any loan of money which is deposited into the committee's accounts. However, other debts and obligations owed for the provision of goods or services to the committee (which are not monetary advances deposited into the committee's account) shall be reported on Schedule D, not on Schedule F.

4.18(2) *Report of lump sum of unpaid loans carried over from last report.* The schedule shall contain a beginning entry of the total unpaid loans as of the last report. Loans received and itemized on prior reports should not be re-itemized on the current report, except as necessary to indicate repayment activity.

4.18(3) *Date received.* The schedule shall include the complete date (month/day/year) the loan was physically received by a person on behalf of the committee. If the loan was by check, the date of the loan to be reported is the date the check is physically received by a person on behalf of the committee, even if this date is different from the date shown on the check.

4.18(4) *Date paid.* The schedule shall include the complete date (month/day/year) a full or partial loan repayment is made by the committee. The date of the repayment is the date the check is issued. Full or partial loan repayments shall be shown on this schedule and should not be reported on Schedule B. However, loan interest payments shall be reported on Schedule B (see rule 351—4.15(68A,68B)) and not on Schedule F. Loans which may be and are forgiven in full or in part are considered in-kind contributions and shall be itemized on Schedule E, with a cross-reference entry in the space provided on Schedule F.

4.18(5) *Name and address of lender.* The schedule shall include the name and address of each person who has made one or more loans of money to the committee during the reporting period, or to whom the committee makes a full or partial loan repayment during the reporting period. If the person who made the loan to the committee is not the original source of the money, when the original source of the money is a third party (such as a bank which loans money to an individual who loans it to the committee) or if a third party has personally paid and assumed a loan from the original lender (such as an individual who pays off the loan to the bank with the expectation of receiving the loan repayment from the committee), the report shall also identify the name and address of the third party.

4.18(6) *Relationship to candidate.* In the case of monetary loans to candidates' committees, the schedule shall include information indicating whether the lender is related to the candidate within the third degree of consanguinity or affinity, as defined in subrule 4.14(5).

This rule is intended to implement Iowa Code Supplement section 68A.402.

351—4.19(68A) Schedule G - Breakdown of Monetary Expenditures by Consultants. A committee that enters into a contract with a consultant for future or continuing performance shall be required to report expenditures made to the consultant and the nature of the performance of the consultant that is expected to be received by the committee. A committee is required to report in Part 1 of Schedule G any contracts with consultants that it has negotiated, the complete name and address of the consultant, the period of time during which the contract is in effect, and estimates of performance to be derived from the contract. Expenditures made to the consultant during a reporting period shall be reported with all other expenditures on Schedule B, and debts incurred with the consultant during the reporting period shall be reported with all other debts on Schedule D. Additionally, a detailed breakdown of the expenditures made by the consultant shall be reported by the committee in Part 2 of Schedule G and shall include the date of the expenditure, the purpose of the expenditure and the amount of the expenditure. The description of the purpose of the expenditure shall be consistent with the provisions of subrule 4.15(3).

For purposes of this rule, "contract" means an oral or written agreement between two parties for the supply or delivery of specific services in the course of the campaign. "Performance" means the execution or fulfillment of the contractual agreement. "Nature of performance" means a clear description of the specific services received or benefit derived as the result of a contract with a consultant. "Estimate of

performance" means a clear description of the services the committee reasonably expects to receive or the benefit the committee reasonably expects to derive during the period of the contract.

This rule is intended to implement Iowa Code sections 68A.102(9) as amended by 2005 Iowa Acts, House File 312, section 3, and 68A.402A.

351—4.20(68A,68B) Schedule H - Campaign Property.

4.20(1) *Ongoing inventory.* Equipment, supplies, or other materials purchased with campaign funds or received in kind are campaign property. Campaign property, other than consumable campaign property, with a value of $500 or more when acquired by the committee shall be listed on the inventory section of the schedule. The property shall be listed on each report until it is disposed of by the committee or its residual value falls below $100 and the property is listed once as having a residual value of less than $100. "Consumable campaign property" means stationery, yard signs, and other campaign materials that have been permanently imprinted to be specific to a candidate or election. For property purchased by the committee, the date purchased shall be the earlier of the date the committee attained physical possession of the property or the date the committee issued payment for the property. For in-kind contributions, the date received shall be the date on which the committee attained physical possession of the property. The committee shall provide the complete date (month/day/year). The schedules shall include the purchase price of property purchased by the committee and the actual or estimated fair market value of property received as an in-kind contribution, as well as the actual or estimated current fair market value of the property at the end of the current reporting period.

4.20(2) *Sales or transfers of campaign property.* The schedule shall include information regarding the sale or transfer of campaign property, other than consumable campaign property, which occurred during the current reporting period. The information shall include the complete date of the transaction (month/day/year), the name and address of the purchaser or donee, and a description of the property. If the property is sold, the information shall include the sales price received; if the property is donated, the information shall include the fair market value of the property at the time of the transfer.

This rule is intended to implement Iowa Code Supplement sections 68A.304 and 68A.402.

351—4.21(68A) Filing of reconciled bank statement. A candidate, a committee, an independent expenditure committee, or a sole individual filing Form Ind-Exp-I shall submit a copy of a campaign bank statement including a reconciliation to justify outstanding checks and other discrepancies between the ending balance on the bank statement and the ending balance on a campaign statement or report when requested to do so by the board. A committee that files a final campaign statement or report for purposes of dissolving shall comply with the requirements of subrule 4.55(5) concerning the filing of a final bank statement. The board may impose sanctions as provided in Iowa Code chapter 68B and rule 351—9.4(68B) against a person for failing to file a requested reconciled bank statement.

This rule is intended to implement Iowa Code sections 68A.402A and 68B.32A(4).

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10; **ARC 9216B**, IAB 11/3/10, effective 12/8/10]

351—4.22(68A,68B) Verification of reports; incomplete reports.

4.22(1) The board staff will review and desk audit each disclosure report. The board may contact other parties to verify the accuracy and completeness of the reports. The board may contact a representative of the committee and may contact other parties to determine the authenticity of information provided about filed reports.

4.22(2) If, upon review, board staff determine that a committee's report is incomplete because required information has been omitted or has been incorrectly reported, the staff shall communicate the deficiencies to the committee. A failure to satisfactorily respond to or to remedy the error or omission may be grounds for a violation of Iowa Code Supplement section 68A.402 as a failure to file a report which conforms to the requirements of that provision.

This rule is intended to implement Iowa Code Supplement section 68A.402 and Iowa Code section 68B.32A.

351—4.23(68A,68B) Amendment—statements, disclosure reports and notices. A committee may amend a previously filed statement of organization, disclosure report or notice of dissolution. To amend a previously filed statement, report or notice, the committee shall file an amended document on the approved form and shall designate on the form in the space provided, if applicable, that the document being filed is an amendment to a previously filed statement, report or notice. The term "amended document" as used in this rule shall mean a document on forms issued by the board which includes only the information which is being added, deleted or changed from a previously filed statement of organization or notice of dissolution.

This rule is intended to implement Iowa Code Supplement section 68A.402.

351—4.24(68A) Reporting of state party building fund transactions. Pursuant to Federal Election Commission Advisory Opinion 2004-28, the board will permit a state statutory political committee (state party committee) to receive contributions from corporations, insurance companies, and financial institutions when those contributions are placed in the state party building fund account, the contributions are used to pay for costs associated with the building, and all transactions involving the fund are disclosed pursuant to this rule.

A state party committee filing a state party building fund report under this rule shall use either the report form prescribed by the board or a computer-generated report so long as the report includes the information required under subrule 4.24(2).

4.24(1) *Period covered.* A state party building fund report shall cover the time period from January 1 through December 31 of the previous year.

4.24(2) *Information to be disclosed.* The following information shall be disclosed on a state party building fund report:

a. The name and address of the state party committee.

b. The name and address of each person who makes a contribution in excess of $200, or contributions in the aggregate that exceed $200 during the period covered, to the state party building fund. If no contributions were received for the fund, the report shall disclose $0.00 as contributions received.

c. The date and the amount of the contribution. If aggregate contributions from one person are received that exceed $200, the amount to be disclosed shall be the total amount received from that person for the period covered and the date to be disclosed shall be the date of the last contribution.

d. The total amount of all contributions of $200 or less received during the period covered. This total amount shall be disclosed as being received from "unitemized" with the date of the contribution being the last day of the reporting period.

e. The name and mailing address of each person to whom an expenditure that exceeds $200 is made, or expenditures in the aggregate that exceed $200 during the period covered, from the state party building fund. If no expenditures were made from the fund, the report shall disclose $0.00 as expenditures made.

f. The date and the amount of the expenditure. If aggregate expenditures that exceed $200 are made to one person, the amount to be disclosed shall be the total amount made to that person for the period covered and the date to be disclosed shall be the date of the last expenditure.

g. The total amount of all expenditures of $200 or less made during the period covered. This total amount shall be disclosed as being expended to "unitemized" with the date of the expenditure being the last day of the reporting period.

h. The signature and date of the individual filing the state party building fund report.

4.24(3) *Place of filing.* A state party building fund report shall be filed with the board at 510 E. 12th Street, Suite 1A, Des Moines, Iowa 50319, or by fax at (515)281-3701.

4.24(4) *Time of filing.* A state party building fund report shall be filed on or before January 31 of each year. If mailed, the report must bear a United States Postal Service postmark dated on or before the due date. A faxed report must be submitted on or before 11:59 p.m. on the due date. If January 31 falls on a Saturday, Sunday, or holiday on which the board office is closed, the due date shall be extended to the next working day when the board office is open.

4.24(5) *Failure to file.* If the board determines that a state party committee has failed to timely file a state party building fund report, the state party committee is subject to the possible imposition of board sanctions.

This rule is intended to implement Iowa Code sections 68A.402A(1)*"k"* and 68A.503.

351—4.25(68A,68B) Legitimate expenditures of campaign funds.

4.25(1) Expenses which may be paid from campaign funds for campaign purposes include, but are not limited to, the following items so long as the items promote or enhance the candidacy of the candidate:

a. Electronic media advertising, such as radio, cable television and commercial television.

b. Published advertising, such as newspaper, magazine, newsletter and shopper advertising.

c. Printed promotional materials, such as brochures, leaflets, flyers, invitations, stationery, envelopes, reply cards, return envelopes, campaign business cards, direct mailings, postcards and "cowboy" political cards.

d. Political signs, such as yard signs, car signs, portable outdoor advertising, stationary outdoor advertising and billboards.

e. Political advertising specialty items, such as campaign buttons, campaign stickers, bumper stickers, campaign pins, pencils, pens, matchbooks, balloons, scratch pads, calendars, magnets, key chains, and articles of clothing that are political advertising.

f. Travel and lodging expenses of the campaign workers for campaign purposes and political party activities. Travel and lodging expenses for a candidate to attend a national political party convention are also permitted.

g. Contributions to political party committees.

h. The purchase of tickets to a meal for the candidate and one guest so long as the attendance at the meal by the candidate and guest is for the sole purpose of enhancing the candidacy of any person.

i. General campaign expenditures, such as printing, copy machine charges, office supplies, campaign photographs, gambling permits, fund-raiser prizes, postage stamps, postage meter costs, bulk mail permits, telephone installation and service, facsimile charges, and computer services. However, the purchase or rental of formal wear to attend a political event is not a permissible general campaign expenditure.

j. Purchase or lease of campaign equipment, such as copy machines, telephones, facsimile machines, computer hardware, software and printers.

k. Purchase or lease of campaign office space, parking lots or storage space and the payment for campaign office utilities and maintenance.

l. Payment of salaries, fringe benefits, bonuses, and payroll taxes of paid campaign staff. As provided in Iowa Code section 68A.302(2) as amended by 2009 Iowa Acts, Senate File 50, section 1, family members who perform actual work or services for a campaign and are not the candidate, candidate's spouse, or candidate's dependent children may be compensated for such work or services.

m. Payment for check printing and financial institution banking service charges.

n. Lease or rental of a campaign vehicle, provided that a detailed trip log which provides dates, miles driven, destination and purpose is maintained, and that noncampaign miles are reimbursed to the committee at an amount not to exceed the current rate of reimbursement allowed under the standard mileage rate for computations of business expenses pursuant to the Internal Revenue Code. However, the purchase of a campaign vehicle is prohibited.

o. Reimbursement to candidates and campaign workers for mileage driven for campaign purposes in a personal vehicle, provided that a detailed trip log which provides dates, miles driven, destination and purpose is maintained, and that reimbursement is paid at an amount not to exceed the current rate of reimbursement allowed under the standard mileage rate for computations of business expenses pursuant to the Internal Revenue Code.

p. Payment for food expenses and supplies for campaign-related activities, such as the purchase of food, beverages and table service for fund-raising events or campaign volunteers. However, except as provided in paragraph *"h,"* the purchase of tickets for meals or fund-raising events for other candidates is prohibited, and the purchase of groceries for the candidate or candidate's family is also prohibited.

Payment for meals for the candidate (other than those involving tickets for fund-raiser events as addressed in paragraph *"h"*) is permitted as an allowable expenditure for campaign purposes if the meal was associated with campaign-related activities.

q. Payment of civil penalties and hearing costs assessed by the board.

r. Payment for the services of attorneys, accountants, consultants or other professional persons when those services relate to campaign activities.

s. Subscriptions to newspapers and periodicals that circulate within the area represented by the office that a candidate is seeking or holds, that contain information of a general nature about the state of Iowa, or that contain information useful to all candidates such as The Wall Street Journal and Roll Call. Candidates who are unsure whether a subscription is permissible shall seek guidance from the board prior to paying for the subscription with campaign funds.

t. Membership in service organizations including a local chamber of commerce that the candidate joins solely for the purpose of enhancing the candidate's candidacy.

u. Repayment of campaign loans made to the committee. As provided in Iowa Code section 68A.302(2) as amended by 2009 Iowa Acts, Senate File 50, section 1, candidates who make loans to their own committees shall not charge interest on the loans.

v. Purchase of reports of other candidates and political committees so long as the reports' contents are not used for solicitation or commercial purposes.

w. Donations to charitable organizations unless the candidate or the candidate's spouse, child, stepchild, brother, brother-in-law, stepbrother, sister, sister-in-law, stepsister, parent, parent-in-law, or stepparent is employed by the charitable organization and will receive a direct financial benefit from a donation.

x. Contributions to federal, state, county and city political party committees.

y. Refunds to contributors when a contribution has been accepted in error, or when a committee chooses to dispose of leftover funds by refunding them in prorated shares to the original contributors.

z. Payment for items with a purchase price not to exceed $250 per person that are presented to committee workers in recognition of services to the committee.

aa. Expenses incurred with respect to an election recount as provided in Iowa Code section 50.48.

bb. The sharing of information in any format such as computer databases containing yard sign locations or lists of registered voters with another candidate's committee.

4.25(2) Expenses which may be paid from campaign funds for educational and other expenses associated with the duties of office include, but are not limited to, the following items:

a. Purchase or lease of office supplies and equipment, such as paper, copy machines, telephones, facsimile machines, computer hardware, software and printers.

b. Travel, lodging and registration expenses associated with attendance at an educational conference of a state, national, or regional organization whose memberships and officers are primarily composed of state or local government officials or employees. However, meal expenses are not allowable as expenses associated with the duties of office under any circumstances.

c. Meals and other expenses incurred in connection with attending a local meeting to which the officeholder is invited and attends due to the officeholder's official position as an elected official.

d. Purchases of small, incidental items such as pencils, pens, rulers and bookmarks provided to members of the public touring the offices of the state or a political subdivision. However, such items distributed on public property shall not expressly advocate the election or defeat of a candidate or the adoption or defeat of a ballot issue as prohibited in Iowa Code Supplement section 68A.505. For example, a bookmark bearing the state seal could be distributed on public property, while a bookmark that identified the donor as a candidate for office could not be distributed on public property.

e. Gifts purchased for foreign dignitaries when the officeholder is part of an official trip out of the country such as a trade mission or exchange program.

f. Printing of additional stationery and supplies above the standard allotment of the state or political subdivision.

4.25(3) Expenses which may be paid from campaign funds for constituency services include, but are not limited to, the following items:

a. Mailings and newsletters sent to constituents.

b. Polls and surveys conducted to determine constituent opinions.

c. Travel expenses incurred in communicating with members of an elected official's constituency, provided that a detailed trip log which provides dates, miles driven, destination and purpose is maintained, and that reimbursement is paid at an amount not to exceed the current rate of reimbursement allowed under the standard mileage rate for computations of business expenses pursuant to the Internal Revenue Code. However, meal expenses are not allowable as expenses associated with constituency services under any circumstances.

d. Holiday and other greeting cards sent to constituents.

This rule is intended to implement Iowa Code Supplement sections 68A.301, 68A.302, and 68A.303.
[**ARC 7647B**, IAB 3/25/09, effective 4/29/09; **ARC 7801B**, IAB 6/3/09, effective 7/8/09]

351—4.26(68A) Transfers between candidates.

4.26(1) *Transfer of assets between different candidates.* A candidate's committee may transfer an asset to a candidate's committee established by a different candidate so long as the recipient committee pays the transferring committee the fair market value of the asset and the transaction is properly disclosed on each committee's disclosure report.

4.26(2) *Transfer of assets for same candidate.* A candidate's committee may transfer funds, assets, loans, and debts to a committee established for a different office when the same candidate established both committees. A candidate seeking to transfer funds, assets, loans, or debts under this subrule shall file either an amended statement of organization disclosing information for the new office sought or register a new committee regardless of whether the $750 financial filing threshold for the new office will be exceeded.

This rule is intended to implement Iowa Code Supplement section 68A.303.
[**ARC 7992B**, IAB 7/29/09, effective 9/2/09]

351—4.27(68A) Filing of independent expenditure statement. Pursuant to 2009 Iowa Code Supplement section 68A.404 as amended by 2010 Iowa Acts, Senate File 2354, section 3, any person except a candidate, a committee filing a statement of organization, a federal committee, or an out-of-state committee that makes one or more independent expenditures in excess of $750 in the aggregate shall file Form Ind-Exp-O. A sole individual making one or more independent expenditures in excess of $750 in the aggregate shall file Form Ind-Exp-I. A committee that has registered by filing a statement of organization shall disclose an independent expenditure on the appropriate campaign disclosure report.

4.27(1) *Independent expenditure defined.* "Independent expenditure" means an expenditure as defined in 2009 Iowa Code Supplement section 68A.404(1) as amended by 2010 Iowa Acts, Senate File 2354, section 3.

4.27(2) *Independent expenditure reporting.* When applicable under 2009 Iowa Code Supplement section 68A.404 as amended by 2010 Iowa Acts, Senate File 2354, section 3, and rule 351—4.27(68A), Form Ind-Exp-O shall be filed by a person and Form Ind-Exp-I shall be filed by a sole individual. Both forms shall be in a format that will enable a person or sole individual making an independent expenditure to comply with all of the reporting requirements in 2009 Iowa Code Supplement section 68A.404 as amended by 2010 Iowa Acts, Senate File 2354, section 3.

4.27(3) *Place of filing.* Form Ind-Exp-O and Form Ind-Exp-I shall be filed with the board electronically via the board's Web site at www.iowa.gov/ethics.

4.27(4) *Time of filing.* Form Ind-Exp-O or Form Ind-Exp-I shall be filed within 48 hours of the person's or sole individual's making an independent expenditure exceeding $750 in the aggregate or within 48 hours of disseminating the communication to its intended audience, whichever is earlier. An independent expenditure is deemed made at the time that the cost is incurred regardless of whether or not the costs for the independent expenditure have been billed.

4.27(5) *Failure to file.* The failure to timely file either Form Ind-Exp-O or Form Ind-Exp-I shall be subject to the imposition of civil penalties pursuant to 351—subrule 4.59(7).

4.27(6) *Attribution statement applicable.* Any person that makes an independent expenditure in any amount shall comply with the appropriate "paid for by" attribution statement pursuant to 2009 Iowa

Code Supplement section 68A.405 as amended by 2010 Iowa Acts, Senate File 2354, section 4, and by 2010 Iowa Acts, Senate File 2195, section 7, and rule 351—4.38(68A).

This rule is intended to implement 2009 Iowa Code Supplement section 68A.404 as amended by 2010 Iowa Acts, Senate File 2354, section 3.

[**ARC 7800B**, IAB 6/3/09, effective 7/8/09; **ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.28(68A) Prohibition on contributions and independent expenditures by foreign nationals. As provided in Federal Election Commission regulation 11 CFR 110.20, a foreign national shall not, directly or indirectly, make a monetary or in-kind contribution, or specifically promise to make a contribution, in connection with a state or local campaign or election in Iowa. A foreign national shall not, directly or indirectly, make a contribution to a candidate or to a campaign committee organized under Iowa Code chapter 68A. Pursuant to 2009 Iowa Code Supplement section 68A.404(2)*"c"* as amended by 2010 Iowa Acts, Senate File 2354, section 3, foreign nationals are prohibited from making independent expenditures in relation to any state or local election in Iowa.

4.28(1) *Foreign national defined.* "Foreign national" means a person as defined in 2009 Iowa Code Supplement section 68A.404(2)*"c"* as amended by 2010 Iowa Acts, Senate File 2354, section 3.

4.28(2) *Acceptance of campaign contributions and donations from foreign nationals.* No person shall knowingly accept or receive a campaign contribution from a foreign national. No person shall knowingly accept a monetary donation from a foreign national for purposes of making an independent expenditure.

4.28(3) *Participation by foreign nationals in decisions involving election-related activity.* A foreign national shall not, directly or indirectly, participate in the decision-making process of any person with regard to such person's election-related activities. Decisions including election-related activities include decisions involving the making of contributions, donations, or expenditures in connection with elections for state or local office, ballot issues, or decisions involving the administration of a committee.

This rule is intended to implement 2009 Iowa Code Supplement section 68A.404(2)*"c"* as amended by 2010 Iowa Acts, Senate File 2354, section 3.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.29(68A,68B) Contributions by minors. Persons under 18 years of age may make contributions to a candidate or political committee if all of the following conditions exist:

1. The decision to contribute is made knowingly and voluntarily by the minor;
2. The funds, goods, or services contributed are owned or controlled exclusively by the minor, such as income earned by the minor, the proceeds of a trust for which the minor is the beneficiary, or a savings account opened and maintained exclusively in the minor's name; and
3. The contribution is not made from the proceeds of a gift, the purpose of which was to provide funds to be contributed, or is not in any other way controlled by another person.

This rule is intended to implement Iowa Code Supplement section 68A.404.

351—4.30(68A,68B) Funds from unknown source prohibited; subsequent identification of source; notice to contributors.

4.30(1) *Anonymous contributions in excess of $10 prohibited.* No person shall make a contribution in excess of $10 to a committee without providing the person's name and address to the committee. The committee shall not maintain in any campaign account funds in excess of $10 that cannot be accounted for and reconciled with the committee's disclosure reports.

4.30(2) *Escheat to the state.* Any contribution in excess of $10 from an unknown source or campaign funds in excess of $10 that cannot be accounted for and reconciled shall escheat to the state of Iowa as required by Iowa Code section 68A.501 as amended by 2007 Iowa Acts, Senate File 39, section 8. A committee required to escheat shall escheat such funds by depositing the funds into the committee's campaign account and issuing a committee check to the general fund in the same amount. The committee check shall be sent to the board office at 510 East 12th Street, Suite 1A, Des Moines, Iowa 50319, for transmittal to the office of treasurer of state.

4.30(3) *Subsequent identification of source.* A committee discovering the source of any funds that have been escheated to the state may make an application to the board for a return of the funds if the following requirements are met:

a. The committee has not dissolved;

b. Documentation of the name and address of the source is provided;

c. The amount requested to be returned is in excess of $100; and

d. The application is made within 90 days of the date of the deposit in the general fund of the state of Iowa.

4.30(4) *Notice at fund-raising event.* Pursuant to Iowa Code Supplement section 68A.501, a person requested to make a contribution at a fund-raising event shall be advised that it is illegal to make a contribution in excess of $10 unless the person making the contribution also provides the person's name and address. Notice of the requirement to provide a person's name and address for a contribution in excess of $10 may be made orally or in a written statement that is displayed at the fund-raising event.

This rule is intended to implement Iowa Code section 68A.501.

351—4.31(68A) Information required for a trust to avoid a contribution in the name of another person. A contribution to a committee by a trustee solely in the name of the trust constitutes a contribution in the name of another person as prohibited in Iowa Code Supplement section 68A.502 unless the recipient committee publicly discloses the contribution as provided in this rule.

4.31(1) *Living or revocable trust.* If the contribution involves a trust identified as a revocable trust or a living trust that does not file a separate trust tax return and whose federal tax ID number is the same as the social security number of the grantor who creates the trust and who is also a trustee, the contribution shall be reported by the recipient committee as being made by the "(name) revocable (or living) trust."

4.31(2) *Other trusts.* For a contribution involving a trust that does not qualify under subrule 4.31(1), the recipient committee shall identify the trust, the trustee, and the trustor.

4.31(3) *Registering a committee.* A trust, except for a living or revocable trust, that raises or spends more than $750 for campaign activities shall register a political committee (PAC) and shall file disclosure reports. A trust, except for a living or revocable trust, that makes a one-time contribution in excess of $750 may file Form DR-OTC in lieu of filing a statement of organization and filing disclosure reports.

This rule is intended to implement Iowa Code Supplement sections 68A.402(6) and 68A.502.

351—4.32(68A) Contributions from political committees not organized in Iowa. Iowa committees may receive contributions from committees outside Iowa, and committees outside Iowa may contribute to Iowa committees provided the out-of-state committee complies with either subrule 4.32(1) or subrule 4.32(2). For purposes of this rule, "out-of-state committee" means a committee that is registered with the campaign enforcement agency of another state or is registered with the Federal Election Commission. For purposes of this rule, "contribution" does not include an item purchased at fair market value from an Iowa committee.

4.32(1) *Regular filings.* Out-of-state committees may choose to comply with the regular disclosure filing requirements in Iowa Code Supplement sections 68A.201 and 68A.402 by filing a statement of organization and periodic disclosure reports.

4.32(2) *Verified statement of registration.* In lieu of filing a statement of organization and regular disclosure reports as required by Iowa Code chapter 68A, the out-of-state committee shall file with the board a verified statement registration form (VSR) for each contribution in excess of $50. The VSR shall contain the following information:

a. The complete name, address and telephone number of the out-of-state committee;

b. The state or federal agency with which the out-of-state committee is registered;

c. All parent entities or other affiliates or sponsors of the out-of-state committee;

d. The purpose of the out-of-state committee;

e. The name, address and telephone number of an Iowa resident authorized to receive service on behalf of the out-of-state committee;

f. The name and address of the Iowa recipient committee;

g. The date and amount of the contribution, including description if the contribution is in-kind; and

h. An attested statement that the jurisdiction with which the out-of-state committee is registered has reporting requirements substantially similar to those of Iowa Code chapter 68A. The statement shall include confirmation that the contribution is made from an account that does not accept contributions prohibited by Iowa Code section 68A.503 unless the contribution from the out-of-state committee is made to an Iowa ballot issue committee.

4.32(3) *Signature.* The VSR shall be signed by the individual filing the VSR on behalf of the out-of-state committee. A VSR that is filed electronically using the board's Web site is deemed signed when filed.

4.32(4) *Where filed.* Every VSR filed for a contribution in excess of $50 shall be filed with the board at 510 East 12th Street, Suite 1A, Des Moines, Iowa 50319, electronically using the board's Web site at www.iowa.gov/ethics, as an E-mail attachment, or by fax at (515)281-4073.

4.32(5) *When filed.* The VSR shall be filed with the board on or before the fifteenth day after the date of the contribution, or mailed bearing a United States Postal Service postmark dated on or before the fifteenth day after the date of the contribution. For purposes of this subrule, "date of the contribution" means the day, month, and year the contribution check is dated. If the board deems it necessary, a copy of any contribution check may be required to be filed with the board. When a copy of a check is required to be filed with the board, the copy shall be filed within ten days after notice by the board.

4.32(6) *Enhanced filing.* An out-of-state committee determining that the jurisdiction under which the committee is registered does not have reporting requirements substantially similar to those of Iowa Code Supplement chapter 68A may choose to comply by enhancing the committee's filing in the other jurisdiction. The enhanced filing shall meet the reporting requirements of Iowa Code Supplement chapter 68A for the reporting period during which contributions to Iowa committees are made. The report shall cover a period of at least one month. An out-of-state committee choosing this option shall comply with the VSR procedures in subrule 4.32(2) and attach a signed statement that the report has been enhanced to satisfy the Iowa reporting requirements.

This rule is intended to implement Iowa Code section 68A.201(5).

[**ARC 8286B**, IAB 11/18/09, effective 12/23/09]

351—4.33(68A) Reporting of earmarked contributions. A political committee or a political party committee is permitted to receive a contribution that is earmarked to be donated to another committee. A political committee or political party committee receiving and transferring an earmarked contribution is required to list on its disclosure report the name of the contributor and the name of the candidate or committee for which the contribution was earmarked. The political committee or political party committee shall notify the recipient committee in writing of the name of the individual contributor and the name of the committee that orginally received the contribution. The committee ultimately receiving the earmarked contribution shall disclose on its disclosure report both the name of the individual contributor and the name of the committee that originally received and then transferred the earmarked contribution. A ballot issue committee is not permitted to transfer earmarked contributions except to another ballot issue committee.

This rule is intended to implement 2009 Iowa Code Supplement section 68A.402.

[**ARC 8788B**, IAB 6/2/10, effective 7/7/10]

351—4.34(68A) Copies of reports filed by 527 Committees. Iowa Code section 68A.401A requires the board to adopt a procedure for 527 Committees that file reports with the Internal Revenue Service and engage in issue advocacy in Iowa to file copies of those reports with the board. If a 527 Committee notifies the board that it is filing reports with the Internal Revenue Service, the 527 Committee will be deemed in compliance with Iowa Code section 68A.401A. The board will then establish on its Web site a link to the reports filed with the Internal Revenue Service, or the board will otherwise post on its Web site the reports filed with the Internal Revenue Service.

This rule is intended to implement Iowa Code section 68A.401A.

351—4.35(68A) Permanent organizations forming temporary political committees; one-time contributor filing Form DR-OTC. Pursuant to Iowa Code section 68A.402(9), a permanent organization temporarily engaging in activity that exceeds the $750 financial filing threshold described in rule 351—4.1(68A,68B) is required to organize and register a political committee (PAC), file disclosure reports, and, upon completion of activity, file a notice of dissolution. A permanent organization that is temporarily a political committee shall comply with all of the campaign laws in Iowa Code chapter 68A and this chapter. A permanent organization that makes loans to a candidate or committee or that is owed debts from a candidate or committee is not deemed to be engaging in political activity requiring registration.

4.35(1) *Form DR-OTC.* A permanent organization that makes a one-time contribution in excess of $750 to a committee may, in lieu of filing a statement of organization, disclosure reports, and a notice of dissolution, file Form DR-OTC. The following information shall be disclosed on Form DR-OTC:

a. The name and address of the organization making the contribution.

b. The name and address of a contact person for the organization making the contribution.

c. The name and address of the campaign committee receiving the contribution. If the contribution is to a candidate or a candidate's committee, the source of the original funds used to make the contribution shall be disclosed.

d. The date and amount of the contribution. If the contribution is an in-kind contribution, a description of the provided goods or services must be included.

e. The date of election and the county in which the recipient committee is located if the committee is a county or local committee.

f. The date and signature of the person filing Form DR-OTC. A Form DR-OTC that is filed electronically using the board's Web site is deemed signed when filed.

A permanent organization that makes more than one contribution is not eligible to file Form DR-OTC and is required to file a statement of organization, file disclosure reports, and file a notice of dissolution.

4.35(2) *Place of filing.* Form DR-OTC shall be filed with the board at 510 East 12th Street, Suite 1A, Des Moines, Iowa 50319, filed by fax at (515)281-4073, or filed electronically using the board's Web site at www.iowa.gov/ethics.

4.35(3) *Time of filing.* Form DR-OTC shall be filed with the board within ten days after the one-time contribution in excess of $750 is made. The form must be physically received by the board or, if mailed, must bear a United States Postal Service postmark dated on or before the report due date. A faxed or electronically filed Form DR-OTC must be submitted on or before 11:59 p.m. of the tenth day after the organization of the committee is required. If the tenth day falls on a Saturday, Sunday, or holiday on which the board office is closed, the filing deadline is extended to the next working day when the board office is open.

4.35(4) *Failure to register.* If the board discovers that a permanent organization has become subject to the provisions of Iowa Code Supplement chapter 68A but did not timely file a statement of organization or file Form DR-OTC, as applicable, the permanent organization is subject to the possible imposition of board sanctions.

4.35(5) *Partial refund of contribution.* A committee that receives a contribution from a permanent organization that causes the organization to become subject to the provisions of Iowa Code Supplement chapter 68A may refund all or part of a contribution to the organization so as to reduce the contribution to $750 or less and remove the organization's filing obligations.

This rule is intended to implement Iowa Code sections 68A.102(18) and 68A.402.

351—4.36(68A) Cash transactions. All disbursements, including all expenditures and any other withdrawals from committee funds, shall be by check, debit card, or credit card. Cash withdrawals and "petty cash" accounts are not permitted. If a committee fundraising activity necessitates a cash drawer for making change or other cash transactions, the committee may issue a check payable to the committee treasurer or the candidate, in the case of a candidate's committee, or payable to the committee treasurer or the committee chairperson, in the case of a political committee. The purpose of the expenditure shall be reported on Schedule B as "cash advance for (describe activity, e.g., concession stand cash drawer)."

Upon completion of the fundraising activity, the committee shall redeposit the same amount as that which was advanced into the committee account. The redeposit shall be reported as a reverse entry on Schedule B as a "redeposit of cash advance for (describe activity)." The proceeds of the fundraising activity (excluding the cash advance) shall be reported on Schedule A - Contributions Received.

This rule is intended to implement Iowa Code sections 68A.203 as amended by 2005 Iowa Acts, House File 312, section 5, and 68A.402A.

351—4.37(68A,68B) Record keeping.

4.37(1) *Copies of reports.* A committee shall preserve a copy of every report it files for at least three years following the filing of the report.

4.37(2) *Supporting documentation.* The documentation which supports a committee's disclosure report shall be preserved by the committee for at least five years after the due date of the report that covers the activity documented in the records; however, a committee is not required to preserve these records for more than three years from the certified date of dissolution of the committee. At a minimum, the supporting documentation shall consist of all of the following:

a. A ledger or similar record-keeping device which details all contributions received by the committee. This record shall include the name and address of each person making a contribution in excess of $10, with the date and amount of the contribution. In lieu of or in addition to a ledger, the committee may record contributions received through a receipt book or other method of individually documenting the contributions, such as by making and keeping copies of the contribution checks.

b. The check register for the committee's account(s).

c. Bank statements for the committee's account(s).

d. Copies of canceled or duplicate checks for committee expenditures, if available.

e. Copies of bills or receipts for committee expenditures.

f. For committees which pay reimbursement for committee-related mileage, copies of vehicle mileage logs, including travel dates, distance driven, and travel purpose (description of event or activity). For a candidate's committee which leases a vehicle, the mileage log shall detail all mileage driven on the vehicle, including non-committee-related mileage.

4.37(3) *Records forwarded.* An officer of a committee who is replaced by another officer shall forward within seven days any committee records to the subsequently appointed or elected committee officer. The board may grant an extension of time for good cause. The failure to forward records pursuant to this subrule may subject the former officer to board sanctions.

This rule is intended to implement Iowa Code Supplement sections 68A.203, 68A.302, 68A.402 and 68A.403 and Iowa Code section 68B.32A.

[**ARC 7998B**, IAB 7/29/09, effective 9/2/09]

DIVISION III
POLITICAL MATERIAL—ATTRIBUTION STATEMENTS

351—4.38(68A) Political attribution statement—contents. Published material that expressly advocates for or against a clearly identified candidate or ballot issue shall contain a statement identifying the person paying for the published material. This statement is referred to as the "attribution statement." The term "published material" means any newspaper, magazine, shopper, outdoor advertising facility, poster, direct mailing, brochure, Internet Web site, television, video, or motion picture advertising, campaign sign larger than 32 square feet, or any other form of printed political advertising.

4.38(1) *Registered committee.* If the person paying for the published material is a committee that has filed a statement of organization, the words "paid for by" and the name of the committee shall appear on the material. An "independent expenditure committee" is not a "registered committee."

4.38(2) *Individual, married couple, or unregistered candidate's committee.* If the person paying for the published material is an individual, the words "paid for by" and the name and address of the individual shall appear on the material. Published material that is jointly paid for by a married couple shall include the words "paid for by" and the name and address of one member of the married couple. For purposes of

this subrule, "individual" includes a candidate who has not filed a statement of organization to register a committee.

4.38(3) *Multiple individuals.* If more than one individual paid for the published material, the words "paid for by", the names of the individuals, and either the addresses of the individuals or a statement that the addresses of the individuals are on file with the Iowa ethics and campaign disclosure board shall appear on the material. The addresses shall be provided to the board and made available for public inspection.

4.38(4) *Organization or unregistered political committee.* If the person paying for the published material is an organization, the words "paid for by", the name and address of the organization, and the name of one officer of the organization shall appear on the material. For purposes of this subrule, "organization" includes an organization advocating the passage or defeat of a ballot issue but that has not filed a statement of organization to register a political committee.

4.38(5) *Pooled efforts.* If the published material is paid for by more than one person, the words "paid for by" and the identification of the persons as set out in this rule shall appear on the material.

4.38(6) *Corporations.* If the person paying for the published material is a corporation, the words "paid for by", the name and address of the corporation, and the name and title of the corporation's chief executive officer shall appear on the material.

4.38(7) *Independent expenditures.* A person, including a sole individual, making an independent expenditure shall provide the attribution statement according to the appropriate category under this rule. The attribution statement shall also include a statement that the published material was not authorized by any candidate, candidate's committee, or ballot issue committee.

This rule is intended to implement 2009 Iowa Code Supplement section 68A.405 as amended by 2010 Iowa Acts, Senate File 2354, section 4, and by 2010 Iowa Acts, Senate File 2195, section 7.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.39(68A) Specific items exempted from or subject to attribution statement requirement; multiple pages. 2009 Iowa Code Supplement section 68A.405 as amended by 2010 Iowa Acts, Senate File 2354, section 4, and by 2010 Iowa Acts, Senate File 2195, section 7, and rule 351—4.38(68A) require the placement of a "paid for by" attribution statement on published material that expressly advocates for or against a clearly identified candidate or ballot issue, with certain exceptions.

4.39(1) *Items exempted from requirement.* The requirement to place a "paid for by" attribution statement does not apply to the following:

a. Editorials or news articles of a media organization that are not political advertisements.

b. Small items upon which the inclusion of the attribution statement would be impracticable, such as campaign signs 32 square feet or smaller that have been placed or posted on real property, bumper stickers, pins, buttons, pens, pencils, emery boards, matchbooks and, except as set out in subrule 4.39(2), items that are smaller than 2 inches by 4 inches. For purposes of this rule, 32 square feet is the total dimension of the campaign sign regardless of whether or not both sides of the sign are used for campaign advertising.

c. T-shirts, caps, and other articles of clothing that expressly advocate for or against a candidate or ballot issue.

d. Radio advertisements, live telephone calls, or auto-generated telephone messages.

e. Published material placed by an individual who acts independently and spends $100 or less of the individual's own resources to expressly advocate the passage or defeat of a ballot issue.

4.39(2) *Items subject to requirement.* The requirement to place a "paid for by" attribution statement applies to the following:

a. Published material such as campaign signs larger than 32 square feet that have been placed or posted on real property, billboards, posters, portable sign carriers, and signs affixed or painted to the side or top of a building or vehicle. A campaign sign placed on a building or vehicle shall contain the appropriate attribution statement regardless of the size of the sign.

b. Published material in a newspaper, magazine, shopper, or other periodical regardless of the size of the material.

c. Direct mailings, flyers, brochures, postcards, or any other form of published material that is larger than 2 inches by 4 inches and not otherwise set out in 351—4.39(68A).

d. Campaign Web sites. A blog that is not owned or controlled by a candidate or committee is not required to include an attribution statement disclosing who paid for the costs of the blog. A political advertisement on a blog is required to include the appropriate attribution statement disclosing who paid for the advertisement.

e. Television, video, and motion picture advertising. The attribution statement shall be displayed on the advertisement in a clearly readable manner for at least four seconds.

4.39(3) *Multiple pages.* If the published material consists of more than one page, the "paid for by" attribution statement need only appear on one page of the material. For a campaign Web site, the attribution statement need only appear on the home page of the site. A scratch pad need only include the attribution statement on the pad and not on each individual page of the pad.

This rule is intended to implement 2009 Iowa Code Supplement section 68A.405 as amended by 2010 Iowa Acts, Senate File 2354, section 4, and by 2010 Iowa Acts, Senate File 2195, section 7.
[**ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.40(68A,68B) Newspaper or magazine. For the purposes of these rules and Iowa Code Supplement section 68A.405, "newspaper or magazine" means a regularly scheduled publication of news, articles of opinion, and features available to the general public which does not require membership in or employment by a specific organization.

This rule is intended to implement Iowa Code Supplement section 68A.405.

351—4.41(68A,68B) Apparent violations; remedial action.

4.41(1) *Administrative resolution.* In an effort to informally resolve apparent violations of the requirement to place a "paid for by" attribution statement, the board may order administrative resolution of the matter. The board may direct the person responsible for placing the original published political material that did not include the attribution statement to place a correction notice in a local newspaper that reaches the same or substantially the same portion of the public that received the original published political material. A person may also resolve a violation of the "paid for by" attribution statement by resending corrected published political material to the same portion of the public that received the original published political material and by filing a copy of the corrected material with the board.

4.41(2) *Form of correction notice.* The correction notice shall be in substantially the following form: "On (date) (describe the type of published political material) was distributed that did not state who paid for it. The (describe the type of published political material) was paid for by (insert name)."

4.41(3) *Board notice.* The board shall notify the person who paid for the original published political material of the requirements of this rule.

4.41(4) *Refusal to place correction notice.* The board may initiate a contested case proceeding and impose discipline against any person who refuses to place a correction notice under this rule.

This rule is intended to implement Iowa Code section 68A.405 and Iowa Code Supplement section 68B.32A(8) as amended by 2006 Iowa Acts, House File 2512, section 3.

351—4.42(56,68B) Specific items exempted from or subject to attribution statement requirement. Rescinded IAB 2/4/04, effective 3/10/04.

351—4.43(56,68B) Apparent violations; remedial actions. Rescinded IAB 2/4/04, effective 3/10/04.

DIVISION IV
CORPORATE POLITICAL ACTIVITY

351—4.44(68A,68B) Prohibited corporate activity. As provided in 2009 Iowa Code Supplement section 68A.503 as amended by 2010 Iowa Acts, Senate File 2354, section 5, a financial institution, insurance company, or corporation is prohibited from using its resources to make monetary or in-kind campaign contributions to a candidate, candidate's committee, political committee that expressly

advocates for or against a candidate, or a political party committee. For purposes of this chapter, "corporate entity" shall include financial institutions, insurance companies, and corporations.

4.44(1) The prohibition on corporate political activity does not apply to any of the following:

a. An LLC, LLP, or any other organization that does not file articles of incorporation and is not owned in whole or in part by a corporation.

b. Monetary or in-kind campaign contributions to a ballot issue committee.

c. Independent expenditure communications.

d. A campaign committee using a corporate entity computer to generate and file a campaign disclosure statement or report.

4.44(2) For purposes of this rule, prohibited corporate activity shall include, but not be limited to, the following:

a. The physical placement of campaign materials on corporate property except as permitted under Iowa Code sections 68A.406 and 68A.503.

b. The use of motor vehicles, telephone equipment, long-distance lines, computers, typewriters, office space, duplicating equipment and supplies, stationery, envelopes, labels, postage, postage meters or communication systems of corporate entities.

c. The use of corporate entity facilities, premises, recreational facilities and housing that are not ordinarily available to the general public.

d. The furnishing of beverages and other refreshments that cost in excess of $50 and that are not ordinarily available to the general public.

e. The contributing of money of the corporate entity.

f. Any other transaction conducted between a corporate entity and a candidate, candidate's committee, political committee that expressly advocates for or against candidates, or a political party committee. Such transaction is presumed to be a corporate contribution unless it is sufficiently demonstrated to the board that the transaction should not be considered a prohibited contribution under 2009 Iowa Code Supplement section 68A.503 as amended by 2010 Iowa Acts, Senate File 2354, section 5.

This rule is intended to implement 2009 Iowa Code Supplement section 68A.503 as amended by 2010 Iowa Acts, Senate File 2354, section 5.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10; **ARC 1390C**, IAB 4/2/14, effective 5/7/14]

351—4.45(68A,68B) Corporate-sponsored political committee. These rules do not prevent a corporate entity from soliciting eligible members to join or contribute to its own corporate-sponsored political committee (PAC), so long as the corporate entity adheres to the provisions of Iowa Code Supplement section 68A.503.

This rule is intended to implement Iowa Code Supplement section 68A.503.

351—4.46(68A) Voter education. Rescinded IAB 6/2/10, effective 5/17/10.

351—4.47(68A,68B) Permitted activity—reimbursement required. The prohibitions against certain transactions between corporate entities and candidates or committees expressly advocating the election or defeat of candidates contained in Iowa Code Supplement section 68A.503 and in rule 351—4.44(68A,68B) are not construed to prohibit activity that occurs consistent with this rule.

4.47(1) *Purchase or rental of office facility.* A candidate's committee or any other committee that expressly advocates the election or defeat of a candidate may purchase or rent property belonging to a corporate entity, so long as the purchase or rental is at fair market value. For the purpose of this subrule, "fair market value" means the amount that a member of the general public would expect to pay to purchase or rent a similar property within the community in which the property is located.

4.47(2) *Use of corporate facilities to produce or mail materials.* Any person who uses the facilities of a corporate entity to produce or mail materials in connection with a candidate election is required to reimburse the corporate entity within a commercially reasonable time for the normal and usual charge for producing or mailing such materials in the commercial market. For example, if it would otherwise

cost 10 cents per page to have a brochure copied at a commercial printer, the corporate entity must be reimbursed at 10 cents per page even if the overhead and operating cost is only 5 cents per page. Likewise, the corporate entity must be reimbursed at the first-class mail rate even if the direct cost to the corporate entity is less through the use of its bulk mail permit. This subrule does not affect the ability of a commercial vendor to charge an amount for postage which is less than for first-class mail where the reduced or bulk mail charge is available to all similarly situated customers without respect to the political identity of the customer.

4.47(3) *Use or rental of corporate facilities by other persons.* Persons other than stockholders, administrative officers or employees of a corporate entity who make any use of corporate facilities, such as using telephones, facsimile machines, typewriters or computers or borrowing office furniture for activity in connection with a candidate election, are required to reimburse the corporate entity within a commercially reasonable time in the amount of the normal and usual rental charge. If one or more telephones of a corporate entity are used as a telephone bank, a rebuttable presumption is established that $3 per telephone per hour, plus any actual long distance charges, is acceptable as a normal and usual rental charge.

4.47(4) *Use of airplanes and other means of transportation.*

a. *Air travel.* A candidate, candidate's agent, or person traveling on behalf of a candidate who uses noncommercial air transportation made available by a corporate entity shall, in advance, reimburse the corporate entity as follows:

(1) Where the destination is served by regularly scheduled commercial service, the coach class airfare (without discounts).

(2) Where the destination is not served by a regularly scheduled commercial service, the usual charter rate.

b. *Other transportation.* A candidate, candidate's agent, or person traveling on behalf of a candidate who uses other means of transportation made available by a corporate entity shall, within a commercially reasonable time, reimburse the corporate entity at the normal and usual rental charge.

4.47(5) *Equal access not required.* For the purpose of this rule, it is not necessary that the corporate entity be in the business of selling or renting the property, good or service to the general public; further, it is not necessary that the corporate entity provide access to the same property, good or service to other candidates or committees.

4.47(6) *Commercially reasonable time.* For the purpose of this rule, a rebuttable presumption is established that reimbursement to the corporate entity within ten business days is acceptable as within a commercially reasonable time.

4.47(7) *Loans and debts.* A financial institution may make a loan to a candidate or candidate's committee so long as the loan is repaid and all proper public disclosure of the transaction is made pursuant to rule 351—4.18(68A,68B). A candidate or candidate's committee may owe a debt to an insurance company, financial institution, or corporation so long as the debt is repaid and all proper public disclosure of the transaction is made pursuant to rule 351—4.16(68A,68B). The repayment of a loan or debt under this subrule shall be made prior to the dissolution of the committee pursuant to rule 351—4.57(68A,68B).

This rule is intended to implement Iowa Code Supplement section 68A.503.

351—4.48(68A) Sham newspapers subject to campaign laws. Iowa Code chapter 68A provides that when a media organization discusses candidates and public affairs, the media organization does not trigger the campaign laws. 2009 Iowa Code Supplement section 68A.503(5)*"b"* as amended by 2010 Iowa Acts, Senate File 2354, section 5, directs the board to adopt a rule requiring the owner, publisher, or editor of a sham newspaper who is using the sham newspaper to promote in any way the candidacy of any person for public office to comply with the requirements of Iowa Code chapter 68A.

4.48(1) *Factors.* In determining whether or not a publication is entitled to the press exception or is a sham newspaper that triggers the campaign laws, the board will consider the following factors:

a. Whether the publication is published and made available on a regular schedule or interval;

b. The proximity to the election in which the candidates and public affairs are discussed;

c. Whether the publication contains news items and articles of opinion of a general character separate from discussions concerning candidates and public affairs;

d. How widely the publication is circulated or is otherwise made available to the public in comparison to a targeted audience for potential campaign purposes;

e. Whether the publication discusses all candidates for a particular election or otherwise gives all candidates equal space; and

f. Whether the publication expressly advocates for the candidacy of any person.

4.48(2) *Definitions.* For purposes of this rule, the following definitions apply:

"Express advocacy" means "express advocacy" as defined in Iowa Code section 68A.102(14) and rule 351—4.53(68A).

"Media organization" means "media organization" as defined in rule 351—4.51(68A).

"Sham newspaper" means "sham newspaper" as defined in 2009 Iowa Code Supplement section 68A.503(5)*"b"* as amended by 2010 Iowa Acts, Senate File 2354, section 5.

This rule is intended to implement 2009 Iowa Code Supplement section 68A.503(5)*"b"* as amended by 2010 Iowa Acts, Senate File 2354, section 5.

[**ARC 7866B**, IAB 6/17/09, effective 7/22/09; **ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.49(68A,68B) Individual property. These rules do not apply to the personal or real property of corporate officers or of individuals employed or associated with a corporate entity and shall not abridge the free-speech rights and privileges of individuals.

This rule is intended to implement Iowa Code Supplement section 68A.503.

351—4.50(68A) Political corporations. Rescinded IAB 6/2/10, effective 5/17/10.

351—4.51(68A) Candidate debate—media organization; debate structure; debate funding; contribution reporting inapplicable. Iowa Code Supplement section 68A.503 prohibits corporations from making contributions to state or local candidates in Iowa. This prohibition does not apply to incorporated media organizations that host candidate debates described in this rule.

4.51(1) *Media organization defined.* "Media organization" means a broadcaster, cable television operator, television programmer, television producer, bona fide newspaper, magazine, or any other periodical publication. The media organization shall not be owned or controlled by a political party, political committee, or candidate.

4.51(2) *Debate structure.* The structure of the debate shall be left to the discretion of the media organization provided that at least two or more candidates for the particular office are invited to participate. The debate shall not be structured to promote or advance one candidate over another. In choosing which candidates to invite to a debate, the media organization shall use good faith editorial judgment that is reasonable and viewpoint-neutral.

4.51(3) *Funding debates.* A media organization may use its own funds and may accept funds donated by corporations to defray costs incurred in staging a candidate debate under this rule.

4.51(4) *Contribution reporting inapplicable.* The costs of a debate under this rule are not a reportable monetary or in-kind contribution under Iowa Code Supplement section 68A.402.

This rule is intended to implement Iowa Code Supplement sections 68A.402 and 68A.503.

351—4.52(68A,68B) Corporate involvement with political committee funds.

4.52(1) *Corporate payroll deductions.* For purposes of interpretation of Iowa Code Supplement section 68A.503, the administrative functions performed by a corporation (profit or nonprofit corporation including, but not limited to, a bank, savings and loan institution, credit union or insurance company) to make payroll deductions for an employee organization's political committee and to transmit the deductions in lump sum to the treasurer of the political committee shall not be a prohibited corporate activity so long as the corporate entity is serving only as a conduit for the contributions.

4.52(2) *Electronic transfer of deposits.* A corporation, financial institution, or insurance company may receive and deposit checks that include both dues and PAC contributions. Contributions for the PAC

shall be transferred as soon as possible into the PAC checking account and all disclosure, record-keeping, and record-retention requirements of Iowa Code chapter 68A shall be followed.

4.52(3) *Allowable costs of administration.* For the purposes of interpreting Iowa Code Supplement section 68A.503, subsection 3, which permits an entity otherwise forbidden from contributing to a candidate or a candidate's committee for "financing the administration of a committee sponsored by that entity," the following are considered to be allowable costs of administration:

a. Full or partial compensation for political committee staff, which may include both wages and benefits.

b. Expenses of transportation and travel incurred by political committee staff; however, this does not include expenses of transportation or travel if provided by a political committee or a staff member to a candidate, nor does this include expenses of meals or events held on behalf of a candidate.

c. Printing and office supplies related to routine office administration so long as the printing and supplies are not used to expressly advocate for or against any candidate.

d. Postage and stationery, including that necessary for mailing contributions to specific candidates. Postage and stationery necessary for distributing political material expressly advocating a specific candidate to persons other than the committee membership are not permitted.

e. Expenses of maintaining committee records and preparing financial disclosure reports, including costs associated with services provided by an accountant or other professional.

f. Promotional materials, such as stickers, pens, and coffee cups, so long as the items promote the political committee itself, but not a specific candidate.

An item which is excluded by this subrule from being an allowable cost of administration may still be provided by the committee, so long as that cost is paid for from contributions or other sources of funds other than the parent entity.

This rule is intended to implement Iowa Code Supplement section 68A.503.

DIVISION V
INDEPENDENT EXPENDITURES AND IN-KIND CONTRIBUTIONS

351—4.53(68A,68B) Express advocacy; in-kind contributions; independent expenditures—definitions. For the purposes of Iowa Code Supplement chapter 68A, the following definitions apply.

4.53(1) *Express advocacy.* "Express advocacy" means any communication as defined in Iowa Code Supplement section 68A.102(14). "Express advocacy" includes a communication that uses any word, term, phrase, or symbol that exhorts an individual to vote for or against a clearly identified candidate or for the passage or defeat of a clearly identified ballot issue.

4.53(2) *In-kind contribution.* "In-kind contribution" means the provision of any good or service to a committee without charge or at a charge that is less than the usual and normal charge for such good or service. If a good or service is provided at less than the usual and normal charge, the amount of the in-kind contribution is the difference between the usual and normal charge for the good or service at the time of the contribution and the amount charged the committee. An in-kind contribution also includes any expenditure that meets the definition of a coordinated expenditure in subrule 4.53(4).

4.53(3) *Independent expenditure.* "Independent expenditure" means "independent expenditure" as defined in 2009 Iowa Code Supplement section 68A.404(1) as amended by 2010 Iowa Acts, Senate File 2354, section 3.

4.53(4) *Coordinated expenditure.*

a. "Coordinated expenditure" means an expenditure made with the knowledge and approval of a candidate, candidate's committee, political party committee, or political committee. "Coordinated expenditure" also means that there has been arrangement, coordination, or direction by the candidate, candidate's committee, political party committee, or political committee, or an agent or officer of the candidate's committee or a ballot issue committee prior to the procurement or purchase of the good or service, or the publication, distribution, display, or broadcast of an express advocacy communication.

b. An expenditure will be presumed to be coordinated when it is:

(1) Based on information provided to the expending person by the candidate, the candidate's committee, or the ballot issue committee with a view toward having an expenditure made; or

(2) Made by or through any person who is or has been authorized to raise or expend funds; who is or has been an officer of the candidate's committee or the ballot issue committee; or who is or has been receiving any form of compensation or reimbursement from the candidate, the candidate's committee, or the ballot issue committee.

c. Pursuant to 2009 Iowa Code Supplement section 68A.404(7) as amended by 2010 Iowa Acts, Senate File 2354, section 3, a person making an independent expenditure shall not engage or retain an advertising firm or consultant that has also been engaged or retained within the prior six months by the candidate, candidate's committee, or ballot issue PAC that is benefited by the independent expenditure. "Engage or retain" shall not include the purchase of goods or products from an advertising firm or consultant when the advertising firm or consultant does not provide guidance, assistance, or advice to the person making the purchase concerning the good or product.

This rule is intended to implement 2009 Iowa Code Supplement section 68A.404 as amended by 2010 Iowa Acts, Senate File 2354, section 3.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10]

DIVISION VI
COMMITTEE DISSOLUTION

351—4.54(68A) Committee dissolution; disposition of property; resolution of loans or debts. A committee shall not dissolve until all loans and debts are paid, forgiven, or transferred, and the remaining funds in the committee's campaign account are distributed according to Iowa Code sections 68A.302 and 68A.303 and rule 351—4.25(68A,68B). In the case of a candidate's committee, the disposition of all campaign property with a residual value of $100 or more must be accomplished before dissolution.

4.54(1) *Manner of disposition—candidates' committees.* A candidate's committee shall dispose of campaign property with a residual value of $100 or more through a sale of the property at fair market value, with proceeds treated as any other campaign funds, or through donation of the property as set out in Iowa Code section 68A.303(1). The candidate's committee shall disclose on the committee's campaign report the manner of disposition.

4.54(2) *Resolution of loans and debts.* The loans and debts of a committee may be transferred, assumed, or forgiven except that a loan or debt owed to a financial institution, insurance company, or corporation may not be forgiven unless the committee is a ballot issue committee. The committee shall disclose on the committee's campaign report the transfer, assumption, or forgiveness of a loan or debt on the appropriate reporting schedules.

4.54(3) *Settlement of disputed loans and debts.* A dispute concerning a loan or debt may be resolved for less than the original amount if the committee discloses on the committee's campaign report the resolution of the dispute. If the dispute is between a candidate's committee and a financial institution, insurance company, or corporation, the candidate's committee shall submit a written statement to the board describing the loan or debt, the controversy, and the steps taken to settle or collect the loan or debt. The board will review the statement and determine whether to permit the candidate's committee to report the loan or debt as discharged.

4.54(4) *Unavailable creditor.* If the committee cannot locate a person to whom it owes a loan or debt, the committee shall provide the board with a written statement describing the steps the committee has taken to locate the creditor and shall request direction from the board as to what additional steps, if any, should be taken. If a candidate's committee owes a loan or debt to a financial institution, insurance company, or corporation, resolution of the matter shall include payment to a charitable organization or the general fund of the state of Iowa.

This rule is intended to implement Iowa Code section 68A.402B.

351—4.55(68A) Statement of dissolution; final report; final bank statement.

4.55(1) *Statement of dissolution.* A statement of dissolution (Form DR-3) shall be filed after the committee terminates its activity, disposes of its funds and assets, and has discharged all of its loans and

debts. The statement shall be either typewritten or printed legibly in black ink and shall be signed by the person filing the statement. A statement of dissolution filed electronically using the board's Web site is deemed signed when filed.

4.55(2) *Place of filing.* Statements of dissolution mandated by statute to be filed electronically with the board shall be filed through the board's Web site at www.iowagov/ethics. A statement of dissolution not mandated by statute to be filed electronically may be filed with the board at 510 East 12th Street, Suite 1A, Des Moines, Iowa 50319; by fax at (515)281-4073; or as an E-mail attachment.

4.55(3) *Time of filing.* A committee seeking dissolution shall file a statement of dissolution within 30 days of terminating activity, disposing of funds and assets, and discharging all loans and debts. A statement must be physically received by the board or, if mailed, must bear a United States Postal Service postmark dated on or before the required due date. Faxed or electronically filed statements must be submitted at or before 11:59 p.m. on the required due date. If the due date falls on a Saturday, Sunday, or holiday on which the board office is closed, the due date is extended to the next working day.

4.55(4) *Final report.* The committee shall file a final report disclosing the committee's closing transactions. Once the board staff reviews the report and determines that the committee has complied with all of the requirements of Iowa Code chapter 68A, the committee is no longer required to file campaign reports. If the board staff determines that the committee has not complied with all of the requirements of Iowa Code chapter 68A, the committee, prior to being dissolved, shall resolve all issues.

4.55(5) *Final bank statement.* A copy of the committee's final bank statement showing the committee's closing transactions and a zero balance shall be attached to or submitted with the committee's final report. A committee participating in an election at the county, city, school, or other political subdivision level, an independent expenditure committee, or a sole individual making an independent expenditure is not required to file a final bank statement unless requested to do so by the board. A committee seeking a waiver from the requirements of this subrule may do so in accordance with 351—Chapter 15.

This rule is intended to implement Iowa Code section 68A.402B as amended by 2010 Iowa Acts, Senate File 2354, section 2.

[**ARC 8826B**, IAB 6/2/10, effective 5/17/10; **ARC 9031B**, IAB 8/25/10, effective 9/29/10]

351—4.56(68A,68B) Disposition of property for dissolution of committee. Rescinded IAB 6/22/05, effective 7/27/05.

351—4.57(68A,68B) Assumption or settlement of debts and obligations. Rescinded IAB 6/22/05, effective 7/27/05.

DIVISION VII
CIVIL PENALTIES FOR LATE REPORTS

351—4.58(68B) Late-filed campaign disclosure reports. A campaign disclosure report is deemed filed late if it is not received by the board on or before the date and time the report is mandated to be filed pursuant to statute or board rule.

This rule is intended to implement Iowa Code section 68B.32A(8).

[**ARC 8290B**, IAB 11/18/09, effective 12/23/09]

351—4.59(68B) Routine civil penalty assessment for late-filed disclosure reports.

4.59(1) *Administrative resolution.* In administrative resolution of violations for late-filed disclosure reports, the board shall assess and collect monetary penalties for all late-filed disclosure reports. The board shall notify any person assessed a penalty of the amount of the assessment and the person's ability to request a waiver under rule 351—4.60(68B). A person using the board's electronic filing system shall not be assessed a civil penalty if the board's electronic filing system is not properly functioning and causes the person to be unable to timely file the report.

4.59(2) *County and local committee assessments.* County, county statutory, city, school, other political subdivision, and local ballot issue committees shall be assessed civil penalties for late-filed reports in accordance with the following schedule:

Date report received	First-time delinquency	Repeat delinquency by same committee in 12-month period
1 to 14 consecutive days delinquent	$20	$50
15 to 30 consecutive days delinquent	$50	$100
31 to 45 consecutive days delinquent	$100	$200

4.59(3) *State committee assessments.* Statewide, general assembly, state statutory, and state political committees, and a judge standing for retention shall be assessed civil penalties for late-filed reports, except for supplementary and special election reports, in accordance with the following schedule:

Date report received	First-time delinquency	Repeat delinquency by same committee in 12-month period
1 to 14 consecutive days delinquent	$50	$100
15 to 30 consecutive days delinquent	$100	$200
31 to 45 consecutive days delinquent	$200	$300

4.59(4) *Supplementary report assessments.* General assembly candidates' committees required to file supplementary disclosure reports shall be assessed a $200 civil penalty for filing a supplementary report one or more days late. Statewide committees required to file supplementary disclosure reports shall be assessed a $400 civil penalty for filing a supplementary report one or more days late.

4.59(5) *Special election assessments.* The committees of general assembly candidates to fill vacancies in special elections shall be assessed a $100 civil penalty for filing a special election report one or more days late. The committees of statewide candidates to fill vacancies in special elections shall be assessed a $200 civil penalty for filing a special election report one or more days late.

4.59(6) *Verified statement of registration assessments.* An out-of-state committee that chooses to file a verified statement of registration (VSR) as provided in Iowa Code Supplement section 68A.201 and rule 351—4.32(68A), but fails to file the VSR on or before the fifteenth day after the date of the contribution, shall be assessed a $25 civil penalty per late-filed VSR. However, if there is a repeat delinquency by the committee in a 12-month period, the penalty shall be $50.

For purposes of this subrule, "date of the contribution" means the day, month and year the contribution check is dated.

4.59(7) *Independent expenditure assessment.* An individual who is delinquent in timely filing Form Ind-Exp-I shall be assessed a $25 civil penalty. If there is a repeat delinquency by the individual in timely filing Form Ind-Exp-I within a 12-month period, the penalty shall be $50. A person that is designated by the board as an independent expenditure committee that fails to timely file Form Ind-Exp-O shall be assessed a $50 civil penalty. If there is a repeat delinquency by the person in timely filing Form Ind-Exp-O within a 12-month period, the penalty shall be $100.

4.59(8) *Form DR-OTC assessment.* A permanent organization that has not previously made a contribution in excess of $750 and that fails to file Form DR-OTC within ten days of notice to do so by the board shall be assessed a $20 civil penalty. A permanent organization that has previously made a contribution in excess of $750 and that fails to file Form DR-OTC within ten days of the date on which the contribution check is issued shall be assessed a $20 civil penalty.

4.59(9) *Additional sanctions.* The issuance of a civil penalty under this rule does not prohibit the board from imposing sanctions pursuant to the process set out in Iowa Code chapter 68B and rule 351—9.4(68B) if the board determines that there was evidence of an intentional failure to timely file the report.

This rule is intended to implement Iowa Code section 68B.32A(8).

[**ARC 7645B**, IAB 3/25/09, effective 4/29/09; **ARC 8826B**, IAB 6/2/10, effective 5/17/10]

351—4.60(68B) Requests for waiver of penalties. If a person believes that there are mitigating circumstances that prevented the timely filing of a report, the person may make a written request to the board for waiver of the penalty by filing a Petition for Waiver of Civil Penalty form. A person seeking a waiver must submit the request to the board within 30 days of receiving a civil penalty assessment order. Waivers may be granted only under exceptional or very unusual circumstances. The board will review the request and issue a waiver or denial of the request. If a waiver is granted, the board will determine how much of the penalty is waived based on the circumstances. If a denial or partial waiver is issued, the person shall promptly pay the assessed penalty or seek a contested case proceeding pursuant to rule 351—4.61(68B).

This rule is intended to implement Iowa Code section 68B.32A(8).

[**ARC 7996B**, IAB 7/29/09, effective 9/2/09]

351—4.61(68B) Contested case challenge.

4.61(1) *Request.* If the person accepts administrative resolution of a matter through the payment of the assessed penalty, the matter shall be closed. If the person chooses to contest the board's decision to deny the request or grant a partial waiver of an assessed penalty, the person shall make a written request for a contested case proceeding within 30 days of being notified of the board's decision.

4.61(2) *Procedure.* Upon timely receipt of a request for a contested case proceeding, the board shall provide for the issuance of a statement of charges and notice of hearing. The hearing shall be conducted in accordance with the provisions of Iowa Code section 68B.32C and the board's rules. The burden shall be on the board's legal counsel to prove that a violation occurred.

4.61(3) *Failure to request hearing.* Failure to request a contested case proceeding to appeal the board's decision on a waiver request is failure to exhaust administrative remedies for purposes of seeking judicial review in accordance with Iowa Code chapter 17A and Iowa Code section 68B.33.

This rule is intended to implement Iowa Code Supplement section 68B.32A(8).

351—4.62(68B) Payment of penalty.

4.62(1) *Where payment made.* Checks or money orders shall be made payable and forwarded to: Iowa Ethics and Campaign Disclosure Board, 510 E. 12th Street, Suite 1A, Des Moines, Iowa 50319. Such funds shall be deposited in the general fund of the state of Iowa.

4.62(2) *Who may make payment.* Payment may be made at the person's discretion, including from funds of a committee or from personal funds of an officer of a committee.

4.62(3) *Disclosure of payment.* Rescinded IAB 3/25/09, effective 4/29/09.

This rule is intended to implement Iowa Code Supplement sections 68A.503 and 68B.32A(8).

[**ARC 7648B**, IAB 3/25/09, effective 4/29/09]

[Filed 10/17/95, Notice 8/25/75—published 11/3/75, effective under emergency provision 11/21/75]
[Filed 10/28/75, Notice 8/25/75—published 11/17/75, effective 12/22/75]
[Filed 11/26/75, Notice 8/25/75—published 12/15/75, effective 2/1/76]
[Amendment filed without notice 11/26/75—published 12/15/75]
[Filed emergency 2/11/76—published 3/8/76, effective 2/11/76]
[Filed 2/19/76, Notice 11/17/75—published 3/8/76, effective 4/12/76]
[Filed 4/1/76, Notice 11/17/75—published 4/19/76, effective 5/24/76]
[Filed 6/4/76—published 6/28/76, effective 8/2/76]
[Filed emergency 7/14/76—published 8/9/76, effective 7/14/76]
[Filed 1/7/77, Notice 12/1/76—published 1/26/77, effective 3/2/77]
[Filed 4/30/79, Notice 3/21/79—published 5/30/79, effective 7/4/79][1]
[Filed 8/29/80, Notice 5/28/80—published 9/17/80, effective 10/22/80]
[Filed 11/6/81, Notice 9/3/81—published 11/25/81, effective 1/1/82]
[Filed 11/4/83, Notice 8/3/83—published 11/23/83, effective 1/1/84]
[Filed 5/16/86, Notice 3/12/86—published 6/4/86, effective 9/3/86]
[Filed 8/21/87, Notice 6/17/87—published 9/9/87, effective 10/14/87]
[Filed 4/26/89, Notice 2/22/89—published 5/17/89, effective 6/21/89]

[Filed 4/23/92, Notice 2/19/92—published 5/13/92, effective 6/17/92]
[Filed 11/17/92, Notice 9/16/92—published 12/9/92, effective 1/13/93]
[Filed emergency 1/15/93—published 2/3/93, effective 1/15/93]
[Filed 9/23/93, Notice 4/28/93—published 10/13/93, effective 11/17/93]
[Filed 3/11/94, Notice 1/5/94—published 3/30/94, effective 5/4/94]
[Filed emergency 6/16/94—published 7/6/94, effective 6/16/94]
[Filed 7/29/94, Notice 5/25/94—published 8/17/94, effective 9/21/94]
[Filed 12/16/94, Notice 8/17/94—published 1/4/95, effective 2/8/95]◊
[Filed 7/28/95, Notice 5/24/95—published 8/16/95, effective 9/20/95]
[Filed 7/28/95, Notice 6/21/95—published 8/16/95, effective 9/20/95]◊
[Filed 10/6/95, Notice 7/19/95—published 10/25/95, effective 11/29/95]
[Filed 7/12/96, Notice 4/24/96—published 7/31/96, effective 9/4/96]◊
[Filed 10/18/96, Notice 8/28/96—published 11/6/96, effective 12/11/96]
[Filed 12/24/96, Notice 11/6/96—published 1/15/97, effective 2/19/97]
[Filed 6/13/97, Notice 5/7/97—published 7/2/97, effective 8/6/97]
[Filed 5/15/98, Notice 3/11/98—published 6/3/98, effective 7/8/98]◊
[Filed 7/10/98, Notice 6/3/98—published 7/29/98, effective 9/2/98]
[Filed 3/3/99, Notice 1/13/99—published 3/24/99, effective 4/28/99]
[Filed emergency 6/9/99—published 6/30/99, effective 6/9/99]
[Filed 6/21/02, Notice 5/15/02—published 7/10/02, effective 8/14/02]◊
[Filed 8/1/02, Notice 6/12/02—published 8/21/02, effective 9/25/02]◊
[Filed 8/1/02, Notice 6/26/02—published 8/21/02, effective 9/25/02]
[Filed 8/30/02, Notice 7/10/02—published 9/18/02, effective 10/23/02]
[Filed 11/1/02, Notice 8/21/02—published 11/27/02, effective 1/1/03]◊
[Filed 11/1/02, Notice 9/4/02—published 11/27/02, effective 1/1/03]◊
[Filed 4/23/03, Notice 3/5/03—published 5/14/03, effective 7/1/03]
[Filed 8/28/03, Notice 7/9/03—published 9/17/03, effective 10/22/03]◊
[Filed 8/28/03, Notice 7/23/03—published 9/17/03, effective 10/22/03]
[Filed 10/9/03, Notice 8/20/03—published 10/29/03, effective 12/3/03]◊
[Filed 11/6/03, Notice 10/1/03—published 11/26/03, effective 12/31/03]◊
[Filed 1/14/04, Notice 11/26/03—published 2/4/04, effective 3/10/04]◊
[Filed 2/6/04, Notice 12/24/03—published 3/3/04, effective 4/7/04]◊
[Filed 4/23/04, Notice 3/3/04—published 5/12/04, effective 6/16/04]◊
[Filed without Notice 4/29/04—published 5/26/04, effective 7/1/04]
[Filed without Notice 5/3/04—published 5/26/04, effective 7/1/04]
[Filed without Notice 5/4/04—published 5/26/04, effective 7/1/04]
[Filed 6/24/04, Notice 5/12/04—published 7/21/04, effective 8/25/04]◊
[Filed 8/26/04, Notice 7/21/04—published 9/15/04, effective 10/20/04]
[Filed 10/22/04, Notice 9/15/04—published 11/10/04, effective 12/15/04]
[Filed 1/28/05, Notice 11/10/04—published 2/16/05, effective 3/23/05]◊
[Filed 1/28/05, Notice 12/22/04—published 2/16/05, effective 3/23/05]
[Filed 5/23/05, Notice 3/16/05—published 6/22/05, effective 7/27/05]◊
[Filed without Notice 5/24/05—published 6/22/05, effective 7/27/05]◊
[Filed 8/17/05, Notice 5/11/05—published 9/14/05, effective 10/19/05]
[Filed 12/2/05, Notice 9/14/05—published 12/21/05, effective 1/25/06]
[Filed 12/2/05, Notice 10/26/05—published 12/21/05, effective 1/25/06]
[Filed 2/8/06, Notice 12/21/05—published 3/1/06, effective 4/5/06]◊
[Filed 7/13/06, Notice 4/26/06—published 8/2/06, effective 9/6/06]◊
[Filed 9/25/06, Notice 8/2/06—published 10/25/06, effective 11/29/06]◊
[Filed 3/7/07, Notice 1/17/07—published 3/28/07, effective 5/2/07]
[Filed without Notice 7/11/07—published 8/1/07, effective 9/5/07]◊
[Filed without Notice 7/12/07—published 8/1/07, effective 9/5/07]◊

[Filed 4/2/08, Notice 2/13/08—published 4/23/08, effective 5/28/08]
[Filed 9/2/08, Notice 6/18/08—published 9/24/08, effective 10/29/08]
[Filed without Notice 9/5/08—published 9/24/08, effective 10/29/08][◊]
[Filed without Notice 11/11/08—published 12/3/08, effective 1/7/09][◊]
[Filed 12/8/08, Notice 9/24/08—published 12/31/08, effective 2/4/09][◊]
[Filed ARC 7646B (Notice ARC 7377B, IAB 12/3/08), IAB 3/25/09, effective 4/29/09]
[Filed ARC 7647B (Notice ARC 7373B, IAB 12/3/08), IAB 3/25/09, effective 4/29/09]
[Filed ARC 7648B (Notice ARC 7380B, IAB 12/3/08), IAB 3/25/09, effective 4/29/09]
[Filed ARC 7645B (Notice ARC 7455B, IAB 12/31/08), IAB 3/25/09, effective 4/29/09]
[Filed Without Notice ARC 7800B, IAB 6/3/09, effective 7/8/09]
[Filed Without Notice ARC 7801B, IAB 6/3/09, effective 7/8/09]
[Filed ARC 7866B (Notice ARC 7705B, IAB 4/8/09), IAB 6/17/09, effective 7/22/09]
[Filed ARC 7995B (Notice ARC 7806B, IAB 6/3/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 7994B (Notice ARC 7807B, IAB 6/3/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 7992B (Notice ARC 7809B, IAB 6/3/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 7998B (Notice ARC 7803B, IAB 6/3/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 7996B (Notice ARC 7805B, IAB 6/3/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 8286B (Notice ARC 7999B, IAB 7/29/09), IAB 11/18/09, effective 12/23/09]
[Filed Without Notice ARC 8290B, IAB 11/18/09, effective 12/23/09]
[Filed Without Notice ARC 8289B, IAB 11/18/09, effective 12/23/09]
[Filed Emergency ARC 8826B, IAB 6/2/10, effective 5/17/10]
[Filed Without Notice ARC 8787B, IAB 6/2/10, effective 7/7/10]
[Filed Without Notice ARC 8788B, IAB 6/2/10, effective 7/7/10]
[Filed ARC 9031B (Notice ARC 8795B, IAB 6/2/10), IAB 8/25/10, effective 9/29/10]
[Filed ARC 9216B (Notice ARC 9041B, IAB 9/8/10), IAB 11/3/10, effective 12/8/10]
[Filed ARC 1390C (Notice ARC 1020C, IAB 9/18/13), IAB 4/2/14, effective 5/7/14]

◊ Two or more ARCs

[1] Effective date of rule 4.16 delayed by the Administrative Rules Review Committee 45 days after convening of the next General Assembly pursuant to §17A.8(9).

CHAPTER 9
COMPLAINT, INVESTIGATION, AND RESOLUTION PROCEDURES

[Prior to 9/9/87, Campaign Finance Disclosure[190] Ch 1]
[Prior to 3/30/94, Campaign Finance Disclosure Commission[121] Ch 1]
[Prior to 8/21/02, see 351—Ch 1]
[Prior to 9/17/03, see 351—Ch 5]

351—9.1(68B) Complaints.

9.1(1) *Form.* A complaint shall be on forms provided by the board and shall be certified under penalty of perjury. The complaint shall contain all information required by Iowa Code section 68B.32B(1). The complainant may attach up to 20 pages of supporting documents to the complaint.

9.1(2) *Board acceptance.* A complaint shall not be deemed accepted by the board until completion of the legal review required by Iowa Code section 68B.32B(4). If the board's legal counsel opines that the complaint contains a legally sufficient allegation, the complaint is deemed accepted. If the board's legal counsel opines that the complaint does not contain a legally sufficient allegation and the board, upon review, makes a determination that the complaint does contain a legally sufficient allegation, the complaint is then deemed accepted. If both the board's legal counsel and the board opine that the complaint does not contain a legally sufficient allegation, the complaint shall be dismissed.

9.1(3) *Notice.* Notice to the subject of a complaint is made only when a complaint is accepted, subject to the conditions of Iowa Code section 68B.32B(3). A complaint is a public record, subject to the conditions of Iowa Code section 68B.32B(11).

9.1(4) *Board review.* The board's review of a formal complaint for legal sufficiency is not a contested case proceeding and shall be made solely on the facts alleged in the complaint.

9.1(5) *Information provided to board.* The board may, on its own motion and without the filing of a complaint, initiate investigations into matters that the board believes may be subject to the board's jurisdiction. As provided in Iowa Code section 68B.32B(7), persons may provide information to the board for possible board-initiated investigation instead of filing a complaint.

[**ARC 1389C**, IAB 4/2/14, effective 5/7/14]

351—9.2(68B) Investigations—board action.

9.2(1) *Referral to staff.* Upon a determination that a complaint contains a legally sufficient allegation, the board shall refer the complaint to staff for investigation.

9.2(2) *Board-initiated investigation.* On its own motion the board may refer to staff for investigation matters that the board believes may be subject to the board's jurisdiction, including matters brought to the board's attention by members of the public.

9.2(3) *Subpoenas.* Investigations may include the issuance and enforcement of investigative subpoenas requiring the production of books, papers, records, and other real evidence, as well as requiring the attendance and testimony of witnesses.

9.2(4) *Completion.* Upon completion of an investigation, staff shall make a report to the board and may provide a recommendation for board action.

9.2(5) *Board action.* Upon receipt and review of the staff investigative report and any recommendations, the board may:

a. Redirect the matter for further investigation;

b. Dismiss the matter for lack of probable cause to believe a violation has occurred;

c. Dismiss the matter without a determination regarding probable cause as an exercise of administrative discretion;

d. Make a determination that probable cause exists to believe a violation has occurred and direct administrative resolution of the matter as provided in subrule 9.4(2); or

e. Make a determination that probable cause exists to believe a violation has occurred and direct the issuance of a statement of charges to initiate a contested case proceeding.

351—9.3(68B) Grounds for disciplinary action. The board may impose discipline against a person subject to the board's jurisdiction who commits a violation of Iowa Code chapter 68A, Iowa Code chapter 68B, Iowa Code section 8.7, or rules adopted by the board.

This rule is intended to implement Iowa Code section 68B.32A(9).

[Editorial change: IAC Supplement 4/8/09]

351—9.4(68B) Disciplinary remedies; administrative resolution of enforcement matters.

9.4(1) *Action after hearing.* If it is determined after a contested case proceeding that a violation of statute or rule under the board's jurisdiction has occurred, the board may impose any of the actions set out in Iowa Code section 68B.32D, including as a remedial action the assessment of direct costs related to the hearing for printing, postage, long-distance telephone charges, witness fees, and compensation paid to the presiding officer.

9.4(2) *Administrative resolution.* Violations may be handled by administrative resolution rather than through the full investigative and contested case proceeding process. The board may order administrative resolution by directing that the person take specified remedial action. The board may also order administrative resolution by issuing a letter of reprimand or by imposing a civil penalty as set out in subrule 9.4(7).

9.4(3) *Response to administrative resolution.* A person subject to board discipline may accept administrative resolution, but is not required to do so. If the person accepts the administrative resolution by complying with the directed remedial action or accepting a letter of reprimand, the matter shall be closed. If the person wishes to appeal the administrative resolution, the person shall make a written request for a contested case proceeding and shall submit the request within 30 days of the date of the correspondence informing the person of the board's decision.

9.4(4) *Statement of charges.* The board shall issue a statement of charges upon timely receipt of a request for a contested case proceeding to appeal the administrative resolution. The contested case shall be conducted in accordance with the provisions in 351—Chapter 11. The board's legal counsel shall have the burden of proving the violation. Failure to challenge the administrative resolution through a request for a contested case proceeding is a failure to exhaust administrative remedies for purposes of seeking judicial review.

9.4(5) *Automatic civil penalties.* The board may administratively resolve late-filed reports by the assessment of automatic civil penalties, subject to the civil penalty waiver process, as set out by board rule. The board may retain two dollars of any civil penalty that is ultimately not waived by the board or by a court of law as return receipts covering incidental costs such as printing and postage. The remainder of the civil penalty shall be deposited in the state general fund.

9.4(6) *Admonishment.* The board may admonish any person who it believes has committed a minor violation to exercise care. An admonishment is not discipline and is not subject to a contested case proceeding appeal.

9.4(7) *Civil penalty for violation.* If the board determines that probable cause exists to believe that a violation of any statute or rule under its jurisdiction has occurred, except for a late-filed disclosure report, the board may order administrative resolution of the violation by imposing a civil penalty not to exceed $500. A person assessed a civil penalty may appeal the decision by requesting within 30 days of the date of the correspondence informing the person of the board's decision a contested case proceeding to be held under the process set out in subrule 9.4(4).

[**ARC 7993B**, IAB 7/29/09, effective 9/2/09; **ARC 7991B**, IAB 7/29/09, effective 9/2/09]

351—9.5(68B) Settlements. Settlements may be negotiated during an investigation or after the commencement of a contested case proceeding. Negotiations shall be conducted between the board's legal counsel and any person subject to the investigation or contested case proceeding. A settlement shall be in writing and is subject to approval of a majority of the board. If the board declines to approve a proposed settlement, the settlement shall be of no force or effect.

351—9.6(68B) Whistle-blower protection. A person who discharges or discriminates against an employee because the employee filed a complaint, provided information to the board for a possible

board-initiated investigation, or provided information during the course of a board investigation shall be subject to the board's complaint process if the employee filed the complaint or provided the information in good faith. If it is determined after a contested case proceeding that a person has impermissibly discharged or discriminated against an employee, the board may impose sanctions as set out in Iowa Code section 68B.32D.

For purposes of this rule, "good faith" means that any statements or materials in a complaint, in information provided to the board for a possible board-initiated investigation, or provided in information during the course of a board investigation were made or provided with a reasonable belief that such statements or materials were true and accurate.

This rule is intended to implement Iowa Code sections 68B.32A(14) and 68B.32B.

[Editorial change: IAC Supplement 4/8/09]

351—9.7(68B) Providing false information to the board during an investigation. A person providing false information to the board during a board investigation of a potential violation of Iowa Code chapter 68A or 68B, Iowa Code section 8.7, or rules adopted by the board may be subject to the complaint or administrative resolution process as provided under Iowa Code chapter 68B and rule 351—9.4(68B). For purposes of this rule, "providing false information" means the intentional providing of a false material statement of fact, falsely denying knowledge of a material fact, or providing a material statement of fact with a reckless disregard for the truth of the statement.

This rule is intended to implement 2009 Iowa Code Supplement section 68B.32A as amended by 2010 Iowa Acts, Senate File 2067, section 5.

[**ARC 9037B**, IAB 8/25/10, effective 9/29/10]

These rules are intended to implement Iowa Code section 68B.32B.

[Filed July 3, 1974]
[Filed 10/28/75, Notice 8/25/75—published 11/17/75, effective 12/22/75]
[Filed emergency 2/11/76—published 3/8/76, effective 2/11/76]
[Filed emergency 4/1/76—published 4/19/76, effective 4/1/76]
[Filed 11/6/81, Notice 9/30/81—published 11/25/81, effective 1/1/82]
[Filed 8/21/87, Notice 6/17/87—published 9/9/87, effective 10/14/87]
[Filed 4/23/92, Notice 2/19/92—published 5/13/92, effective 6/17/92]
[Filed 9/23/93, Notice 4/28/93—published 10/13/93, effective 11/17/93]
[Filed 3/11/94, Notice 1/5/94—published 3/30/94, effective 5/4/94]
[Filed 7/29/94, Notice 5/25/94—published 8/17/94, effective 9/21/94]
[Filed 12/1/95, Notice 10/25/95—published 12/20/95, effective 1/24/96]
[Filed 3/3/99, Notice 1/13/99—published 3/24/99, effective 4/28/99]
[Filed 8/1/02, Notice 6/26/02—published 8/21/02, effective 9/25/02]
[Filed 8/28/03, Notice 7/23/03—published 9/17/03, effective 10/22/03]
[Filed 1/28/05, Notice 11/10/04—published 2/16/05, effective 3/23/05]
[Filed 9/25/06, Notice 8/2/06—published 10/25/06, effective 11/29/06]
[Filed 4/2/08, Notice 2/13/08—published 4/23/08, effective 5/28/08]
[Editorial change: IAC Supplement 4/8/09]
[Filed ARC 7993B (Notice ARC 7808B, IAB 6/3/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 7991B (Notice ARC 7810B, IAB 6/3/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 9037B (Notice ARC 8803B, IAB 6/2/10), IAB 8/25/10, effective 9/29/10]
[Filed ARC 1389C (Notice ARC 1019C, IAB 9/18/13), IAB 4/2/14, effective 5/7/14]

CHAPTER 58
NURSING FACILITIES
[Prior to 7/15/87, Health Department[470] Ch 58]

481—58.1(135C) Definitions. For the purpose of these rules, the following terms shall have the meaning indicated in this chapter. The definitions set out in Iowa Code section 135C.1 shall be considered to be incorporated verbatim in the rules. The use of the words "shall" and "must" indicates those standards are mandatory. The use of the words "should" and "could" indicates those standards are recommended.

"Accommodation" means the provision of lodging, including sleeping, dining, and living areas.

"Administrator" means a person licensed pursuant to Iowa Code chapter 147 who administers, manages, supervises, and is in general administrative charge of a nursing facility, whether or not such individual has an ownership interest in such facility, and whether or not the functions and duties are shared with one or more individuals.

"Ambulatory" means the condition of a person who immediately and without aid of another is physically or mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

"Basement" means that part of a building where the finish floor is more than 30 inches below the finish grade.

"Board" means the regular provision of meals.

"Chairfast" means capable of maintaining a sitting position but lacking the capacity of bearing own weight, even with the aid of a mechanical device or another individual.

"Communicable disease" means a disease caused by the presence of viruses or microbial agents within a person's body, which agents may be transmitted either directly or indirectly to other persons.

"Department" means the state department of inspections and appeals.

"Distinct part" means a clearly identifiable area or section within a health care facility, consisting of at least a residential unit, wing, floor, or building containing contiguous rooms.

"Medication" means any drug including over-the-counter substances ordered and administered under the direction of the physician.

"Nonambulatory" means the condition of a person who immediately and without aid of another is not physically or mentally capable of traveling a normal path to safety, including the ascent and descent of stairs.

"Nourishing snack" is defined as a verbal offering of items, single or in combination, from the basic food groups. Adequacy of the "nourishing snack" will be determined both by resident interviews and by evaluation of the overall nutritional status of residents in the facility.

"Person directed care environment" means the provision of care and services provided in a facility that promotes decision making and choices by the resident, enhances the primary caregiver's capacity to respond to each resident's needs, and promotes a homelike environment. Examples of a person directed care environment include, but are not limited to, the Green House concept, the Eden alternative, service houses and neighborhoods.

"Personal care" means assistance with the activities of daily living which the recipient can perform only with difficulty. Examples are assistance in getting in and out of bed, assistance with personal hygiene and bathing, assistance with dressing, meal assistance, and supervision over medications which can be self-administered.

"Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinum, or in raw shell eggs, the growth of salmonella enteritidis. Potentially hazardous food includes an animal food (a food of animal origin) that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic and oil mixtures that are not acidified or otherwise modified at a food processing plant in a way that results in mixtures that do not support growth of bacteria.

"Program of care" means all services being provided for a resident in a health care facility.

"Qualified intellectual disabilities professional" means a psychologist, physician, registered nurse, educator, social worker, physical or occupational therapist, speech therapist or audiologist who meets the educational requirements for the profession, as required in the state of Iowa, and having one year's experience working with persons with an intellectual disability.

"Qualified nurse" means a registered nurse or a licensed practical nurse, as defined in Iowa Code chapter 152.

"Rate" means that daily fee charged for all residents equally and shall include the cost of all minimum services required in these rules and regulations.

"Responsible party" means the person who signs or cosigns the admission agreement required in 481—58.13(135C) or the resident's guardian or conservator if one has been appointed. In the event that a resident does not have a guardian, conservator or other person signing the admission agreement, the term "responsible party" shall include the resident's sponsoring agency, e.g., the department of human services, the U.S. Department of Veterans Affairs, religious groups, fraternal organizations, or foundations that assume responsibility and advocate for their client patients and pay for their health care.

"Restraints" means any chemical, manual method or physical or mechanical device, material, or equipment attached to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body.

"Substantial evening meal" is defined as an offering of three or more menu items at one time, one of which includes a high protein such as meat, fish, eggs or cheese. The meal would represent no less than 20 percent of the day's total nutritional requirements.

[**ARC 0766C**, IAB 5/29/13, effective 7/3/13; **ARC 1398C**, IAB 4/2/14, effective 5/7/14]

481—58.2(135C) Variances. Variances from these rules may be granted by the director of the department of inspections and appeals for good and sufficient reason when the need for variance has been established; no danger to the health, safety, or welfare of any resident results; alternate means are employed or compensating circumstances exist and the variance will apply only to an individual nursing facility. Variances will be reviewed at the discretion of the director of the department of inspections and appeals.

58.2(1) To request a variance, the licensee must:

a. Apply for variance in writing on a form provided by the department;

b. Cite the rule or rules from which a variance is desired;

c. State why compliance with the rule or rules cannot be accomplished;

d. Explain alternate arrangements or compensating circumstances which justify the variance;

e. Demonstrate that the requested variance will not endanger the health, safety, or welfare of any resident.

58.2(2) Upon receipt of a request for variance, the director of inspections and appeals will:

a. Examine the rule from which variance is requested to determine that the request is necessary and reasonable;

b. If the request meets the above criteria, evaluate the alternate arrangements or compensating circumstances against the requirement of the rules;

c. Examine the effect of the requested variance on the health, safety, or welfare of the residents;

d. Consult with the applicant if additional information is required.

58.2(3) Based upon these studies, approval of the variance will be either granted or denied within 120 days of receipt.

481—58.3(135C) Application for licensure.

58.3(1) Initial application and licensing. In order to obtain an initial nursing facility license, for a nursing facility which is currently licensed, the applicant must:

a. Meet all of the rules, regulations, and standards contained in 481—Chapters 58 and 61. Applicable exceptions found in rule 481—61.2(135C) shall apply based on the construction date of the facility.

b. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;

c. Make application at least 30 days prior to the change of ownership of the facility on forms provided by the department;

d. Submit a floor plan of each floor of the nursing facility, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which room will be put and window and door location;

e. Submit a photograph of the front and side elevation of the nursing facility;

f. Submit the statutory fee for a nursing facility license;

g. Meet the requirements of a nursing facility for which licensure application is made;

h. Comply with all other local statutes and ordinances in existence at the time of licensure;

i. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

58.3(2) In order to obtain an initial nursing facility license for a facility not currently licensed as a nursing facility, the applicant must:

a. Meet all of the rules, regulations, and standards contained in 481—Chapters 58 and 61. Exceptions noted in 481—subrule 61.1(2) shall not apply;

b. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;

c. Make application at least 30 days prior to the change of ownership of the facility on forms provided by the department;

d. Submit a floor plan of each floor of the nursing facility, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which room will be put and window and door locations;

e. Submit a photograph of the front and side elevation of the nursing facility;

f. Submit the statutory fee for a nursing facility license;

g. Comply with all other local statutes and ordinances in existence at the time of licensure;

h. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

58.3(3) *Renewal application.* In order to obtain a renewal of the nursing facility license, the applicant must:

a. Submit the completed application form 30 days prior to annual license renewal date of nursing facility license;

b. Submit the statutory license fee for a nursing facility with the application for renewal;

c. Have an approved current certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations;

d. Submit appropriate changes in the résumé to reflect any changes in the resident care program or other services.

58.3(4) Licenses are issued to the person or governmental unit which has responsibility for the operation of the facility and authority to comply with all applicable statutes, rules or regulations.

The person or governmental unit must be the owner of the facility or, if the facility is leased, the lessee.

481—58.4(135C) General requirements.

58.4(1) The license shall be displayed in a conspicuous place in the facility which is viewed by the public. (III)

58.4(2) The license shall be valid only in the possession of the licensee to whom it is issued.

58.4(3) The posted license shall accurately reflect the current status of the nursing facility. (III)

58.4(4) Licenses expire one year after the date of issuance or as indicated on the license.

58.4(5) No nursing facility shall be licensed for more beds than have been approved by the health facilities construction review committee.

58.4(6) Each citation or a copy of each citation issued by the department for a class I or class II violation shall be prominently posted by the facility in plain view of the residents, visitors, and persons inquiring about placement in the facility. The citation or copy of the citation shall remain posted until the violation is corrected to the satisfaction of the department. (III)

481—58.5(135C) Notifications required by the department. The department shall be notified:

58.5(1) Within 48 hours, by letter, of any reduction or loss of nursing or dietary staff lasting more than seven days which places the staffing ratio below that required for licensing. No additional residents shall be admitted until the minimum staffing requirements are achieved; (III)

58.5(2) Of any proposed change in the nursing facility's functional operation or addition or deletion of required services; (III)

58.5(3) Thirty days before addition, alteration, or new construction is begun in the nursing facility or on the premises; (III)

58.5(4) Thirty days in advance of closure of the nursing facility; (III)

58.5(5) Within two weeks of any change in administrator; (III)

58.5(6) When any change in the category of license is sought; (III)

58.5(7) Prior to the purchase, transfer, assignment, or lease of a nursing facility, the licensee shall:

a. Inform the department of the pending sale, transfer, assignment, or lease of the facility; (III)

b. Inform the department of the name and address of the prospective purchaser, transferee, assignee, or lessee at least 30 days before the sale, transfer, assignment, or lease is completed; (III)

c. Submit a written authorization to the department permitting the department to release all information of whatever kind from the department's files concerning the licensee's nursing facility to the named prospective purchaser, transferee, assignee, or lessee. (III)

58.5(8) Pursuant to the authorization submitted to the department by the licensee prior to the purchase, transfer, assignment, or lease of a nursing facility, the department shall upon request send or give copies of all recent licensure surveys and of any other pertinent information relating to the facility's licensure status to the prospective purchaser, transferee, assignee, or lessee; costs for such copies shall be paid by the prospective purchaser.

481—58.6(135C) Witness fees. Rescinded IAB 3/30/94, effective 5/4/94. See 481—subrule 50.6(4).

481—58.7(135C) Licenses for distinct parts.

58.7(1) Separate licenses may be issued for distinct parts of a health care facility which are clearly identifiable, containing contiguous rooms in a separate wing or building or on a separate floor of the facility and which provide care and services of separate categories.

58.7(2) The following requirements shall be met for a separate licensing of a distinct part:

a. The distinct part shall serve only residents who require the category of care and services immediately available to them within that part; (III)

b. The distinct part shall meet all the standards, rules, and regulations pertaining to the category for which a license is being sought;

c. A distinct part must be operationally and financially feasible;

d. A separate staff with qualifications appropriate to the care and services being rendered must be regularly assigned and working in the distinct part under responsible management; (III)

e. Separately licensed distinct parts may have certain services such as management, building maintenance, laundry, and dietary in common with each other.

481—58.8(135C) Administrator.

58.8(1) Each nursing facility shall have one person in charge, duly licensed as a nursing home administrator or acting in a provisional capacity. (III)

58.8(2) A licensed administrator may act as an administrator for not more than two nursing facilities.

a. The distance between the two facilities shall be no greater than 50 miles. (II)

b. The administrator shall spend the equivalent of three full eight-hour days per week in each facility. (II)

c. The administrator may be responsible for no more than 150 beds in total if the administrator is an administrator of more than one facility. (II)

58.8(3) The licensee may be the licensed nursing home administrator providing the licensee meets the requirements as set forth in these regulations and devotes the required time to administrative duties. Residency in the facility does not in itself meet the requirement. (III)

58.8(4) A provisional administrator may be appointed on a temporary basis by the nursing facility licensee to assume the administrative duties when the facility, through no fault of its own, has lost its administrator and has been unable to replace the administrator provided that no facility licensed under Iowa Code chapter 135C shall be permitted to have a provisional administrator for more than 12 months in any 12-month period and further provided that:

a. The department has been notified prior to the date of the administrator's appointment; (III)

b. The board of examiners for nursing home administrators has approved the administrator's appointment and has confirmed such appointment in writing to the department. (III)

58.8(5) In the absence of the administrator, a responsible person shall be designated in writing to the department to be in charge of the facility. The administrator shall not be absent from the facility for more than 3 months without approval of the department. (III)

The person designated shall:

a. Be knowledgeable of the operation of the facility; (III)

b. Have access to records concerned with the operation of the facility; (III)

c. Be capable of carrying out administrative duties and of assuming administrative responsibilities; (III)

d. Be at least 21 years of age; (III)

e. Be empowered to act on behalf of the licensee during the administrator's absence concerning the health, safety, and welfare of the residents; (III)

f. Have had training to carry out assignments and take care of emergencies and sudden illness of residents. (III)

58.8(6) A licensed administrator in charge of two facilities shall employ an individual designated as a full-time assistant administrator for each facility. (III)

58.8(7) An administrator of only one facility shall be considered as a full-time employee. Full-time employment is defined as 40 hours per week. (III)

[**ARC 1398C**, IAB 4/2/14, effective 5/7/14]

481—58.9(135C) Administration.

58.9(1) The licensee shall:

a. Assume the responsibility for the overall operation of the nursing facility; (III)

b. Be responsible for compliance with all applicable laws and with the rules of the department; (III)

c. Establish written policies, which shall be available for review, for the operation of the nursing facility. (III)

58.9(2) The administrator shall:

a. Be responsible for the selection and direction of competent personnel to provide services for the resident care program; (III)

b. Be responsible for the arrangement for all department heads to annually attend a minimum of ten contact hours of educational programs to increase skills and knowledge needed for the position; (III)

c. Be responsible for a monthly in-service educational program for all employees and to maintain records of programs and participants; (III)

d. Make available the nursing facility payroll records for departmental review as needed; (III)

e. Be required to maintain a staffing pattern of all departments. These records must be maintained for six months and are to be made available for departmental review. (III)

481—58.10(135C) General policies.

58.10(1) There shall be written personnel policies in facilities of more than 15 beds to include hours of work, and attendance at educational programs. (III)

58.10(2) There shall be a written job description developed for each category of worker. The job description shall include title of job, job summary, qualifications (formal education and experience), skills needed, physical requirements, and responsibilities. (III)

58.10(3) There shall be written personnel policies for each facility. Personnel policies shall include the following requirements:

a. Employees shall have a physical examination before employment. (I, II, III)

b. Employees shall have a physical examination at least every four years. (I, II, III)

c. Screening and testing for tuberculosis shall be conducted pursuant to 481—Chapter 59. (I, II, III)

58.10(4) Health certificates for all employees shall be available for review. (III)

58.10(5) Rescinded IAB 10/19/88, effective 11/23/88.

58.10(6) There shall be written policies for emergency medical care for employees and residents in case of sudden illness or accident which includes the individual to be contacted in case of emergency. (III)

58.10(7) The facility shall have a written agreement with a hospital for the timely admission of a resident who, in the opinion of the attending physician, requires hospitalization. (III)

58.10(8) Infection control program. Each facility shall have a written and implemented infection control and exposure control program with policies and procedures based on the guidelines issued by the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (I, II, III) CDC guidelines are available at http://www.cdc.gov/ncidod/dhqp/index.html.

58.10(9) Infection control committee. Each facility shall establish an infection control committee of representative professional staff responsible for overall infection control in the facility. (III)

a. The committee shall annually review and revise the infection control policies and procedures to monitor effectiveness and suggest improvement. (III)

b. The committee shall meet at least quarterly, submit reports to the administrator, and maintain minutes in sufficient detail to document its proceedings and actions. (III)

c. The committee shall monitor the health aspect and the environment of the facility. (III)

58.10(10) There shall be written policies for resident care programs and services as outlined in these rules. (III)

58.10(11) Prior to the removal of a deceased resident/patient from a facility, the funeral director or person responsible for transporting the body shall be notified by the facility staff of any special precautions that were followed by the facility having to do with the mode of transmission of a known or suspected communicable disease. (III)

[**ARC 0663C**, IAB 4/3/13, effective 5/8/13]

481—58.11(135C) Personnel.

58.11(1) *General qualifications.*

a. No person with a current record of habitual alcohol intoxication or addiction to the use of drugs shall serve in a managerial role of a nursing facility. (II)

b. No person under the influence of alcohol or intoxicating drugs shall be permitted to provide services in a nursing facility. (II)

c. No person shall be allowed to provide services in a facility if the person has a disease:

(1) Which is transmissible through required workplace contact, (I, II, III)

(2) Which presents a significant risk of infecting others, (I, II, III)

(3) Which presents a substantial possibility of harming others, and (I, II, III)

(4) For which no reasonable accommodation can eliminate the risk. (I, II, III)

Refer to Guidelines for Infection Control in Hospital Personnel, Centers for Disease Control, U.S. Department of Health and Human Services, PB85-923402 to determine (1), (2), (3) and (4).

d. Reserved.

e. Individuals with either physical or mental disabilities may be employed for specific duties, but only if that disability is unrelated to that individual's ability to perform the duties of the job. (III)

f. Persons employed in all departments, except the nursing department of a nursing facility shall be qualified through formal training or through prior experience to perform the type of work for which they have been employed. Prior experience means at least 240 hours of full-time employment in a field related to their duties. Persons may be hired in laundry, housekeeping, activities and dietary without experience or training if the facility institutes a formal in-service training program to fit the job description in question and documents such as having taken place within 30 days after the initial hiring of such untrained employees. (III)

g. Rescinded, effective 7/14/82.

h. The health services supervisor shall be a qualified nurse as defined in these regulations. (II)

i. Those persons employed as nurse's aides, orderlies, or attendants in a nursing facility who have not completed the state-approved 75-hour nurse's aide program shall be required to participate in a structured on-the-job training program of 20 hours' duration to be conducted prior to any resident contact, except that contact required by the training program. This educational program shall be in addition to facility orientation. Each individual shall demonstrate competencies covered by the curriculum. This shall be observed and documented by an R.N. and maintained in the personnel file. No aide shall work independently until this is accomplished, nor shall the aide's hours count toward meeting the minimum hours of nursing care required by the department. The curriculum shall be approved by the department. An aide who has completed the state-approved 75-hour course may model skills to be learned.

Further, such personnel shall be enrolled in a state-approved 75-hour nurse's aide program to be completed no later than six months from the date of employment. If the state-approved 75-hour program has been completed prior to employment, the on-the-job training program requirement is waived. The 20-hour course is in addition to the 75-hour course and is not a substitute in whole or in part. The 75-hour program, approved by the department, may be provided by the facility or academic institution.

Newly hired aides who have completed the state-approved 75-hour course shall demonstrate competencies taught in the 20-hour course upon hire. This shall be observed and documented by an R.N. and maintained in the personnel file.

All personnel administering medications must have completed the state-approved training program in medication administration. (II)

j. There shall be an organized ongoing in-service educational and training program planned in advance for all personnel in all departments. (II, III)

k. Nurse aides, orderlies or attendants in a nursing facility who have received training other than the Iowa state-approved program, must pass a challenge examination approved by the department of inspections and appeals. Evidence of prior formal training in a nursing aide, orderly, attendant, or other comparable program must be presented to the facility or institution conducting the challenge examination before the examination is given. The approved facility or institution, following department of inspections and appeals guidelines, shall make the determination of who is qualified to take the examination. Documentation of the challenge examinations administered shall be maintained.

58.11(2) *Nursing supervision and staffing.*

a. Rescinded IAB 8/7/91, effective 7/19/91.

b. Where only part-time nurses are employed, one nurse shall be designated health service supervisor. (III)

c. A qualified nurse shall be employed to relieve the supervising nurses, including charge nurses, on holidays, vacation, sick leave, days off, absences or emergencies. Pertinent information for contacting such relief person shall be posted at the nurse's station. (III)

d. When the health service supervisor serves as the administrator of a facility 50 beds and over, a qualified nurse must be employed to relieve the health service supervisor of nursing responsibilities. (III)

e. The department may establish on an individual facility basis the numbers and qualifications of the staff required in the facility using as its criteria the services being offered and the needs of the residents. (III)

f. Additional staffing, above the minimum ratio, may be required by the department commensurate with the needs of the individual residents. (III)

g. The minimum hours of resident care personnel required for residents needing intermediate nursing care shall be 2.0 hours per resident day computed on a seven-day week. A minimum of 20 percent of this time shall be provided by qualified nurses. If the maximum medical assistance rate is reduced below the 74th percentile, the requirement will return to 1.7 hours per resident per day computed on a seven-day week. A minimum of 20 percent of this time shall be provided by qualified nurses. (II, III)

h. The health service supervisor's hours worked per week shall be included in computing the 20 percent requirement.

i. A nursing facility of 75 beds or more shall have a qualified nurse on duty 24 hours per day, seven days a week. (II, III)

j. In facilities under 75 beds, if the health service supervisor is a licensed practical nurse, the facility shall employ a registered nurse, for at least four hours each week for consultation, who must be on duty at the same time as the health service supervisor. (II, III)

(1) This shall be an on-site consultation and documentation shall be made of the visit. (III)

(2) The registered nurse-consultant shall have responsibilities clearly outlined in a written agreement with the facility. (III)

(3) Consultation shall include but not be limited to the following: counseling the health service supervisor in the management of the health services; (III) reviewing and evaluating the health services in determining that the needs of the residents are met; (II, III) conducting a review of medications at least monthly if the facility does not employ a registered nurse part-time. (II, III)

k. Facilities with 75 or more beds must employ a health service supervisor who is a registered nurse. (II)

l. There shall be at least two people who shall be capable of rendering nursing service, awake, dressed, and on duty at all times. (II)

m. Physician's orders shall be implemented by qualified personnel. (II, III)

58.11(3) *Employee criminal record checks, child abuse checks and dependent adult abuse checks and employment of individuals who have committed a crime or have a founded abuse.* The facility shall comply with the requirements found in Iowa Code section 135C.33 as amended by 2013 Iowa Acts, Senate File 347, and rule 481—50.9(135C) related to completion of criminal record checks, child abuse checks, and dependent adult abuse checks and to employment of individuals who have committed a crime or have a founded abuse. (I, II, III)

[**ARC 0903C**, IAB 8/7/13, effective 9/11/13]

481—58.12(135C) Admission, transfer, and discharge.

58.12(1) *General admission policies.*

a. No resident shall be admitted or retained in a nursing facility who is in need of greater services than the facility can provide. (II, III)

b. No nursing facility shall admit more residents than the number of beds for which it is licensed, except guest rooms for visitors. (II, III)

c. There shall be no more beds erected than is stipulated on the license. (II, III)

d. There shall be no more beds erected in a room than its size and other characteristics will permit. (II, III)

e. The admission of a resident to a nursing facility shall not give the facility or any employee of the facility the right to manage, use, or dispose of any property of the resident except with the written authorization of the resident or the resident's legal representative. (III)

f. The admission of a resident shall not grant the nursing facility the authority or responsibility to manage the personal affairs of the resident except as may be necessary for the safety of the resident and safe and orderly management of the facility as required by these rules. (III)

g. A nursing facility shall provide for the safekeeping of personal effects, funds, and other property of its residents. The facility may require that items of exceptional value or which would

convey unreasonable responsibilities to the licensee be removed from the premises of the facility for safekeeping. (III)

h. Rescinded, effective 7/14/82.

i. Funds or properties received by the nursing facility belonging to or due a resident, expendable for the resident's account, shall be trust funds. (III)

j. Infants and children under the age of 16 shall not be admitted to health care facilities for adults unless given prior written approval by the department. A distinct part of a health care facility, segregated from the adult section, may be established based on a program of care submitted by the licensee or applicant which is commensurate with the needs of the residents of the health care facility and has received the department's review and approval. (III)

k. No health care facility, and no owner, administrator, employee or representative thereof shall act as guardian, trustee, or conservator for any resident's property, unless such resident is related to the person acting as guardian within the third degree of consanguinity.

l. Within 30 days of a resident's admission to a health care facility receiving reimbursement through the medical assistance program under Iowa Code chapter 249A, the facility shall ask the resident or the resident's personal representative whether the resident is a veteran and shall document the response. If the facility determines that the resident is a potential veteran, the facility shall report the resident's name along with the names of the resident's spouse and any dependent children, as well as the name of the contact person for this information, to the Iowa department of veterans affairs. Where appropriate, the facility may also report such information to the Iowa department of human services.

If a resident is eligible for benefits through the United States Department of Veterans Affairs or other third-party payor, the facility first shall seek reimbursement from the identified payor source before seeking reimbursement from the medical assistance program established under Iowa Code chapter 249A.

The provisions of this paragraph shall not apply to the admission of an individual as a resident to a state mental health institute for acute psychiatric care or to the admission of an individual to the Iowa Veterans Home. (II, III)

58.12(2) *Discharge or transfer.*

a. Prior notification shall be made to the resident, as well as the resident's next of kin, legal representative, attending physician, and sponsoring agency, if any, prior to transfer or discharge of any resident. (III)

b. Proper arrangements shall be made by the nursing facility for the welfare of the resident prior to transfer or discharge in the event of an emergency or inability to reach the next of kin or legal representative. (III)

c. The licensee shall not refuse to discharge or transfer a resident when the physician, family, resident, or legal representative requests such a discharge or transfer. (II, III)

d. Advance notification will be made to the receiving facility prior to the transfer of any resident. (III)

e. When a resident is transferred or discharged, the appropriate record as set forth in 58.15(2)*"k"* of these rules will accompany the resident. (II, III)

f. Prior to the transfer or discharge of a resident to another health care facility, arrangements to provide for continuity of care shall be made with the facility to which the resident is being sent. (II, III)

481—58.13(135C) Contracts. Each contract shall:

58.13(1) State the base rate or scale per day or per month, the services included, and the method of payment; (III)

58.13(2) Contain a complete schedule of all offered services for which a fee may be charged in addition to the base rate. Furthermore, the contract shall: (III)

a. Stipulate that no further additional fees shall be charged for items not contained in complete schedule of services as set forth in 58.13(3); (III)

b. State the method of payment of additional charges; (III)

c. Contain an explanation of the method of assessment of such additional charges and an explanation of the method of periodic reassessment, if any, resulting in changing such additional charges; (III)

d. State that additional fees may be charged to the resident for nonprescription drugs, other personal supplies, and services by a barber, beautician, etc.; (III)

58.13(3) Contain an itemized list of those services, with the specific fee the resident will be charged and method of payment, as related to the resident's current condition, based on the nursing assessment at the time of admission, which is determined in consultation with the administrator; (III)

58.13(4) Include the total fee to be charged initially to the specific resident; (III)

58.13(5) State the conditions whereby the facility may make adjustments to the facility's overall fees for resident care as a result of changing costs. (III) Furthermore, the contract shall provide that the facility shall give:

a. Written notification to the resident, or responsible party when appropriate, of changes in the overall rates of both base and additional charges at least 30 days prior to effective date of such changes; (III)

b. Notification to the resident, or responsible party when appropriate, of changes in additional charges, based on a change in the resident's condition. Notification must occur prior to the date such revised additional charges begin. If notification is given orally, subsequent written notification must also be given within a reasonable time, not to exceed one week, listing specifically the adjustments made; (III)

58.13(6) State the terms of agreement in regard to refund of all advance payments in the event of transfer, death, voluntary or involuntary discharge; (III)

58.13(7) State the terms of agreement concerning the holding and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons. The terms shall contain a provision that the bed will be held at the request of the resident or the resident's responsible party.

a. The facility shall ask the resident or responsible party if the resident wants the bed held. This request shall be made before the resident leaves or within 48 hours after the resident leaves. The inquiry and the response shall be documented. (II)

b. The facility shall reserve the bed when requested for as long as payments are made in accordance with the contract. (II)

58.13(8) State the conditions under which the involuntary discharge or transfer of a resident would be effected; (III)

58.13(9) State the conditions of voluntary discharge or transfer; (III)

58.13(10) Set forth any other matters deemed appropriate by the parties to the contract. No contract or any provision thereof shall be drawn or construed so as to relieve any health care facility of any requirement or obligation imposed upon it by this chapter or any standards or rules in force pursuant to this chapter; (III)

58.13(11) Each party shall receive a copy of the signed contract. (III)

481—58.14(135C) Medical services.

58.14(1) Each resident in a nursing facility shall designate a licensed physician who may be called when needed. Professional management of a resident's care shall be the responsibility of the hospice program when:

a. The resident is terminally ill, and

b. The resident has elected to receive hospice services under the federal Medicare program from a Medicare-certified hospice program, and

c. The facility and the hospice program have entered into a written agreement under which the hospice program takes full responsibility for the professional management of hospice care.

58.14(2) Each resident admitted to a nursing facility shall have had a physical examination prior to admission. If the resident is admitted directly from a hospital, a copy of the hospital admission physical

and discharge summary may be made part of the record in lieu of an additional physical examination. A record of the examination, signed by the physician, shall be a part of the resident's record. (III)

58.14(3) Arrangements shall be made to have a physician available to furnish medical care in case of emergency. (II, III)

58.14(4) Rescinded, effective 7/14/82.

58.14(5) The person in charge shall immediately notify the physician of any accident, injury, or adverse change in the resident's condition. (I, II, III)

58.14(6) A schedule listing the names and telephone numbers of the physicians shall be posted in each nursing station. (III)

58.14(7) Residents shall be admitted to a nursing facility only on a written order signed by a physician certifying that the individual being admitted requires no greater degree of nursing care than the facility is licensed to provide. (III)

58.14(8) Physician delegation of tasks. Each resident, including private pay residents, shall be visited by or shall visit the resident's physician at least twice a year. The year period shall be measured from the date of admission and is not to include preadmission physicals.

a. For a skilled nursing patient, the resident must be seen by a physician for the initial comprehensive visit. Additional visits are required at least once every 30 days for 90 days after admission and at least once every 60 days thereafter. After the initial comprehensive visit, alternate required visits may be performed by an advanced registered nurse practitioner, clinical nurse specialist or physician assistant who is working in collaboration with a physician, as outlined in Table 1. (III)

b. Notwithstanding the provisions of 42 CFR 483.40, any required physician task or visit in a nursing facility may also be performed by an advanced registered nurse practitioner, clinical nurse specialist, or physician assistant who is working in collaboration with a physician, as outlined in Table 1. (III)

c. In dually certified skilled nursing/nursing facilities, the advanced registered nurse practitioner, clinical nurse specialist, and physician assistant must follow the skilled nursing facility requirements for services for skilled nursing facility stays. For nursing facility stays in skilled nursing/nursing facilities, any required physician task or visit may be performed by an advanced registered nurse practitioner, clinical nurse specialist, or physician assistant working in collaboration with the physician. (III)

d. Nurse practitioners, clinical nurse specialists, and physician assistants may perform other tasks that are not reserved to the physician such as visits outside the normal schedule needed to address new symptoms or other changes in medical status. (III)

Table 1: Authority for non-physician practitioners to perform visits, sign orders, and sign certifications/recertifications when permitted by state law*

	Initial Comprehensive Visit/Orders	Other Required Visits[1]	Other Medically Necessary Visits and Orders[2]	Certification/ Recertification
Skilled Nursing Facilities				
Physician assistant, nurse practitioner and clinical nurse specialist employed by the facility	May not perform/May not sign	May perform alternate visits	May perform and sign	May not sign
Physician assistant, nurse practitioner and clinical nurse specialist not a facility employee	May not perform/May not sign	May perform alternate visits	May perform and sign	May sign subject to state requirements

	Initial Comprehensive Visit/Orders	Other Required Visits[1]	Other Medically Necessary Visits and Orders[2]	Certification/ Recertification
Nursing Facilities				
Nurse practitioner, clinical nurse specialist, and physician assistant employed by the facility	May not perform/May not sign	May not perform	May perform and sign	Not applicable[+]
Nurse practitioner, clinical nurse specialist, and physician assistant not a facility employee	May perform/May sign	May perform	May perform and sign	Not applicable[+]

*As permitted by state law governing the scope and practice of nurse practitioners, clinical nurse specialists, and physician assistants.

[1] Other required visits include the skilled nursing resident monthly visits that may be alternated between physician and advanced registered nurse practitioners, clinical nurse specialists, or physician assistants after the initial comprehensive visit is completed.

[2] Medically necessary visits may be performed prior to the initial comprehensive visit.

[+] This requirement relates specifically to coverage of Part A Medicare stays, which can take place only in a Medicare-certified skilled nursing facility.

[**ARC 1048C**, IAB 10/2/13, effective 11/6/13; **ARC 1398C**, IAB 4/2/14, effective 5/7/14]

481—58.15(135C) Records.

58.15(1) *Resident admission record.* The licensee shall keep a permanent record on all residents admitted to a nursing facility with all entries current, dated, and signed. This shall be a part of the resident clinical record. (III) The admission record form shall include:

a. Name and previous address of resident; (III)

b. Birth date, sex, and marital status of resident; (III)

c. Church affiliation; (III)

d. Physician's name, telephone number, and address; (III)

e. Dentist's name, telephone number, and address; (III)

f. Name, address, and telephone number of next of kin or legal representative; (III)

g. Name, address, and telephone number of person to be notified in case of emergency; (III)

h. Mortician's name, telephone number, and address; (III)

i. Pharmacist's name, telephone number, and address. (III)

58.15(2) *Resident clinical record.* There shall be a separate clinical record for each resident admitted to a nursing facility with all entries current, dated, and signed. (III) The resident clinical record shall include:

a. Admission record; (III)

b. Admission diagnosis; (III)

c. Physical examination: The record of the admission physical examination and medical history shall portray the current medical status of the resident and shall include the resident's name, sex, age, medical history, tuberculosis status, physical examination, diagnosis, statement of chief complaints, estimation of restoration potential and results of any diagnostic procedures. The report of the physical examination shall be signed by the physician. (III)

d. Physician's certification that the resident requires no greater degree of nursing care than the facility is licensed to provide; (III)

e. Physician's orders for medication, treatment, and diet in writing and signed by the physician quarterly; (III)

f. Progress notes.

(1) Physician shall enter a progress note at the time of each visit; (III)

(2) Other professionals, i.e., dentists, social workers, physical therapists, pharmacists, and others shall enter a progress note at the time of each visit; (III)

g. All laboratory, X-ray, and other diagnostic reports; (III)

h. Nurse's record including:

(1) Admitting notes including time and mode of transportation; room assignment; disposition of valuables; symptoms and complaints; general condition; vital signs; and weight; (II, III)

(2) Routine notes including physician's visits; telephone calls to and from the physician; unusual incidents and accidents; change of condition; social interaction; and P.R.N. medications administered including time and reason administered, and resident's reaction; (II, III)

(3) Discharge or transfer notes including time and mode of transportation; resident's general condition; instructions given to resident or legal representative; list of medications and disposition; and completion of transfer form for continuity of care; (II, III)

(4) Death notes including notification of physician and family to include time, disposition of body, resident's personal possessions and medications; and complete and accurate notes of resident's vital signs and symptoms preceding death; (III)

i. Medication record.

(1) An accurate record of all medications administered shall be maintained for each resident. (II, III)

(2) Schedule II drug records shall be kept in accordance with state and federal laws; (II, III)

j. Death record. In the event of a resident's death, notations in the resident's record shall include the date and time of the resident's death, the circumstances of the resident's death, the disposition of the resident's body, and the date and time that the resident's family and physician were notified of the resident's death; (III)

k. Transfer form.

(1) The transfer form shall include identification data from the admission record, name of transferring institution, name of receiving institution, and date of transfer; (III)

(2) The nurse's report shall include resident attitudes, behavior, interests, functional abilities (activities of daily living), unusual treatments, nursing care, problems, likes and dislikes, nutrition, current medications (when last given), and condition on transfer; (III)

(3) The physician's report shall include reason for transfer, medications, treatment, diet, activities, significant laboratory and X-ray findings, and diagnosis and prognosis; (III)

l. Consultation reports shall indicate services rendered by allied health professionals in the facility or in health-centered agencies such as dentists, physical therapists, podiatrists, oculists, and others. (III)

58.15(3) *Resident personal record.* Personal records may be kept as a separate file by the facility.

a. Personal records may include factual information regarding personal statistics, family and responsible relative resources, financial status, and other confidential information.

b. Personal records shall be accessible to professional staff involved in planning for services to meet the needs of the resident. (III)

c. When the resident's records are closed, the information shall become a part of the final record. (III)

d. Personal records shall include a duplicate copy of the contract(s). (III)

58.15(4) *Incident record.*

a. Each nursing facility shall maintain an incident record report and shall have available incident report forms. (III)

b. Report of incidents shall be in detail on a printed incident report form. (III)

c. The person in charge at the time of the incident shall prepare and sign the report. (III)

d. The report shall cover all accidents where there is apparent injury or where hidden injury may have occurred. (III)

e. The report shall cover all accidents or unusual occurrences within the facility or on the premises affecting residents, visitors, or employees. (III)

f. A copy of the incident report shall be kept on file in the facility. (III)

58.15(5) *Retention of records.*

a. Records shall be retained in the facility for five years following termination of services. (III)

b. Records shall be retained within the facility upon change of ownership. (III)

c. Rescinded, effective 7/14/82.

d. When the facility ceases to operate, the resident's record shall be released to the facility to which the resident is transferred. If no transfer occurs, the record shall be released to the individual's physician. (III)

58.15(6) *Reports to the department.* The licensee shall furnish statistical information concerning the operation of the facility to the department on request. (III)

58.15(7) *Personnel record.*

a. An employment record shall be kept for each employee, consisting of the following information: name and address of employee, social security number of employee, date of birth of employee, date of employment, experience and education, references, position in the home, criminal history and dependent adult abuse background checks, and date and reason for discharge or resignation. (III)

b. The personnel records shall be made available for review upon request by the department. (III)

481—58.16(135C) Resident care and personal services.

58.16(1) Beds shall be made daily and adjusted as necessary. A complete change of linen shall be made at least once a week and more often if necessary. (III)

58.16(2) Residents shall receive sufficient supervision so that their personal cleanliness is maintained. (II, III)

58.16(3) Residents shall have clean clothing as needed to present a neat appearance, to be free of odors, and to be comfortable. Clothing shall be based on resident choice and shall be appropriate to residents' activities and to the weather. (III)

58.16(4) Rescinded, effective 7/14/82.

58.16(5) Residents shall be encouraged to leave their rooms and make use of the recreational room or living room of the facility. (III)

58.16(6) Residents shall not be required to pass through another's bedroom to reach a bathroom, living room, dining room, corridor, or other common areas of the facility. (III)

58.16(7) Rescinded, effective 7/14/82.

58.16(8) Uncontrollable residents shall be transferred or discharged from the facility in accordance with contract arrangements and requirements of Iowa Code chapter 135C. (II, III)

58.16(9) Except for those who request differently, residents who are not bedfast shall be fully dressed each day to maintain self-esteem and promote the residents' normal lifestyles. (III)

58.16(10) Residents shall receive a bath of their choice, based on the facility's accommodations, as needed to maintain proper hygiene. (II, III)

481—58.17 Rescinded, effective 7/14/82.

481—58.18(135C) Nursing care.

58.18(1) Individual health care plans shall be based on resident treatment decisions, the nature of the illness or disability, treatment, and care prescribed. Goals shall be developed by each discipline providing service, treatment, and care. These plans shall be in writing, revised as necessary, and kept current. They shall be made available to all those rendering the services and for review by the department. (III)

58.18(2) Rescinded IAB 4/2/14, effective 5/7/14.

58.18(3) The facility shall provide resident and family education as an integral part of restorative and supportive care. (III)

58.18(4) The facility shall provide prompt response from qualified staff for the resident's use of the nurse call system. (II, III) (Prompt response being considered as no longer than 15 minutes.)

[**ARC 1398C**, IAB 4/2/14, effective 5/7/14]

481—58.19(135C) Required nursing services for residents. The resident shall receive and the facility shall provide, as appropriate, the following required nursing services under the 24-hour direction of qualified nurses with ancillary coverage as set forth in these rules:

58.19(1) *Activities of daily living.*

a. Bathing; (II, III)

b. Daily oral hygiene (denture care); (II, III)

c. Routine shampoo; (II, III)

d. Nail care; (III)

e. Shaving; (III)

f. Daily care and application of prostheses (glasses, hearing aids, glass eyes, limb prosthetics, braces, or other assistive devices); (II, III)

g. Ambulation with equipment if applicable, or transferring, or positioning; (I, II, III)

h. Daily routine range of motion; (II, III)

i. Mobility (assistance with wheelchair, mechanical lift, or other means of locomotion); (I, II, III)

j. Elimination.

(1) Assistance to and from the bathroom and perineal care; (II, III)

(2) Bedpan assistance; (II, III)

(3) Care for incontinent residents; (II, III)

(4) Bowel and bladder training programs including in-dwelling catheter care (i.e., insertion and irrigation), enema and suppository administration, and monitoring and recording of intake and output, including solid waste; (I, II, III)

k. Colostomy care (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse); (I, II, III)

l. Ileostomy care (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse); (I, II, III)

m. All linens necessary; (III)

n. Nutrition and meal service.

(1) Regular, therapeutic, modified diets, and snacks; (I, II, III)

(2) Mealtime preparation of resident; (II, III)

(3) Assistance to and from meals; (II, III)

(4) In-room meal service or tray service; (II, III)

(5) Assistance with food preparation and meal assistance including total assistance if needed; (II, III)

(6) Assistance with adaptive devices; (II, III)

(7) Enteral nutrition (to be performed by a registered nurse or licensed practical nurse only); (I, II, III)

o. Promote initiation of self-care for elements of resident care; (II, III)

p. Oral suctioning (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse). (I, II)

58.19(2) *Medication and treatment.*

a. Administration of all medications as ordered by the physician including oral, instillations, topical, injectable (to be injected by a registered nurse or licensed practical nurse only); (I, II)

b. Provision of the appropriate care and treatment of wounds, including pressure sores, to promote healing, prevent infection, and prevent new sores from developing; (I, II)

c. Blood glucose monitoring; (I, II)

d. Vital signs, blood pressure, and weights; (I, II)

e. Ambulation and transfer; (II, III)

f. Provision of restraints; (I, II)

g. Administration of oxygen (to be performed only by a registered nurse or licensed practical nurse or by a qualified aide under the direction of a registered nurse or licensed practical nurse); (I, II)

h. Provision of all treatments; (I, II, III)

i. Provision of emergency medical care, including arranging for transportation, in accordance with written policies and procedures of the facility; (I, II, III)

j. Provision of accurate assessment and timely intervention for all residents who have an onset of adverse symptoms which represent a change in mental, emotional, or physical condition. (I, II, III)

[**ARC 1398C**, IAB 4/2/14, effective 5/7/14]

481—58.20(135C) Duties of health service supervisor. Every nursing facility shall have a health service supervisor who shall:

58.20(1) Direct the implementation of the physician's orders; (I, II)

58.20(2) Plan for and direct the nursing care, services, treatments, procedures, and other services in order that each resident's needs and choices, where practicable, are met; (II, III)

58.20(3) Review the health care needs and choices, where practicable, of each resident admitted to the facility and assist the attending physician in planning for the resident's care; (II, III)

58.20(4) Develop and implement a written health care plan in cooperation with, to the extent practicable, the resident, the resident's family or the resident's legal representative, and others in accordance with instructions of the attending physician as follows:

a. The written health care plan, based on the assessment and reassessment of the resident's health needs and choices, where practicable, is personalized for the individual resident and indicates care to be given, goals to be accomplished, and methods, approaches, and modifications necessary to achieve best results; (III)

b. The health service supervisor is responsible for preparing, reviewing, supervising the implementation, and revising the written health care plan; (III)

c. The health care plan is readily available for use by all personnel caring for the resident; (III)

58.20(5) Initiate preventative and restorative nursing procedures for each resident so as to achieve and maintain the highest possible degree of function, self-care, and independence based on resident choice, where practicable; (II, III)

58.20(6) Supervise health services personnel to ensure they perform the following restorative measures in their daily care of residents:

a. Maintaining good bodily alignment and proper positioning; (II, III)

b. Making every effort to keep the resident active except when contraindicated by physician's orders, and encouraging residents to achieve independence in activities of daily living by teaching self-care, transfer, and ambulation activities; (III)

c. Assisting residents to adjust to their disabilities, to use their prosthetic devices, and to redirect their interests as necessary; (III)

d. Assisting residents to carry out prescribed therapy exercises between visits of the therapist; (III)

e. Assisting residents with routine range of motion exercises; (III)

58.20(7) Plan and conduct nursing staff orientation and in-service programs and provide for training of nurse's aides; (III)

58.20(8) Plan with the resident and the resident's physician and family and health-related agencies for the care of the resident upon discharge; (III)

58.20(9) Designate a responsible person to be in charge during absences; (III)

58.20(10) Be responsible for all assignments and work schedules for all health services personnel to ensure that the health needs of the residents are met; (III)

58.20(11) Ensure that all nurse's notes are descriptive of the care rendered including the resident's response; (III)

58.20(12) Visit each resident routinely to be knowledgeable of the resident's current condition; (III)

58.20(13) Evaluate in writing the performance of each individual on the health care staff on at least an annual basis. This evaluation shall be available for review in the facility to the department; (III)

58.20(14) Keep the administrator informed of the resident's status; (III)

58.20(15) Teach and coordinate rehabilitative health care including activities of daily living, promotion and maintenance of optimal physical and mental functioning; (III)

58.20(16) Supervise serving of meals to ensure that individuals unable to assist themselves are promptly fed and that special eating adaptive devices are available as needed; (II, III)

58.20(17) Make available a nursing procedure manual which shall include all procedures practiced in the facility; (III)

58.20(18) Participate with the administrator in the formulation of written policies and procedures for resident services; (III)

58.20(19) The person in charge shall immediately notify the family of any accident, injury, or adverse change in the resident's condition requiring physician's notification. (III)

481—58.21(135C) Drugs, storage, and handling.

58.21(1) Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

a. A cabinet with a lock, convenient to nursing service, shall be provided and used for storage of all drugs, solutions, and prescriptions; (III)

b. The drug storage cabinet shall be kept locked when not in use; (III)

c. The medication cabinet key shall be in the possession of the person directly responsible for issuing medications; (II, III)

d. Double-locked storage of Schedule II drugs shall not be required under single unit package drug distribution systems in which the quantity stored does not exceed a three-day supply and a missing dose can be readily detected. (II)

58.21(2) Drugs for external use shall be stored separately from drugs for internal use. (III)

58.21(3) Medications requiring refrigeration shall be kept in a refrigerator and separated from food and other items. A method for locking these medications shall be provided. (III)

58.21(4) All potent, poisonous, or caustic materials shall be stored separately from drugs. They shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet, or storeroom and made accessible only to authorized persons. (I, II)

58.21(5) All flammable materials shall be specially stored and handled in accordance with applicable local and state fire regulations. (II)

58.21(6) A properly trained person shall be charged with the responsibility of administering nonparenteral medications.

a. The individual shall have knowledge of the purpose of the drugs, their dangers, and contraindications.

b. This person shall be a licensed nurse or physician or shall have successfully completed a department-approved medication aide course or passed a department-approved medication aide challenge examination administered by an area community college.

c. Prior to taking a department-approved medication aide course, the individual shall:

(1) Successfully complete an approved nurse aide course, nurse aide training and testing program or nurse aide competency examination.

(2) Be employed in the same facility for at least six consecutive months prior to the start of the medication aide course. This requirement is not subject to waiver.

(3) Have a letter of recommendation for admission to the medication aide course from the employing facility.

d. A person who is a nursing student or a graduate nurse may take the challenge examination in place of taking a medication aide course. This individual shall do all of the following before taking the medication aide challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination;

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination;

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating the individual is competent in medication administration.

(4) Successfully complete a department-approved nurse aide competency evaluation.

e. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination.

The requirements of paragraph *"c"* of this subrule do not apply to this individual.

58.21(7) Unless the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by personally preparing the dose, observing the actual act of swallowing the oral medication, and charting the medication. (II) In facilities where the unit dose system is used, the person assigned the responsibility must complete the procedure by observing the actual act of swallowing the medication and charting the medication. Medications shall be prepared on the same shift of the same day that they are administered, (II) unless the unit dose system is used.

58.21(8) An accurate written record of medications administered shall be made by the individual administering the medication. (III)

58.21(9) Records shall be kept of all Schedule II drug medications received and dispensed in accordance with the controlled drug and substance Act. (III)

58.21(10) Any unusual resident reaction shall be reported to the physician at once. (II)

58.21(11) A policy shall be established by the facility in conjunction with a licensed pharmacist to govern the distribution of prescribed medications to residents who are on leave from the facility. (III)

a. Medication may be issued to residents who will be on leave from a facility for less than 24 hours. Notwithstanding the prohibition against paper envelopes in 58.21(14)*"a,"* non-child-resistant containers may be used. Each container may hold only one medication. A label on each container shall indicate the date, the resident's name, the facility, the medication, its strength, dose, and time of administration.

b. Medication for residents on leave from a facility longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy examiners.

c. Medication distributed as above may be issued only by a nurse responsible for administering medication. (I, II, III)

58.21(12) Emergency medications. A nursing facility shall provide emergency medications pursuant to the following requirements: (III)

a. Prescription drugs as well as nonprescription items must be prescribed or approved by the physician, in consultation with the pharmacist, who provides emergency service to the facility; (III)

b. The emergency medications shall be stored in an accessible place; (III)

c. A list of the emergency medications and quantities of each item shall be maintained by the facility; (III)

d. The container holding the emergency medications shall be closed with a seal which may be broken when drugs are required in an emergency or for inspection; (III)

e. Any item removed from the emergency medications shall be replaced within 48 hours; (III)

f. A permanent record shall be kept of each time the emergency medications are used; (III)

g. The emergency medications shall be inspected by a pharmacist at least once every three months to determine the stability of items. (III)

58.21(13) Drug handling.

a. Bulk supplies of prescription drugs shall not be kept in a nursing facility unless a licensed pharmacy is established in the facility under the direct supervision and control of a pharmacist. (III)

b. Inspection of drug storage condition shall be made by the health service supervisor and a registered pharmacist not less than once every three months. The inspection shall be verified by a report signed by the nurse and pharmacist and filed with the administrator. The report shall include, but not be limited to, certifying absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current physician's order, and drugs improperly stored. (III)

c. If the facility permits licensed nurses to dilute or reconstitute drugs at the nursing station, distinctive supplementary labels shall be available for the purpose. The notation on the label shall be so made as to be indelible. (III)

d. Dilution and reconstitution of drugs and their labeling shall be done by the pharmacist whenever possible. If not possible, the following shall be carried out only by the licensed nurse:

(1) Specific directions for dilution or reconstitution and expiration date should accompany the drug; (III)

(2) A distinctive supplementary label shall be affixed to the drug container when diluted or reconstituted by the nurse for other than immediate use. (III) The label shall bear the following: resident's name, dosage and strength per unit/volume, nurse's name, expiration date, and date and time of dilution. (III)

58.21(14) Drug safeguards.

a. All prescribed medications shall be clearly labeled indicating the resident's full name, physician's name, prescription number, name and strength of drug, dosage, directions for use, date of issue, and name and address and telephone number of pharmacy or physician issuing the drug. Where unit dose is used, prescribed medications shall, as a minimum, indicate the resident's full name, physician's name, name and strength of drug, and directions for use. Standard containers shall be utilized for dispensing drugs. Paper envelopes shall not be considered standard containers. (III)

b. Medication containers having soiled, damaged, illegible or makeshift labels, or medication samples shall be returned to the issuing pharmacist, pharmacy, or physician for relabeling or disposal. (III)

c. There shall be no medications or any solution in unlabeled containers. (II, III)

d. The medications of each resident shall be kept or stored in the originally received containers. (II, III)

e. Labels on containers shall be clearly legible and firmly affixed. No label shall be superimposed on another label of a drug container. (II, III)

f. When a resident is discharged or leaves the facility, the unused prescription shall be sent with the resident or with a legal representative only upon the written order of a physician. (III)

g. Unused prescription drugs prescribed for residents who are deceased shall be returned to the supplying pharmacist. (III)

h. Prescriptions shall be refilled only with the permission of the attending physician. (II, III)

i. No medications prescribed for one resident may be administered to or allowed in the possession of another resident. (II)

j. Instructions shall be requested of the Iowa board of pharmacy examiners concerning disposal of unused Schedule II drugs prescribed for residents who have died or for whom the Schedule II drug was discontinued. (III)

k. There shall be a formal routine for the proper disposal of discontinued medications within a reasonable but specified time. These medications shall not be retained with the resident's current medications. Discontinued drugs shall be destroyed by the responsible nurse with a witness and a notation made to that effect or returned to the pharmacist for destruction or resident credit. Drugs listed under the Schedule II drugs shall be disposed of in accordance with the provisions of the Iowa board of pharmacy examiners. (II, III)

l. All medication orders which do not specifically indicate the number of doses to be administered or the length of time the drug is to be administered shall be stopped automatically after a given time period. The automatic stop order may vary for different types of drugs. The physician, in consultation with the pharmacist serving the home, shall institute policies and provide procedures for review and endorsement of stop orders on drugs. This policy shall be conveniently located for personnel administering medications. (II, III)

m. No resident shall be allowed to keep possession of any medications unless the attending physician has certified in writing on the resident's medical record that the resident is mentally and physically capable of doing so. (II)

n. Residents who have been certified in writing by the physician as capable of taking their own medications may retain these medications in their bedroom, but locked storage must be provided. (II)

o. No medications or prescription drugs shall be administered to a resident without a written order signed by the attending physician. (II)

p. A qualified nurse shall:

(1) Establish a medication schedule system which identifies the time and dosage of each medication prescribed for each resident, is based on the resident's desired routine, and is approved by the resident's physician. (II, III)

(2) Establish a medication record containing the information specified above needed to monitor each resident's drug regimen. (II, III)

q. Telephone orders shall be taken by a qualified nurse. Orders shall be written into the resident's record and signed by the person receiving the order. Telephone orders shall be submitted to the physician for signature within 48 hours. (III)

r. A pharmacy operating in connection with a nursing facility shall comply with the provisions of the pharmacy law requiring registration of pharmacies and the regulations of the Iowa board of pharmacy examiners. (III)

s. In a nursing facility with a pharmacy or drug supply, service shall be under the personal supervision of a pharmacist licensed to practice in the state of Iowa. (III)

58.21(15) Drug administration.

a. Injectable medications shall be administered as permitted by Iowa law by a qualified nurse, physician, pharmacist, or physician assistant (PA). In the case of a resident who has been certified by the resident's physician or physician assistant (PA) as capable of taking the resident's own insulin, the resident may inject the resident's own insulin. (II)

b. An individual inventory record shall be maintained for each Schedule II drug prescribed for each resident. (II)

c. The health service supervisor shall be responsible for the supervision and direction of all personnel administering medications. (II)

[**ARC 1050C**, IAB 10/2/13, effective 11/6/13]

481—58.22(135C) Rehabilitative services. Rehabilitative services shall be provided to maintain function or improve the resident's ability to carry out the activities of daily living.

58.22(1) *Physical therapy services.*

a. Each facility shall have a written agreement with a licensed physical therapist to provide physical therapy services. (III)

b. Physical therapy shall be rendered only by a physical therapist licensed to practice in the state of Iowa. All personnel assisting with the physical therapy of residents must be under the direction of a licensed physical therapist. (II, III)

c. The licensed physical therapist shall:

(1) Evaluate the resident and prepare a physical therapy treatment plan conforming to the medical orders and goals; (III)

(2) Consult with other personnel in the facility who are providing resident care and plan with them for the integration of a physical therapy treatment program into the overall health care plan; (III)

(3) Instruct the nursing personnel responsible for administering selected restorative procedures between treatments; (III)

(4) Present programs in the facility's in-service education programs. (III)

d. Treatment records in the resident's medical chart shall include:

(1) The physician's prescription for treatment; (III)

(2) An initial evaluation note by the physical therapist; (III)

(3) The physical therapy care plan defining clearly the long-term and short-term goals and outlining the current treatment program; (III)

(4) Notes of the treatments given and changes in the resident's condition; (III)

(5) A complete discharge summary to include recommendations for nursing staff and family. (III)

e. There shall be adequate facilities, space, appropriate equipment, and storage areas as are essential to the treatment or examinations of residents. (III)

58.22(2) *Other rehabilitative services.*

a. The facility shall arrange for specialized and supportive rehabilitative services when such services are ordered by a physician. (III) These may include audiology and occupational therapy.

b. Audiology services shall be under the direction of a person licensed in the state of Iowa by the board of speech pathology and audiology. (II, III)

c. Occupational therapy services shall be under the direction of a qualified occupational therapist who is currently registered by the American Occupational Therapy Association. (II, III)

d. The appropriate professional shall:

(1) Develop the treatment plan and administer or direct treatment in accordance with the physician's prescription and rehabilitation goals; (III)

(2) Consult with other personnel within the facility who are providing resident care and plan with them for the integration of a treatment program into the overall health care plan. (III)

481—58.23(135C) Dental, diagnostic, and other services.

58.23(1) *Dental services.*

a. The nursing facility personnel shall assist residents to obtain regular and emergency dental services. (III)

b. Transportation arrangements shall be made when necessary for the resident to be transported to the dentist's office. (III)

c. Dental services shall be performed only on the request of the resident, responsible relative, or legal representative. The resident's physician shall be advised of the resident's dental problems. (III)

d. All dental reports or progress notes shall be included in the clinical record. (III)

e. Nursing personnel shall assist the resident in carrying out dentist's recommendations. (III)

f. Dentists shall be asked to participate in the in-service program of the facility. (III)

58.23(2) *Diagnostic services.*

a. The nursing facility shall make provisions for promptly securing required clinical laboratory, X-ray, and other diagnostic services. (III)

b. All diagnostic services shall be provided only on the written, signed order of a physician. (III)

c. Agreements shall be made with the local hospital laboratory or independent laboratory to perform specific diagnostic tests when they are required. (III)

d. Transportation arrangements for residents shall be made, when necessary, to and from the source of service. (III)

e. Copies of all diagnostic reports shall be requested by the facility and included in the resident's clinical record. (III)

f. The physician ordering the specific diagnostic service shall be promptly notified of the results. (III)

g. Simple tests such as customarily done by nursing personnel for diabetic residents may be performed in the facility. (III)

58.23(3) *Other services.*

a. The nursing facility shall assist residents to obtain such supportive services as requested by the physician. (III)

b. Transportation arrangements shall be made when necessary. (III)

c. Services could include the need for prosthetic devices, glasses, hearing aids, and other necessary items. (III)

481—58.24(135C) Dietary.

58.24(1) *Organization of dietetic services.* The facility shall meet the needs of the residents and provide the services listed in this standard. If the service is contracted out, the contractor shall meet the same standard. A written agreement shall be formulated between the facility and the contractor and shall convey to the department the right to inspect the food service facilities of the contractor. (III)

a. There shall be written policies and procedures for dietetic services that include staffing, nutrition, menu planning, therapeutic diets, preparation, service, ordering, receiving, storage, sanitation, and staff hygiene. The policies and procedures shall be made available for use by dietetic services. (III)

b. There shall be written job descriptions for each position in dietetic services. The job descriptions shall be made available for use by dietetic services. (III)

58.24(2) *Dietary staffing.*

a. The facility shall employ a qualified dietary supervisor who:

(1) Is a qualified dietitian as defined in 58.24(2)*"e"*; or

(2) Is a graduate of a dietetic technician training program approved by the American Dietetic Association; or

(3) Is a certified dietary manager certified by the certifying board for dietary managers of the Dietary Managers Association (DMA) and maintains that credential through 45 hours of DMA-approved continuing education; or

(4) Has completed a DMA-approved course curriculum necessary to take the certification examination required to become a certified dietary manager; or

(5) Has documented evidence of at least two years' satisfactory work experience in food service supervision and who is in an approved dietary manager association program and will successfully complete the program within 12 months of the date of enrollment; or

(6) Has completed or is in the final 90-hour training course approved by the department. (II, III)

b. The supervisor shall have overall supervisory responsibility for dietetic services and shall be employed for a sufficient number of hours to complete management responsibilities that include:

(1) Participating in regular conferences with consultant dietitian, administrator and other department heads; (III)

(2) Writing menus with consultation from the dietitian and seeing that current menus are posted and followed and that menu changes are recorded; (III)

(3) Establishing and maintaining standards for food preparation and service; (II, III)

(4) Participating in selection, orientation, and in-service training of dietary personnel; (II, III)

(5) Supervising activities of dietary personnel; (II, III)

(6) Maintaining up-to-date records of residents identified by name, location and diet order; (III)

(7) Visiting residents to learn individual needs and communicating with other members of the health care team regarding nutritional needs of residents when necessary; (II, III)

(8) Keeping records of repairs of equipment in dietetic services. (III)

c. The facility shall employ sufficient supportive personnel to carry out the following functions:

(1) Preparing and serving adequate amounts of food that are handled in a manner to be bacteriologically safe; (II, III)

(2) Washing and sanitizing dishes, pots, pans and equipment at temperatures required by procedures described elsewhere; (II, III)

(3) Serving of therapeutic diets as prescribed by the physician and following the planned menu. (II, III)

d. The facility may assign simultaneous duties in the kitchen and laundry, housekeeping, or nursing service to appropriately trained personnel. Proper sanitary and personal hygiene procedures shall be followed as outlined under the rules pertaining to staff hygiene. (II, III)

e. If the dietetic service supervisor is not a licensed dietitian, a consultant dietitian is required. The consultant dietitian shall be licensed by the state of Iowa pursuant to Iowa Code chapter 152A.

f. Consultants' visits shall be scheduled to be of sufficient duration and at a time convenient to:

(1) Record, in the resident's medical record, any observations, assessments and information pertinent to medical nutrition therapy; (I, II, III)

(2) Work with residents and staff on resident care plans; (III)

(3) Consult with the administrator and others on developing and implementing policies and procedures; (III)

(4) Write or approve general and therapeutic menus; (III)

(5) Work with the dietetic supervisor on developing procedures, recipes and other management tools; (III)

(6) Present planned in-service training and staff development for food service employees and others. Documentation of consultation shall be available for review in the facility by the department. (III)

g. In facilities licensed for more than 15 beds, dietetic services shall be available for a minimum of a 12-hour span extending from the time of preparation of breakfast through supper. (III)

58.24(3) *Nutrition and menu planning.*

a. Menus shall be planned and followed to meet the nutritional needs of each resident in accordance with the physician's orders and in consideration of the resident's choices and preferences. (II, III)

b. Menus shall be planned to provide 100 percent of the daily recommended dietary allowances as established by the Food and Nutrition Board of the National Research Council of the National Academy of Sciences. A current copy of the Simplified Diet Manual published by Blackwell Publishing, Ames, Iowa, shall be available and used in the planning and serving of all meals. (II)

c. At least three meals or their equivalent shall be served daily, at regular hours comparable to normal mealtimes in the community. (II)

(1) There shall be no more than a 14-hour span between a substantial evening meal and breakfast except as provided in subparagraph (3) below. (II, III)

(2) The facility shall offer snacks at bedtime daily. (II, III)

(3) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast of the following day. The current resident group must agree to this meal span and a nourishing snack must be served. (II)

d. Menus shall include a variety of foods prepared in various ways. The same menu shall not be repeated on the same day of the following week. (III)

e. Menus shall be written at least one week in advance. The current menu shall be located in an accessible place in the dietetic service department for easy use by persons purchasing, preparing and serving food. (III)

f. Records of menus as served shall be filed and maintained for 30 days and shall be available for review by department personnel. When substitutions are necessary, they shall be of similar nutritive value and recorded. (III)

g. A file of tested recipes adjusted to the number of people to be served in the facility shall be maintained. (III)

h. Alternate foods shall be offered to residents who refuse the food served. (II, III)

58.24(4) *Therapeutic diets.*

a. Therapeutic diets shall be prescribed by the attending physician. A current therapeutic diet manual shall be readily available to attending physicians, nurses and dietetic service personnel. This manual shall be used as a guide for writing menus for therapeutic diets. A licensed dietitian shall be responsible for writing and approving the therapeutic menu and reviewing procedures for preparation and service of food. (III)

b. Personnel responsible for planning, preparing and serving therapeutic diets shall receive instructions on those diets. (III)

58.24(5) *Food preparation and service.*

a. Methods used to prepare foods shall be those which conserve nutritive value and flavor and meet the taste preferences of the residents. (III)

b. Foods shall be attractively served. (III)

c. Foods shall be cut up, chopped, ground or blended to meet individual needs. (II, III)

d. Self-help devices shall be provided as needed. (II, III)

e. Table service shall be attractive. (III)

f. Plasticware, china and glassware that are unsightly, unsanitary or hazardous because of chips, cracks or loss of glaze shall be discarded. (III)

g. All food that is transported through public corridors shall be covered. (III)

h. All potentially hazardous food or beverages capable of supporting rapid and progressive growth of microorganisms that can cause food infections or food intoxication shall be maintained at temperatures of 41°F or below or at 140°F or above at all times, except during necessary periods of preparation. Frozen food shall be maintained frozen. (I, II, III)

i. Potentially hazardous food that is cooked, cooled and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165°F for 15 seconds. (I, II, III)

j. Food must be reheated to 165°F within no more than two hours after the heating process begins. (I, II, III)

k. Cooked potentially hazardous food shall be cooled:

(1) Within two hours, from 140°F to 70°F; and

(2) Within four hours, from 70°F to 41°F or less. (I, II, III)

58.24(6) *Dietary ordering, receiving, and storage.*

a. All food and beverages shall be of wholesome quality and procured from sources approved or considered satisfactory by federal, state and local authorities. Food or beverages from unlabeled, rusty, leaking, broken or damaged containers shall not be served. (I, II, III)

b. A minimum of at least a one-week supply of staple foods and a three-day supply of perishable foods shall be maintained on the premises to meet the planned menu needs until the next food delivery. Supplies shall be appropriate to meet the requirements of the menu. (III)

c. All milk shall be pasteurized. (III)

d. Milk may be served in individual, single-use containers. Milk may be served from refrigerated bulk milk dispensers or from the original container. Milk served from a refrigerated bulk milk dispenser shall be dispensed directly into the glass or other container from which the resident drinks. (II, III)

e. Records which show amount and kind of food purchased shall be retained for three months and shall be made available to the department upon request. (III)

f. Dry or staple items shall be stored at least six inches (15 cm) above the floor in a ventilated room, not subject to sewage or wastewater backflow, and protected from condensation, leakage, rodents or vermin in accordance with the Food Code, 1999 edition. (III)

g. Pesticides, other toxic substances and drugs shall not be stored in the food preparation or storage areas used for food or food preparation equipment and utensils. Soaps, detergents, cleaning compounds or similar substances shall not be stored in food storage rooms or areas. (II)

h. Food storage areas shall be clean at all times. (III)

i. There shall be a reliable thermometer in each refrigerator, freezer and in storerooms used for food. (III)

j. Foods held in refrigerated or other storage areas shall be appropriately covered. Food that was prepared and not served shall be stored appropriately, clearly identifiable and dated. (III)

58.24(7) *Sanitation in food preparation area.*

a. Unless otherwise indicated in this chapter or 481—Chapter 61, the sanitary provisions as indicated in Chapters 3, 4 and 7 of the 1999 Food Code, U.S. Public Health Service, Food and Drug Administration, Washington, DC 20204, shall apply.

b. Residents may be allowed in the food preparation area. (III)

c. The food preparation area may be used as a dining area for residents, staff or food service personnel. (III)

d. All food service areas shall be kept clean, free from litter and rubbish, and protected from rodents, animals, roaches, flies and other insects. (II, III)

e. All utensils, counters, shelves and equipment shall be kept clean, maintained in good repair, and shall be free from breaks, corrosion, cracks and chipped areas. (II, III)

f. There shall be effective written procedures established for cleaning all work and serving areas. (III)

g. A schedule of cleaning duties to be performed daily shall be posted. (III)

h. An exhaust system and hood shall be clean, operational and maintained in good repair. (III)

i. Spillage and breakage shall be cleaned up immediately and disposed of in a sanitary manner. (III)

j. Wastes from the food service that are not disposed of by mechanical means shall be kept in leakproof, nonabsorbent, tightly closed containers when not in immediate use and shall be disposed of frequently. (III)

k. The food service area shall be located so it will not be used as a passageway by residents, guests or non-food service staff. (III)

l. The walls, ceilings and floors of all rooms in which food is prepared and served shall be in good repair, smooth, washable, and shall be kept clean. Walls and floors in wet areas should be moisture-resistant. (III)

m. Ice shall be stored and handled in such a manner as to prevent contamination. Ice scoops should be sanitized daily and kept in a clean container. (III)

n. There shall be no animals or birds in the food preparation area. (III)

o. All utensils used for eating, drinking, and preparing and serving food and drink shall be cleaned and disinfected or discarded after each use. (III)

p. If utensils are washed and rinsed in an automatic dishmachine, one of the following methods shall be used:

(1) When a conventional dishmachine is utilized, the utensils shall be washed in a minimum of 140°F using soap or detergent and sanitized in a hot water rinse of not less than 170°F. (II, III)

(2) When a chemical dishmachine is utilized, the utensils shall be washed in a minimum of 120°F using soap or detergent and sanitized using a chemical sanitizer that is automatically dispensed by the machine and is in a concentration equivalent to 50 parts per million (ppm) available chloride. (II, III)

q. If utensils are washed and rinsed in a three-compartment sink, the utensils shall be thoroughly washed in hot water at a minimum temperature of 110°F using soap or detergent, rinsed in hot water to remove soap or detergent, and sanitized by one of the following methods:

(1) Immersion for at least 30 seconds in clean water at 180°F; (II, III)

(2) Immersion in water containing bactericidal chemical at a minimum concentration as recommended by the manufacturer. (II, III)

r. After sanitation, the utensils shall be allowed to drain and dry in racks or baskets on nonabsorbent surfaces. Drying cloths shall not be used. (III)

s. Procedures for washing and handling dishes shall be followed in order to protect the welfare of the residents and employees. Persons handling dirty dishes shall not handle clean dishes without first washing their hands. (III)

t. A mop and mop pail shall be provided for exclusive use in kitchen and food storage areas. (III)

58.24(8) *Hygiene of food service personnel.*

a. Personnel, if involved in dietetic services, shall be trained in basic food sanitation techniques, shall be clean and wear clean clothing, including a cap or a hairnet sufficient to contain, cover and restrain hair. Beards, mustaches and sideburns that are not closely cropped and neatly trimmed shall be covered. (III)

b. Personnel shall be excluded from duty when affected by skin infections or communicable diseases in accordance with the facility's infection control policies. (II, III)

c. Employee street clothing stored in the food service area shall be in a closed area. (III)

d. Food preparation sinks shall not be used for hand washing. Separate hand-washing facilities with soap, hot and cold running water, and single-use towels shall be used properly. (II, III)

e. The use of tobacco shall be prohibited in the food preparation area. (III)

58.24(9) *Paid nutritional assistants.* A paid nutritional assistant means an individual who meets the requirements of this subrule and who is an employee of the facility or an employee of a temporary employment agency employed by the facility. A facility may use an individual working in the facility as a paid nutritional assistant only if that individual has successfully completed a state-approved training program for paid nutritional assistants. (I, II, III)

a. *Training program requirements.*

(1) A state-approved training program for paid nutritional assistants must include, at a minimum, eight hours of training in the following areas:

1. Feeding techniques.
2. Assistance with feeding and hydration.
3. Communication and interpersonal skills.
4. Appropriate responses to resident behavior.

5. Safety and emergency procedures, including the Heimlich maneuver.
6. Infection control.
7. Resident rights.
8. Recognizing changes in residents that are inconsistent with their normal behavior and reporting these changes to the supervisory nurse.

(2) In addition to the training program requirements specified above, the training program must include at least four hours of classroom study, two hours of supervised laboratory work, and two hours of supervised clinical experience.

(3) A facility that offers a paid nutritional assistant training program must provide sufficient supplies in order to teach the objectives of the course.

(4) All paid nutritional assistant training program instructors shall be registered nurses. Other qualified health care professionals may assist the instructor in teaching the classroom portion and clinical or laboratory experiences. The ratio of students to instructor shall not exceed ten students per instructor in the clinical setting.

(5) Each individual enrolled in a paid nutritional assistant training program shall complete a 50-question multiple choice written test and must obtain a score of 80 percent or higher. In addition, the individual must successfully perform the feeding of a resident in a clinical setting. A registered nurse shall conduct the final competency determination.

(6) If an individual does not pass either the written test or competency demonstration, the individual may retest the failed portion a second time. If the individual does not pass either the written test or competency demonstration portion the second time, the individual shall not be allowed to retest.

b. *Program approval.* A facility or other entity may not offer or teach a paid nutritional assistant training program until the department has approved the program. Individuals trained in a program not approved by the department will not be allowed to function as paid nutritional assistants.

(1) A facility or other institution offering a paid nutritional assistant training program must provide the following information about the training program to the department before offering the program or teaching paid nutritional assistants:

1. Policies and procedures for program administration.
2. Qualifications of the instructors.
3. Maintenance of program records, including attendance records.
4. Criteria for determining competency.
5. Program costs and refund policies.
6. Lesson plans, including the objectives to be taught, skills demonstrations, assignments, quizzes, and classroom, laboratory and clinical hours.

(2) The facility or other institution offering a paid nutritional assistant training program must submit the materials specified above for department review. The department shall, within ten days of receipt of the material, advise the facility or institution whether the program is approved, or request additional information to assist the department in determining whether the curriculum meets the requirements for a paid nutritional assistant training program. Before approving any paid nutritional assistant training program, the department shall determine whether the curriculum meets the requirements specified in this subrule. The department shall maintain a list of facilities and institutions eligible to provide paid nutritional assistant training. (I, II, III)

(3) A facility shall maintain a record of all individuals who have successfully completed the required training program and are used by the facility as paid nutritional assistants. The individual shall complete the training program with a demonstration of knowledge and competency skills necessary to serve as a paid nutritional assistant. (I, II, III)

(4) Upon successful completion of the training program, the facility or other institution providing the training shall, within ten calendar days, provide the individual with a signed and dated certificate of completion. A facility that employs paid nutritional assistants shall maintain on file copies of the completed certificate and skills checklist for each individual who has successfully completed the training program. (I, II, III)

c. *Working restrictions.*

(1) A paid nutritional assistant must work under the supervision of a registered nurse or a licensed practical nurse. In an emergency, a paid nutritional assistant must call a supervisory nurse for help on the resident call system. (I, II, III)

(2) A facility must ensure that a paid nutritional assistant feeds only residents who have no complicated feeding problems. Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube, parenteral or intravenous feedings. The facility must base resident selection on the charge nurse's assessment and the resident's latest assessment and plan of care. (I, II, III)

481—58.25(135C) Social services program.

58.25(1) The administrator or designee shall be responsible for developing a written, organized orientation program for all residents. (III)

58.25(2) The program shall be planned and implemented to resolve or reduce personal, family, business, and emotional problems that may interfere with the medical or health care, recovery, and rehabilitation of the individual. (III)

58.25(3) The social services plan, including specific goals and regular evaluation of progress, shall be incorporated into the overall plan of care. (III)

481—58.26(135C) Resident activities program.

58.26(1) *Organized activities.* Each nursing facility shall provide an organized resident activity program for the group and for the individual resident which shall include suitable activities for evenings and weekends. (III)

a. The activity program shall be designed to meet the needs and interests of each resident and to assist residents in continuing normal activities within limitations set by the resident's physician. This shall include helping residents continue in their individual interests or hobbies. (III)

b. The program shall include individual goals for each resident. (III)

c. The program shall include both group and individual activities. (III)

d. No resident shall be forced to participate in the activity program. (III)

e. The activity program shall include suitable activities for those residents unable to leave their rooms. (III)

f. The program shall be incorporated into the overall health plan and shall be designed to meet the goals as written in the plan.

58.26(2) *Coordination of activities program.*

a. Each nursing facility shall employ a person to direct the activities program. (III)

[1]*b.* [2]Staffing for the activity program shall be provided on the minimum basis of 35 minutes per licensed bed per week. (II, III)

c. The activity coordinator shall have completed the activity coordinators' orientation course offered through the department within six months of employment or have comparable training and experience as approved by the department. (III)

d. The activity coordinator shall attend workshops or educational programs which relate to activity programming. These shall total a minimum of ten contact hours per year. These programs shall be approved by the department. (III)

e. There shall be a written plan for personnel coverage when the activity coordinator is absent during scheduled working hours. (III)

58.26(3) *Duties of activity coordinator.* The activity coordinator shall:

a. Have access to all residents' records excluding financial records; (III)

b. Coordinate all activities, including volunteer or auxiliary activities and religious services; (III)

c. Keep all necessary records including:

(1) Attendance; (III)

(2) Individual resident progress notes recorded at regular intervals (at least quarterly). A copy of these notes shall be placed in the resident's clinical record; (III)

(3) Monthly calendars, prepared in advance. (III)

d. Coordinate the activity program with all other services in the facility; (III)

e. Participate in the in-service training program in the facility. This shall include attending as well as presenting sessions. (III)

58.26(4) *Supplies, equipment, and storage.*

a. Each facility shall provide a variety of supplies and equipment of a nature calculated to fit the needs and interests of the residents. (III) These may include: books (standard and large print), magazines, newspapers, radio, television, and bulletin boards. Also appropriate would be box games, game equipment, songbooks, cards, craft supplies, record player, movie projector, piano, outdoor equipment, etc.

b. Storage shall be provided for recreational equipment and supplies. (III)

c. Locked storage should be available for potentially dangerous items such as scissors, knives, and toxic materials. (III)

[1] Emergency, pursuant to Iowa Code section 17A.5(2)*"b"*(2).

[2] Objection filed 2/14/79; see Objection following 481—Ch 57.

481—58.27(135C) Certified volunteer long-term care ombudsman program. A certified volunteer long-term care ombudsman appointed in accordance with Iowa Code section 231.45 as amended by 2013 Iowa Acts, Senate File 184, shall operate within the scope of the rules for volunteer ombudsmen promulgated by the office of long-term care ombudsman and Iowa department on aging.
[**ARC 1205C**, IAB 12/11/13, effective 1/15/14]

481—58.28(135C) Safety. The licensee of a nursing facility shall be responsible for the provision and maintenance of a safe environment for residents and personnel. (III)

58.28(1) *Fire safety.*

a. All nursing facilities shall meet the fire safety rules and regulations as promulgated by the state fire marshal. (I, II)

b. The size of the facility and needs of the residents shall be taken into consideration in evaluating safety precautions and practices.

58.28(2) *Safety duties of administrator.* The administrator shall have a written emergency plan to be followed in the event of fire, tornado, explosion, or other emergency. (III)

a. The plan shall be posted. (III)

b. In-service shall be provided to ensure that all employees are knowledgeable of the emergency plan. (III)

58.28(3) *Resident safety.*

a. Residents shall be permitted to smoke only where proper facilities are provided. Smoking shall not be permitted in bedrooms. Smoking by residents considered to be careless shall be prohibited except when the resident is under direct supervision. (II, III)

b. Smoking is prohibited in all rooms where oxygen is being administered or in rooms where oxygen is stored. (II, III)

c. Whenever full or empty tanks of oxygen are being used or stored, they shall be securely supported in an upright position. (II, III)

d. Smoking shall be permitted only in posted areas. (II, III)

e. Each resident shall receive adequate supervision to protect against hazards from self, others, or elements in the environment. (I, II, III)

f. Residents shall be protected against physical or environmental hazards to themselves. (I, II, III)
[**ARC 1398C**, IAB 4/2/14, effective 5/7/14]

481—58.29(135C) Resident care.

58.29(1) There shall be a readily available supply of self-help and ambulation devices such as wheelchairs, walkers, and such other devices maintained in good repair that will meet the current needs of all residents. (III)

58.29(2) The facility shall ensure that each ambulatory resident has well-fitting shoes to provide support and prevent slipping. (III)

58.29(3) Equipment for personal care shall be maintained in a safe and sanitary condition. (II, III)

58.29(4) The expiration date for sterile equipment shall be exhibited on its wrappings. (III)

58.29(5) Residents who have been known to wander shall be provided with appropriate means of identification. (II, III)

58.29(6) Electric heating pads, blankets, or sheets shall be used only on the written order of a physician, when allowed by the Life Safety Code or applicable state or local fire regulations. (II, III)

481—58.30 Rescinded, effective 7/14/82.

481—58.31(135C) Housekeeping.

58.31(1) Written procedures shall be established and implemented for daily and weekly cleaning schedules. (III)

58.31(2) Each resident unit shall be cleaned on a routine schedule. (III)

58.31(3) All rooms, corridors, storage areas, linen closets, attics, and basements shall be kept in a clean, orderly condition, free of unserviceable furniture and equipment and accumulations of refuse. (III)

58.31(4) A hallway or corridor shall not be used for storage of equipment. (III)

58.31(5) All odors shall be kept under control by cleanliness and proper ventilation. (III)

58.31(6) Clothing worn by personnel shall be clean and washable. (III)

58.31(7) Housekeeping and maintenance personnel shall be provided with well-constructed and properly maintained equipment appropriate to the function for which it is to be used. (III)

58.31(8) All furniture, bedding, linens, and equipment shall be cleaned periodically and before use by another resident. (III)

58.31(9) Polishes used on floors shall provide a nonslip finish. (III)

58.31(10) *Throw or scatter rugs shall not be permitted. (III)

*Objection. For text of Objection, see IAC Supp., Part I, 9/7/77. For text of Filed rules, 470—Chapter 58, see IAC Supp. 10/5/77.

58.31(11) Entrances, exits, steps, and outside walkways shall be kept free from ice, snow, and other hazards. (II, III)

58.31(12) Residents shall not have access to storage areas for all cleaning agents, bleaches, insecticides, or any other poisonous, dangerous, or flammable materials. (II, III)

58.31(13) Sufficient numbers of noncombustible trash containers, which have covers, shall be available. (III)

58.31(14) Definite procedures shall be established for training housekeeping personnel. (III)

58.31(15) Rescinded IAB 12/6/06, effective 1/10/07.

58.31(16) There shall be provisions for the cleaning and storage of housekeeping equipment and supplies for each nursing unit. (III)

58.31(17) Bathtubs, shower stalls, or lavatories shall not be used for laundering, cleaning of utensils and mops, or for storage. (III)

58.31(18) Bedside utensils shall be stored in enclosed cabinets. (III)

58.31(19) Kitchen sinks shall not be used for the cleaning of mops, soaking of laundry, cleaning of bedside utensils, nursing utensils, or dumping of wastewater. (III)

58.31(20) Personal possessions of residents which may constitute hazards to themselves or others shall be removed and stored. (III)

481—58.32(135C) Maintenance.

58.32(1) Each facility shall establish a maintenance program in writing to ensure the continued maintenance of the facility, to promote good housekeeping procedures, and to ensure sanitary practices throughout the facility. (III)

58.32(2) The building, grounds, and other buildings shall be maintained in a clean, orderly condition and in good repair. (III)

58.32(3) Draperies and furniture shall be clean and in good repair. (III)

58.32(4) Cracks in plaster, peeling wallpaper or paint, and tears or splits in floor coverings shall be promptly repaired or replaced in a professional manner. (III)

58.32(5) The electrical systems, including appliances, cords, and switches, shall be maintained to guarantee safe functioning and comply with the national electrical code. (III)

58.32(6) All plumbing fixtures shall function properly and comply with the state plumbing code. (III)

58.32(7) Yearly inspections of the heating and cooling systems shall be made to guarantee safe operation. Documentation of these inspections shall be available for review. (III)

58.32(8) The building, grounds, and other buildings shall be kept free of breeding areas for flies, other insects, and rodents. (III)

58.32(9) The facility shall be kept free of flies, other insects, and rodents. (III)

58.32(10) Maintenance personnel.

a. A written program shall be established for the orientation of maintenance personnel. (III)

b. Maintenance personnel shall:

(1) Follow established written maintenance programs; (III)

(2) Be provided with appropriate, well-constructed, and properly maintained equipment. (III)

481—58.33(135C) Laundry.

58.33(1) All soiled linens shall be collected in and transported to the laundry room in closed, leakproof laundry bags or covered, impermeable containers. (III)

58.33(2) Except for related activities, the laundry room shall not be used for other purposes. (III)

58.33(3) Procedures shall be written for the proper handling of wet, soiled, and contaminated linens. (III)

58.33(4) Residents' personal laundry shall be marked with an identification. (III)

58.33(5) Bed linens, towels, and washcloths shall be clean and stain-free. (III)

481—58.34(135C) Garbage and waste disposal.

58.34(1) All garbage shall be gathered, stored, and disposed of in a manner that will not permit transmission of disease, create a nuisance, or provide a breeding or feeding place for vermin or insects. (III)

58.34(2) All containers for refuse shall be watertight, rodent-proof, and have tight-fitting covers. (III)

58.34(3) All containers shall be thoroughly cleaned each time the containers are emptied. (III)

58.34(4) All wastes shall be properly disposed of in compliance with local ordinances and state codes. (III)

58.34(5) Special provision shall be made for the disposal of soiled dressings and similar items in a safe, sanitary manner. (III)

481—58.35(135C) Buildings, furnishings, and equipment.

58.35(1) *Buildings—general requirements.*

a. For purposes of computation of usable floor space in bedrooms and other living areas of the facility, that part of the room having no less than seven feet of ceiling height shall be used. Usable floor space may include irregularities in the rooms such as alcoves and offsets with approval of the department. Usable floor space shall not include space needed for corridor door swings or wardrobes being used as a substitute for closet space. (III)

b. Battery-operated, portable emergency lights in good working condition shall be available at all times, at a ratio of one light per one employee on duty from 6 p.m. to 6 a.m. (III)

c. All windows shall be supplied with curtains and shades or drapes which are kept clean and in good repair. (III)

d. Light fixtures shall be so equipped to prevent glare and to prevent hazards to the residents. (III)

e. Exposed heating pipes, hot water pipes, or radiators in rooms and areas used by residents and within reach of residents shall be covered or protected to prevent injury or burns to residents. (II, III)

f. All fans located within seven feet of the floor shall be protected by screen guards of not more than one-half-inch mesh. (III)

g. Whenever glass sliding doors or transparent panels are used, they shall be marked conspicuously. (III)

h. The facility shall meet the equivalent requirements of the appropriate group occupancy of the state building code. (III)

i. No part of any room shall be enclosed, subdivided, or partitioned unless such part is separately lighted and ventilated and meets such other requirements as its usage and occupancy dictates, except closets used for the storage of residents' clothing. (III)

58.35(2) *Furnishings and equipment.*

a. All furnishings and equipment shall be durable, cleanable, and appropriate to its function and in accordance with the department's approved program of care. (III)

b. All resident areas shall be decorated, painted, and furnished to provide a home-like atmosphere. (III)

c. Upholstery materials shall be moisture- and soil-resistant, except on furniture provided by the resident and the property of the resident. (III)

58.35(3) *Dining and living rooms.*

a. Every facility shall have a dining room and a living room easily accessible to all residents. (III)

b. Dining rooms and living rooms shall at no time be used as bedrooms. (III)

c. Dining rooms and living rooms shall be available for use by residents at appropriate times to provide periods of social and diversional individual and group activities. (III)

d. A combination dining room and living room may be permitted if the space requirements of a multipurpose room as provided in 58.35(3)*"e"* are met. (III)

e. Multipurpose rooms. When space is provided for multipurpose dining and activities and recreational purposes, the area shall total at least 30 square feet per licensed bed for the first 100 beds and 27 square feet per licensed bed for all beds in excess of 100. An open area of sufficient size shall be provided to permit group activities such as religious meetings or presentation of demonstrations or entertainment. (III)

f. Living rooms.

(1) Living rooms shall be maintained for the use of residents and their visitors and may be used for recreational activities. (III)

(2) Living rooms shall be suitably provided with parlor furniture, television and radio receivers in good working order, recreational material such as games, puzzles, and cards, and reading material such as current newspapers and magazines. Furnishings and equipment of the room should be such as to allow group activities. (III)

(3) Card tables or game tables shall be made available. The tables should be of a height to allow a person seated in a wheelchair to partake in the games or card playing. (III)

(4) Chairs of proper height and appropriate to their use shall be provided for seating residents at game tables and card tables. (III)

g. Dining rooms.

(1) Dining rooms shall be furnished with dining tables and chairs appropriate to the size and function of the facility. These rooms and furnishings shall be kept clean and sanitary. (III)

(2) Dining tables and chairs shall be provided. (III)

(3) Dining tables should be so constructed that a person seated in a wheelchair can dine comfortably. (III)

(4) Tables shall be of sturdy construction with smooth, durable, nonpermeable tops that can be cleaned with a detergent sanitizing solution. (III)

(5) Dining chairs shall be sturdy and comfortable. Some arm chairs should be provided for ease of movement for some residents. (III)

(6) Residents shall be encouraged to eat in the dining room. (III)

58.35(4) *Bedrooms.*

a. Each resident shall be provided with a standard, single, or twin bed that is substantially constructed and in good repair. Rollaway beds, metal cots, or folding beds are not acceptable. Seventy-five percent of the beds shall have a spring with an adjustable head and foot section. A resident shall have the right to sleep in a chair per the resident's request and to have the bed removed from the room to allow for additional space. (III)

b. Each bed shall be equipped with the following: casters or glides unless a low bed and mattress are being used for fall precautions; a clean, comfortable, well-constructed mattress approximately five inches thick and standard in size for the bed; clean, comfortable pillows of average size; and moisture-proof covers and sheets as necessary to keep the mattress and pillows dry and clean. (III)

c. Each resident shall have a bedside table with a drawer to accommodate personal possessions. (III)

d. There shall be a comfortable chair, either a rocking chair or armchair, per resident bed. The resident's personal wishes shall be considered. (III)

e. There shall be drawer space for each resident's clothing. In a multiple bedroom, drawer space shall be assigned each resident. (III)

f. Walls, ceilings, and floors shall have easily cleanable surfaces and shall be kept clean and in good repair. (III)

g. Beds and other furnishings shall not obstruct free passage to and through doorways. (III)

h. Clothing shall be hung in closets or wardrobes available in each room. (III)

i. Beds shall not be placed with the head of the bed in front of a window or radiator. (III)

j. Beds shall not be placed in such a manner that the side of the bed is against the radiator or in close proximity to it unless it is covered so as to protect the resident from contact with it or from excessive heat. (III)

k. Reading lamps shall be provided each resident in the resident's room. (III)

l. Each room shall have sufficient accessible mirrors to serve the resident's needs. Mirrors are not required if the room is located in a CCDI unit and the mirrors cause concern for the resident. (III)

m. Sturdy, adjustable overbed tables shall be provided for each resident who is unable to eat in the dining room. (III)

n. Each resident bedroom shall have a door. The door shall be the swing type and shall not swing into the corridor. (III)

58.35(5) *Heating.* A centralized heating system capable of maintaining a minimum temperature of 78°F (26°C) shall be provided. Portable units or space heaters are prohibited from being used in the facility except in an emergency. (III)

58.35(6) *Water supply.*

a. Every facility shall have an adequate water supply from an approved source. A municipal source of supply shall be considered as meeting this requirement. (III)

b. Private sources of supply shall be tested annually and the report submitted with the annual application for license. (III)

c. A bacterially unsafe source of supply shall be grounds for denial, suspension, or revocation of license. (III)

d. The department may require testing of private sources of supply at its discretion in addition to the annual test. The facility shall supply reports of such tests as directed by the department. (III)

e. Hot and cold running water under pressure shall be available in the facility. (III)

f. Prior to construction of a new facility or new water source, private sources of supply shall be surveyed and shall comply with the requirements of the department of health. (III)

58.35(7) *Nonambulatory residents.*

a. All nonambulatory residents shall be housed on the grade level floor. (II, III)

b. These provisions in *"a"* above relating to nonambulatory residents are not applicable if the facility has a suitably sized elevator.

481—58.36(135C) Family and employee accommodations.

58.36(1) Children under 14 years of age shall not be allowed into the service areas. (III)

58.36(2) The residents' bedrooms shall not be occupied by employees or family members of the licensee. (III)

58.36(3) In facilities where the total occupancy of family, employees, and residents is five or less, one toilet and one tub or shower shall be the minimum requirement. (III)

58.36(4) In facilities where the total occupancy of family, employees, and residents is more than five, separate bathing and toilet facilities shall be required for the family or employees distinct from such areas provided for residents. (III)

58.36(5) In all health care facilities, if the family or employees live within the facility, separate living quarters and recreation facilities shall be required for the family or employees distinct from such areas provided for residents. (III)

481—58.37(135C) Animals. Animals may be permitted within the facility with prior approval of the department and under controlled conditions. (III)

481—58.38(135C) Supplies.

58.38(1) *Linen supplies.*

a. There shall be an adequate supply of linen so that each resident shall have at least three washcloths, hand towels, and bath towels per week. (III)

b. A complete change of bed linens shall be available in the linen storage area for each bed. (III)

c. Sufficient lightweight, clean, serviceable blankets shall be available. All blankets shall be laundered as often as necessary for cleanliness and freedom from odors. (III)

d. Each bed shall be provided with clean, washable bedspreads. There shall be a supply available when changes are necessary. (III)

e. Uncrowded and convenient storage shall be provided for linens, pillows, and bedding. (III)

58.38(2) *First-aid kit.* A first-aid emergency kit shall be available on each floor in every facility. (II, III)

58.38(3) *Supplies and equipment for nursing services.*

a. All nursing care equipment shall be properly sanitized or sterilized before use by another resident. (II)

b. There shall be disposable or one-time use items available with provisions for proper disposal to prevent reuse except as allowed by 58.10(8)*"h,"*481—paragraph 59.12(10)*"h,"* or 481—paragraph 64.12(14)*"h."* (I, II, III)

c. Convenient, safe storage shall be provided for bath and toilet supplies, bathroom scales, mechanical lifts, and shower chairs. (III)

d. Sanitary and protective storage shall be provided for all equipment and supplies. (III)

e. All items that must be sterilized shall be autoclaved unless sterile disposable items are furnished which are promptly disposed of after a single use. (III)

f. Supplies and equipment for nursing and personal care sufficient in quantities to meet the needs of the residents shall be provided and, as a minimum, include the following: (III)

Bath basins	Rectal tubes
Soap containers	Catheters and catheterization equipment
Denture cups	Douche nozzle
Emesis basins	Oxygen therapy equipment
Mouthwash cups	Naso-gastric feeding equipment
Bedpans	Wheelchairs
Urinals	Moisture-proof draw sheets
Enema equipment	Moisture-proof pillow covers
Commodes	Moisture-proof mattress covers

Quart graduate measure
Thermometer for measurement of bath water temperature
Oral thermometer
Rectal thermometer
Basins for sterilizing thermometers
Basins for irrigations
Asepto syringes
Sphygmomanometer
Paper towels
Paper handkerchiefs
Insulin syringes
2 cc hypodermic syringes
Weight scales
Hypodermic needles
Stethoscope
Ice caps
Hot water bottles
Foot tubs
Metal pitcher
Disinfectant solutions
Alcohol
Lubricating jelly
Skin lotion
Applicators
Tongue blades
Toilet paper
Rubber gloves or disposable gloves
Scales for nonambulatory patients
Tourniquet
Suction machine
Medicine dispensing containers
Bandages
Adhesive
Portable linen hampers
Denture identification equipment
Tracheotomy care equipment

481—58.39(135C) Residents' rights in general.

58.39(1) Each facility shall ensure that policies and procedures are written and implemented which include, at a minimum, all of the following provisions (subrules 58.39(2) to 58.39(6)) and which govern all areas of service provided by the facility. These policies and procedures shall be available to staff, residents, their families or legal representatives and the public and shall be reviewed annually. (II)

58.39(2) Policies and procedures shall address the admission and retention of persons with histories of dangerous or disturbing behavior. For the purposes of the subrule, persons with histories of dangerous or disturbing behavior are those persons who have been found to be seriously mentally impaired pursuant to Iowa Code section 229.13 or 812.1 within six months of the request for admission to the facility. In addition to establishing the criteria for admission and retention of persons so defined, the policies and procedures shall provide for:

a. Reasonable precautions to prevent the resident from harming self, other residents, or employees of the facility.

b. Treatment of persons with mental illness as defined in Iowa Code section 229.1(1) and which is provided in accordance with the individualized health care plan.

c. Ongoing and documented staff training on individualized health care planning for persons with mental illness.

58.39(3) Policies and procedures regarding the admission, transfer, and discharge of residents shall ensure that:

a. Only those persons are accepted whose needs can be met by the facility directly or in cooperation with community resources or other providers of care with which it is affiliated or has contracts. (II)

b. As changes occur in residents' physical or mental condition, necessitating services or care which cannot be adequately provided by the facility, they are transferred promptly to other appropriate facilities. (II)

58.39(4) Policies and procedures regarding the use of chemical and physical restraints shall define the use of said restraints and identify the individual who may authorize the application of physical restraints in emergencies, and describe the mechanism for monitoring and controlling their use. (II)

58.39(5) Policies and procedures shall include a method for submitting complaints and recommendations by residents or their responsible party and for ensuring a response and disposition by the facility. (II)

58.39(6) Policies and procedures shall include provisions governing access to, duplication of, and dissemination of information from the residents' records. (II)

58.39(7) Policies and procedures shall include a provision that each resident shall be fully informed of the resident's rights and responsibilities as a resident and of all rules governing resident conduct and responsibilities. This information must be provided upon admission, or in the case of residents already in the facility, upon the facility's adoption or amendment of residents' rights policies. (II)

a. The facility shall make known to residents what they may expect from the facility and its staff, and what is expected from them. The facility shall communicate these expectations during the period of not more than two weeks before or five days after admission. The communication shall be in writing, e.g., in a separate handout or brochure describing the facility, and interpreted verbally, e.g., as part of a preadmission interview, resident counseling, or in individual or group orientation sessions following admission. (II)

b. Residents' rights and responsibilities shall be presented in language understandable to the resident. If the facility serves residents who are non-English speaking or deaf, steps shall be taken to translate the information into a foreign or sign language. In the case of blind residents, either Braille or a recording shall be provided. Residents shall be encouraged to ask questions about their rights and responsibilities and these questions shall be answered. (II)

c. A statement shall be signed by the resident, or the resident's responsible party, indicating an understanding of these rights and responsibilities, and shall be maintained in the record. The statement shall be signed no later than five days after admission, and a copy of the signed statement shall be given to the resident or responsible party, if applicable. In the case of an intellectually disabled resident, the signature shall be witnessed by a person not associated with or employed by the facility. The witness may be a parent, guardian, Medicaid agency representative, etc. (II)

d. In order to ensure that residents continue to be aware of these rights and responsibilities during their stay, a written copy shall be prominently posted in a location that is available to all residents. (II)

e. All residents shall be advised within 30 days following changes made in the statement of residents' rights and responsibilities. Appropriate means shall be utilized to inform non-English speaking, deaf, or blind residents of such changes. (II)

58.39(8) Each resident or responsible party shall be fully informed in a contract as required in rule 481—58.13(135C), prior to or at the time of admission and during the resident's stay, of services available in the facility, and of related charges including any charges for services not covered under the Title XIX program or not covered by the facility's basic per diem rate. (II)

58.39(9) Each resident or responsible party shall be fully informed by a physician of the resident's health and medical condition unless medically contraindicated (as documented by a physician in the resident's record). Each resident shall be afforded the opportunity to participate in the planning of the resident's total care and medical treatment, which may include, but is not limited to, nursing care, nutritional care, rehabilitation, restorative therapies, activities, and social work services. Each resident only participates in experimental research conducted under the U.S. Department of Health and Human Services' protection from research risks policy and then only upon the resident's informed written consent. Each resident has the right to refuse treatment except as provided by Iowa Code chapter 229. In the case of a confused or intellectually disabled individual, the responsible party shall be informed by the physician of the resident's medical condition and be afforded the opportunity to participate in the planning of the resident's total care and medical treatment, to be informed of the medical condition, and to refuse to participate in experimental research. (II)

a. The requirement that residents shall be informed of their conditions, involved in the planning of their care, and advised of any significant changes in either shall be communicated to every physician responsible for the medical care of residents in the facility. (II)

b. The administrator or designee shall be responsible for working with attending physicians in the implementation of this requirement. (II)

c. If the physician determines or in the case of a confused or intellectually disabled resident the responsible party determines that informing the resident of the resident's condition is contraindicated, this decision and reasons for it shall be documented in the resident's record by the physician. (II)

d. The resident's plan of care shall be based on the physician's orders. It shall be developed upon admission by appropriate facility staff and shall include participation by the resident if capable. Residents shall be advised of alternative courses of care and treatment and their consequences when such alternatives are available. The resident's preference about alternatives shall be elicited and honored if feasible.

e. Any clinical investigation involving residents must be under the sponsorship of an institution with a human subjects review board functioning in accordance with the requirements of Public Law 93-348, as implemented by Part 46 of Title 45 of the Code of Federal Regulations, as amended to December 1, 1981 (45 CFR 46). A resident being considered for participation in experimental research must be fully informed of the nature of the experiment, e.g., medication, treatment, and understand the possible consequences of participating or not participating. The resident's (or responsible party's) written informed consent must be received prior to participation. (II)

This rule is intended to implement Iowa Code section 135C.23(2).

[**ARC 0766C**, IAB 5/29/13, effective 7/3/13]

481—58.40(135C) Involuntary discharge or transfer.

58.40(1) A facility shall not involuntarily discharge or transfer a resident from a facility except: for medical reasons; for the resident's welfare or that of other residents; for nonpayment for the resident's stay (as contained in the contract for the resident's stay), except as prohibited by Title XIX of the Social Security Act, 42 U.S.C. 1396 to 1396k by reason of action pursuant to Iowa Code chapter 229; by reason of negative action by the Iowa department of social services; and by reason of negative action by the professional standards review organization. A resident shall not be transferred or discharged solely because the cost of the resident's care is being paid under Iowa Code chapter 249A, or because the resident's source of payment is changing from private support to payment under chapter 249A. (I, II)

a. "Medical reasons" for transfer or discharge are based on the resident's needs and are determined and documented in the resident's record by the attending physician. Transfer or discharge may be required to provide a different level of care. In the case of transfer or discharge for the reason that the resident's condition has improved such that the resident no longer needs the level of care being provided by the facility, the determination that such medical reason exists is the exclusive province of the professional standards review organization or utilization review process in effect for residents whose care is paid in full or in part by Title XIX. (II)

b. "Welfare" of a resident or that of other residents refers to their social, emotional, or physical well-being. A resident might be transferred or discharged because the resident's behavior poses a continuing threat to the resident (e.g., suicidal) or to the well-being of other residents or staff (e.g., the resident's behavior is incompatible with the resident's needs and rights). Evidence that the resident's continued presence in the facility would adversely affect the resident's own welfare or that of other residents shall be made by the administrator or designee and shall be in writing and shall include specific information to support this determination.

c. Involuntary transfer or discharge of a resident from a facility shall be preceded by a written notice to the resident or responsible party at least 30 days in advance of the proposed transfer or discharge. The 30-day requirement shall not apply in any of the following instances:

(1) If an emergency transfer or discharge is mandated by the resident's health care needs and is in accord with the written orders and medical justification of the attending physician. Emergency transfers or discharges may also be mandated to protect the health, safety, or well-being of other residents and staff from the resident being transferred. (II)

(2) If the transfer or discharge is subsequently agreed to by the resident or the resident's responsible party, and notification is given to the responsible party, physician, and the person or agency responsible for the resident's placement, maintenance, and care in the facility.

(3) If the discharge or transfer is the result of a final, nonappealable decision by the department of social services or the professional standards review organization.

d. The notice required by paragraph *"c"* shall contain all of the following information:

(1) The stated reason for the proposed transfer or discharge. (II)

(2) The effective date of the proposed transfer or discharge. (II)

(3) A statement in not less than 12-point type (elite), which reads: "You have a right to appeal the facility's decision to transfer or discharge you. If you think you should not have to leave this facility, you may request a hearing in writing or verbally with the Iowa state department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department and you will not be transferred prior to a final decision. Provision may be made for extension of the 14-day requirement upon request to the department of inspections and appeals designee in emergency circumstances. If you lose the hearing, you will not be transferred before the expiration of 30 days following receipt of the original notice of the discharge or transfer, or no sooner than 5 days following final decision of such hearing. To request a hearing or receive further information, call the department at (515)281-4115 or you may write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083." (II)

e. A request for a hearing made under 58.40(1)*"d"*(3) shall stay a transfer or discharge pending a hearing or appeal decision. (II)

f. The type of hearing shall be determined by a representative of the department. Notice of the date, time, and place of the hearing shall be sent by certified mail or delivered in person to the licensee, resident, responsible party, and Iowa department on aging long-term care ombudsman of record not later than five full business days after receipt of request. This notice shall also inform the licensee, resident or responsible party that they have a right to appear at the hearing in person or be represented by their attorneys or other individual. The hearing shall be dismissed if neither party is present or represented at the hearing. If only one party appears or is represented, the hearing shall proceed with one party present. The Iowa department on aging long-term care ombudsman shall have the right to appear at the hearing.

g. The hearing shall be heard by a department of inspections and appeals designee pursuant to Iowa Code chapter 17A. (The hearing shall be public unless the resident or representative requests in writing that it be closed.) The licensee or designee shall have the opportunity to present to the representative of the department any oral testimony or written materials to show by a preponderance of the evidence just cause why a transfer or discharge may be made. The resident and responsible party shall also have an opportunity to present to the representative of the department any oral testimony or written material to show just cause why a transfer or discharge should not be made. In a determination as to whether a transfer or discharge is authorized, the burden of proof rests on the party requesting the transfer or discharge.

h. Based upon all testimony and materials submitted to the representative of the department, the representative shall issue, in accordance with Iowa Code chapter 17A, written findings of fact and conclusions of law and issue a decision and order in respect to the adverse action. This decision shall be mailed by certified mail to the licensee, resident, responsible party, and department on aging long-term care ombudsman within 10 working days after the hearing has been concluded. The representative shall have the power to issue fines and citations against the facility in appropriate circumstances.

A request for review of a proposed decision in which the department is the final decision maker shall be made within 15 days of issuance of the proposed decision, unless otherwise provided by statute. Requests shall be mailed or delivered by either party to the Director, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. Failure to request review will preclude judicial review unless the department reviews a proposed decision upon its own motion within 15 days of the issuance of the decision.

i. A copy of the notice required by paragraph *"c"* shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department, the resident's

responsible party, physician, the person or agency responsible for the resident's placement, maintenance, and care in the facility, and the department on aging long-term care ombudsman.

j. If the basis for an involuntary transfer or discharge is the result of a negative action by the Iowa department of human services or the professional standards review organization (Iowa Foundation for Medical Care), appeals shall be filed with those agencies as appropriate. Continued payment shall be consistent with rules of those agencies.

k. If nonpayment is the basis for involuntary transfer or discharge, the resident shall have the right to make full payment up to the date that the discharge or transfer is to be made and then shall have the right to remain in the facility. (II)

l. The involuntary transfer or discharge shall be discussed with the resident, the resident's responsible party, and the person or agency responsible for the resident's placement, maintenance, and care in the facility within 48 hours after notice of discharge has been received. The explanation and discussion of the reasons for involuntary transfer or discharge shall be given by the facility administrator or other appropriate facility representative as the administrator's designee. The content of the discussion and explanation shall be summarized in writing and shall include the names of the individuals involved in the discussions and made part of the resident's record. (II)

m. The resident shall receive counseling services before (by the sending facility) and after (by the receiving facility) the involuntary transfer to minimize the possible adverse effects of the involuntary transfer. Counseling shall be documented in the resident's record. (II)

(1) Counseling shall be provided by a qualified individual who meets one of the following criteria:

1. Has a bachelor's or master's degree in social work from an accredited college. (II)

2. Is a graduate of an accredited four-year college and has had at least one year of full-time paid employment in a social work capacity with a public or private agency. (II)

3. Has been employed in a social work capacity for a minimum of four years in a public or private agency. (II)

4. Is a licensed psychologist or psychiatrist. (II)

5. Is any other person of the resident's choice. (II)

(2) The facility shall develop a plan to provide for the orderly and safe transfer or discharge of each resident to be transferred or discharged. (II)

(3) The receiving health care facility of a resident involuntarily discharged or transferred shall immediately formulate and implement a plan of care which takes into account possible adverse effects the transfer may cause. (II)

n. In the case of an emergency transfer or discharge as outlined in 58.40(1)*"c"*(1), the resident must still be given a written notice prior to or within 48 hours following transfer or discharge. A copy of this notice must be placed in the resident's file and it must contain all the information required by 58.40(1)*"d"*(1) and (2). In addition, the notice must contain a statement in not less than 12-point type (elite), which reads: "You have a right to appeal the facility's decision to transfer or discharge you on an emergency basis. If you think you should not have to leave this facility, you may request a hearing in writing or verbally with the Iowa state department of inspections and appeals within 7 days after receiving this notice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department. You may be transferred or discharged before the hearing is held or before a final decision is rendered. If you win the hearing, you have the right to be transferred back into the facility. To request a hearing or receive further information, call the department at (515)281-4115 or you may write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083." A hearing requested pursuant to this subrule shall be held in accordance with paragraphs *"f," "g,"* and *"h."* (II)

o. Residents shall not have the right to a hearing to contest an involuntary discharge or transfer resulting from the revocation of the facility's license by the department of inspections and appeals. In the case of a facility voluntarily closing, a period of 30 days must be allowed for an orderly transfer of residents to other facilities.

58.40(2) Intrafacility transfer:

a. Residents shall not be relocated from room to room within a licensed health care facility arbitrarily. (I, II) Involuntary relocation may occur only in the following situations and such situation shall be documented in the resident's record.

(1) Incompatibility with or disturbing to other roommates, as documented in the resident's record.

(2) For the welfare of the resident or other residents of the facility.

(3) For medical, nursing or psychosocial reasons, as documented in the resident's record, as judged by the attending physician, nurse or social worker in the case of a facility which groups residents by medical, nursing or psychosocial needs.

(4) To allow a new admission to the facility which would otherwise not be possible due to separation of roommates by sex.

(5) In the case of a resident whose source of payment was previously private, but who now is eligible for Title XIX assistance, the resident may be transferred from a private room to a semiprivate room or from one semiprivate room to another.

(6) Reasonable and necessary administrative decisions regarding the use and functioning of the building.

b. Unreasonable and unjustified reasons for changing a resident's room without the concurrence of the resident, or responsible party include:

(1) Change from private pay status to Title XIX, except as outlined in 58.40(2)*"a"*(5). (II)

(2) As punishment or behavior modification, except as specified in 58.40(2)*"a"*(1). (II)

(3) Discrimination on the basis of race or religion. (II)

c. If intrafacility relocation is necessary for reasons outlined in paragraph *"a,"* the resident shall be notified at least 48 hours prior to the transfer and the reason therefor shall be explained. The responsible party shall be notified as soon as possible. The notification shall be documented in the resident's record and signed by the resident or responsible party. (II)

d. If emergency relocation is required to protect the safety or health of the resident or other residents, the notification requirements may be waived. The conditions of the emergency shall be documented. The family or responsible party shall be notified immediately or as soon as possible of the condition requiring emergency relocation and such notification shall be documented. (II)

481—58.41(135C) Residents' rights. Each resident shall be encouraged and assisted throughout the resident's period of stay, to exercise rights as a resident and as a citizen and may voice grievances and recommend changes in policies and services to administrative staff or to outside representatives of the resident's choice, free from interference, coercion, discrimination, or reprisal. (II)

58.41(1) The facility shall provide ongoing opportunities for residents to be aware of and to exercise their rights as residents. Residents shall be kept informed of issues or pending decisions of the facility that affect them and their views shall be solicited prior to action. (II)

58.41(2) The facility shall implement a written procedure for registering and resolving grievances and recommendations by residents or their responsible party. The procedure shall ensure protection of the resident from any form of reprisal or intimidation. The written procedure shall include:

a. Designation of an employee responsible for handling grievances and recommendations. (II)

b. A method of investigating and assessing the validity of a grievance or recommendation. (II)

c. Methods of resolving grievances. (II)

d. Methods of recording grievances and actions taken. (II)

58.41(3) The facility shall post in a prominent area the name, telephone number, and address of the ombudsman, survey agency, local law enforcement agency, and certified volunteer long-term care ombudsman and the text of Iowa Code section 135C.46 to provide to residents a further course of redress. (II)

[**ARC 1205C**, IAB 12/11/13, effective 1/15/14]

481—58.42(135C) Financial affairs—management. Each resident who has not been assigned a guardian or conservator by the court may manage the resident's own personal financial affairs, and

to the extent, under written authorization by the resident that the facility assists in management, the management shall be carried out in accordance with Iowa Code section 135C.24. (II)

58.42(1) The facility shall maintain a written account of all residents' funds received by or deposited with the facility. (II)

58.42(2) An employee shall be designated in writing to be responsible for resident accounts. (II)

58.42(3) The facility shall keep on deposit personal funds over which the resident has control in accordance with Iowa Code section 135C.24(2). Should the resident request these funds, they shall be given to the resident on request with receipts maintained by the facility and a copy to the resident. In the case of a confused or intellectually disabled resident, the resident's responsible party shall designate a method of disbursing the resident's funds. (II)

58.42(4) If the facility makes financial transactions on a resident's behalf, the resident must receive or acknowledge that the resident has seen an itemized accounting of disbursements and current balances at least quarterly. A copy of this statement shall be maintained in the resident's financial or business record. (II)

58.42(5) A resident's personal funds shall not be used without the written consent of the resident or the resident's guardian. (II)

58.42(6) A resident's personal funds shall be returned to the resident when the funds have been used without the written consent of the resident or the resident's guardian. The department may report findings that resident funds have been used without written consent to the audits division or the local law enforcement agency, as appropriate. (II)

[**ARC 0766C**, IAB 5/29/13, effective 7/3/13]

481—58.43(135C) Resident abuse prohibited. Each resident shall receive kind and considerate care at all times and shall be free from mental, physical, sexual, and verbal abuse, exploitation, neglect, and physical injury. Each resident shall be free from chemical and physical restraints except as follows: when authorized in writing by a physician for a specified period of time; when necessary in an emergency to protect the resident from injury to the resident or to others, in which case restraints may be authorized by designated professional personnel who promptly report the action taken to the physician; and in the case of an intellectually disabled individual when ordered in writing by a physician and authorized by a designated qualified intellectual disabilities professional for use during behavior modification sessions. Mechanical supports used in normative situations to achieve proper body position and balance shall not be considered to be a restraint. (II)

58.43(1) Mental abuse includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation. (II)

58.43(2) Physical abuse includes, but is not limited to, corporal punishment and the use of restraints as punishment. (II)

58.43(3) Drugs such as tranquilizers may not be used as chemical restraints to limit or control resident behavior for the convenience of staff. (II)

58.43(4) Physicians' orders are required to utilize all types of physical restraints and shall be renewed at least quarterly. (II) Physical restraints are defined as the following:

Type I—the equipment used to promote the safety of the individual but is not applied directly to their person. Examples: divided doors and totally enclosed cribs.

Type II—the application of a device to the body to promote safety of the individual. Examples: vest devices, soft-tie devices, hand socks, geriatric chairs.

Type III—the application of a device to any part of the body which will inhibit the movement of that part of the body only. Examples: wrist, ankle or leg restraints and waist straps.

58.43(5) Physical restraints are not to be used to limit resident mobility for the convenience of staff and must comply with life safety requirements. If a resident's behavior is such that it may result in injury to the resident or others and any form of physical restraint is utilized, it should be in conjunction with a treatment procedure(s) designed to modify the behavioral problems for which the resident is restrained, or as a last resort, after failure of attempted therapy. (I, II)

58.43(6) Each time a Type II or III restraint is used documentation on the nurse's progress record shall be made which includes type of restraint and reasons for the restraint and length of time resident was restrained. The documentation of the use of Type III restraint shall also include the time of position change. (II)

58.43(7) Each facility shall implement written policies and procedures governing the use of restraints which clearly delineate at least the following:

a. Physicians' orders shall indicate the specific reasons for the use of restraints. (II)

b. Their use is temporary and the resident will not be restrained for an indefinite amount of time. (I, II)

c. A qualified nurse shall make the decision for the use of a Type II or Type III restraint for which there shall be a physician's order. (II)

d. A resident placed in a Type II or III restraint shall be checked at least every 30 minutes by appropriately trained staff. No form of restraint shall be used or applied in such a manner as to cause injury or the potential for injury and provide a minimum of discomfort to resident restrained. (I, II)

e. Reorders are issued only after the attending physician reviews the resident's condition. (II)

f. Their use is not employed as punishment, for the convenience of the staff, or as a substitute for supervision or program. (I, II)

g. The opportunity for motion and exercise shall be provided for a period of not less than ten minutes during each two hours in which Type II and Type III restraints are employed, except when resident is sleeping. However, when resident awakens, this shall be provided. This shall be documented each time. A check sheet may serve this purpose. (I, II)

h. Locked restraints or leather restraints shall not be permitted except in life-threatening situations. Straight jackets and secluding residents behind locked doors shall not be employed. (I, II)

i. Nursing assessment of the resident's need for continued application of a Type III restraint shall be made every 12 hours and documented on the nurse's progress record. Documentation shall include the type of restraint, reason for the restraint and the circumstances. Nursing assessment of the resident's need for continued application of either a Type I or Type II restraint and nursing evaluation of the resident's physical and mental condition shall be made every 30 days and documented on the nurse's progress record. (II)

j. A divided door equipped with a securing device that may be readily opened by personnel shall be considered an appropriate means of temporarily confining a resident in the resident's room. (II)

k. Divided doors shall be of the type that when the upper half is closed the lower section shall close. (II)

l. Methods of restraint shall permit rapid removal of the resident in the event of fire or other emergency. (I, II)

m. The facility shall provide orientation and ongoing education programs in the proper use of restraints.

58.43(8) In the case of an intellectually disabled individual who participates in a behavior modification program involving use of restraints or aversive stimuli, the program shall be conducted only with the informed consent of the individual's parent or responsible party. Where restraints are employed, an individualized program shall be developed by the interdisciplinary team with specific methodologies for monitoring its progress. (II)

a. The resident's responsible party shall receive a written account of the proposed plan of the use of restraints or aversive stimuli and have an opportunity to discuss the proposal with a representative(s) of the treatment team. (II)

b. The responsible party must consent in writing prior to the use of the procedure. Consent may also be withdrawn in writing. (II)

58.43(9) Allegations of dependent adult abuse. Allegations of dependent adult abuse shall be reported and investigated pursuant to Iowa Code chapter 235E and 481—Chapter 52. (I, II, III)

58.43(10) and **58.43(11)** Rescinded IAB 12/11/13, effective 1/15/14.

This rule is intended to implement Iowa Code sections 135C.14, 235B.3(1), and 235B.3(11).

[**ARC 0766C**, IAB 5/29/13, effective 7/3/13; **ARC 1204C**, IAB 12/11/13, effective 1/15/14]

481—58.44(135C) Resident records. Each resident shall be ensured confidential treatment of all information contained in the resident's records, including information contained in an automatic data bank. The resident's written consent shall be required for the release of information to persons not otherwise authorized under law to receive it. (II)

58.44(1) The facility shall limit access to any medical records to staff and consultants providing professional service to the resident. This is not meant to preclude access by representatives of state and federal regulatory agencies. (II)

58.44(2) Similar procedures shall safeguard the confidentiality of residents' personal records, e.g., financial records and social services records. Only those personnel concerned with the financial affairs of the residents may have access to the financial records. This is not meant to preclude access by representatives of state and federal regulatory agencies. (II)

58.44(3) The resident, or the resident's responsible party, shall be entitled to examine all information contained in the resident's record and shall have the right to secure full copies of the record at reasonable cost upon request, unless the physician determines the disclosure of the record or section thereof is contraindicated in which case this information will be deleted prior to making the record available to the resident or responsible party. This determination and the reasons for it must be documented in the resident's record. (II)

481—58.45(135C) Dignity preserved. The resident shall be treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and in care for personal needs. (II)

58.45(1) Staff shall display respect for residents when speaking with, caring for, or talking about them, as constant affirmation of their individuality and dignity as human beings. (II)

58.45(2) Schedules of daily activities shall allow maximum flexibility for residents to exercise choice about what they will do and when they will do it. Residents' individual preferences regarding such things as menus, clothing, religious activities, friendships, activity programs, entertainment, sleeping and eating, also times to retire at night and arise in the morning shall be elicited and considered by the facility. (II)

58.45(3) Residents shall be examined and treated in a manner that maintains the privacy of their bodies. A closed door or a drawn curtain shall shield the resident from passersby. People not involved in the care of the residents shall not be present without the resident's consent while the resident is being examined or treated. (II)

58.45(4) Privacy of a resident's body also shall be maintained during toileting, bathing, and other activities of personal hygiene, except as needed for resident safety or assistance. (II)

58.45(5) Staff shall knock and be acknowledged before entering a resident's room unless the resident is not capable of a response. This shall not apply in emergency conditions. (II)

481—58.46(135C) Resident work. No resident may be required to perform services for the facility, except as provided by Iowa Code sections 35D.14 and 347B.5. (II)

58.46(1) Residents may not be used to provide a source of labor for the facility against their will. Physician's approval is required for all work programs. (I, II)

58.46(2) If the plan of care requires activities for therapeutic or training reasons, the plan for these activities shall be professionally developed and implemented. Therapeutic or training goals must be clearly stated and measurable and the plan shall be time limited and reviewed at least quarterly. (II)

58.46(3) Residents who perform work for the facility must receive remuneration unless the work is part of their approved training program. Persons on the resident census performing work shall not be used to replace paid employees in fulfilling staffing requirements. (II)

481—58.47(135C) Communications. Each resident may communicate, associate, and meet privately with persons of the resident's choice, unless to do so would infringe upon the rights of other residents, and may send and receive personal mail unopened. (II)

58.47(1) Subject to reasonable scheduling restrictions, visiting policies and procedures shall permit residents to receive visits from anyone they wish. Visiting hours shall be posted. (II)

58.47(2) Reasonable, regular visiting hours shall not be less than 12 hours per day and shall take into consideration the special circumstances of each visitor. A particular visitor(s) may be restricted by the facility for one of the following reasons:

a. The resident refuses to see the visitor(s). (II)

b. The resident's physician documents specific reasons why such a visit would be harmful to the resident's health. (II)

c. The visitor's behavior is unreasonably disruptive to the functioning of the facility (this judgment must be made by the administrator and the reasons shall be documented and kept on file). (II)

58.47(3) Decisions to restrict a visitor are reviewed and reevaluated: each time the medical orders are reviewed by the physician; at least quarterly by the facility's staff; or at the resident's request. (II)

58.47(4) Space shall be provided for residents to receive visitors in reasonable comfort and privacy. (II)

58.47(5) Telephones consistent with ANSI standards (405.1134(c)) shall be available and accessible for residents to make and receive calls with privacy. Residents who need help shall be assisted in using the telephone. (II)

58.47(6) Arrangements shall be made to provide assistance to residents who require help in reading or sending mail. (II)

58.47(7) Residents shall be permitted to leave the facility and environs at reasonable times unless there are justifiable reasons established in writing by the attending physician, qualified intellectual disabilities professional or facility administrator for refusing permission. (II)

58.47(8) Residents shall not have their personal lives regulated beyond reasonable adherence to meal schedules, bedtime hours, and other written policies which may be necessary for the orderly management of the facility and as required by these rules. However, residents shall be encouraged to participate in recreational programs. (II)

[**ARC 0766C**, IAB 5/29/13, effective 7/3/13]

481—58.48(135C) Resident activities. Each resident may participate in activities of social, religious, and community groups at the resident's discretion unless contraindicated for reasons documented by the attending physician or qualified intellectual disabilities professional as appropriate in the resident's record. (II)

58.48(1) Residents who wish to meet with or participate in activities of social, religious, or other community groups in or outside of the facility shall be informed, encouraged, and assisted to do so. (II)

58.48(2) All residents shall have the freedom to refuse to participate in these activities. (II)

[**ARC 0766C**, IAB 5/29/13, effective 7/3/13]

481—58.49(135C) Resident property. Each resident may retain and use personal clothing and possessions as space permits and provided such use is not otherwise prohibited by these rules. (II)

58.49(1) Residents shall be permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility. The personal property shall be kept in a safe location which is convenient to the resident. (II)

58.49(2) Residents shall be advised, prior to or at the time of admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items, e.g., cleaning and laundry. (II)

58.49(3) Any personal clothing or possessions retained by the facility for the resident during the resident's stay shall be identified and recorded on admission and a record placed on the resident's chart. The facility shall be responsible for secure storage of the items, and they shall be returned to the resident promptly upon request or upon discharge from the facility. (II)

58.49(4) A resident's personal property shall not be used without the written consent of the resident or the resident's guardian. (II)

58.49(5) A resident's personal property shall be returned to the resident when it has been used without the written consent of the resident or the resident's guardian. The department may report findings

that a resident's property has been used without written consent to the local law enforcement agency, as appropriate. (II)

481—58.50(135C) Family visits. Each resident, if married, shall be ensured privacy for visits by the resident's spouse; if both are residents in the facility, they shall be permitted to share a room if available. (II)

58.50(1) The facility shall provide for needed privacy in visits between spouses. (II)

58.50(2) Spouses who are residents in the same facility shall be permitted to share a room, if available, unless one of their attending physicians documents in the medical record those specific reasons why an arrangement would have an adverse effect on the health of the resident. (II)

58.50(3) Family members shall be permitted to share a room, if available, if requested by both parties, unless one of their attending physicians documents in the medical record those specific reasons why such an agreement would have an adverse effect on the health of the resident. (II)

481—58.51(135C) Choice of physician and pharmacy. Each resident shall be permitted free choice of a physician and a pharmacy, if accessible. The facility may require the pharmacy selected to utilize a drug distribution system compatible with the system currently used by the facility.

A facility shall not require the repackaging of medications dispensed by the Veterans Administration or an institution operated by the Veterans Administration for the purpose of making the drug distribution system compatible with the system used by the facility. (II)

481—58.52(135C) Incompetent resident.

58.52(1) Each facility shall provide that all rights and responsibilities of the resident devolve to the resident's responsible party when a resident is adjudicated incompetent in accordance with state law or, in the case of a resident who has not been adjudicated incompetent under the laws of the state, in accordance with 42 CFR 483.10. This subrule is not intended to limit the authority of any individual acting pursuant to Iowa Code chapter 144A. (II)

58.52(2) The fact that a resident has been adjudicated incompetent does not absolve the facility from advising the resident of these rights to the extent the resident is able to understand them. The facility shall also advise the responsible party, if any, and acquire a statement indicating an understanding of residents' rights. (II)

481—58.53(135C) County care facilities. In addition to Chapter 58 licensing rules, county care facilities licensed as nursing facilities must also comply with department of human services rules, 441—Chapter 37. Violation of any standard established by the department of human services is a Class II violation pursuant to 481—56.2(135C).

481—58.54(73GA,ch 1016) Special unit or facility dedicated to the care of persons with chronic confusion or a dementing illness (CCDI unit or facility).

58.54(1) A nursing facility which chooses to care for residents in a distinct part shall obtain a license for a CCDI unit or facility. In the case of a distinct part, this license will be in addition to its ICF license. The license shall state the number of beds in the unit or facility. (III)

a. Application for this category of care shall be submitted on a form provided by the department. (III)

b. Plans to modify the physical environment shall be submitted to the department. The plans shall be reviewed based on the requirements of 481—Chapter 61. (III)

58.54(2) A statement of philosophy shall be developed for each unit or facility which states the beliefs upon which decisions will be made regarding the CCDI unit or facility. Objectives shall be developed for each CCDI unit or facility as a whole. The objectives shall be stated in terms of expected results. (II, III)

58.54(3) A résumé of the program of care shall be submitted to the department for approval at least 60 days before a separate CCDI unit or facility is opened. A new résumé of the program of care shall be submitted when services are substantially changed. (II, III)

The résumé of the program of care shall:

a. Describe the population to be served; (II, III)

b. State philosophy and objectives; (II, III)

c. List admission and discharge criteria; (II, III)

d. Include a copy of the floor plan; (II, III)

e. List the titles of policies and procedures developed for the unit or facility; (II, III)

f. Propose a staffing pattern; (II, III)

g. Set out a plan for specialized staff training; (II, III)

h. State visitor, volunteer, and safety policies; (II, III)

i. Describe programs for activities, social services and families; (II, III) and

j. Describe the interdisciplinary care planning team. (II, III)

58.54(4) Separate written policies and procedures shall be implemented in each CCDI unit or facility. There shall be:

a. Admission and discharge policies and procedures which state the criteria to be used to admit residents and the evaluation process which will be used. These policies shall require a statement from the attending physician agreeing to the placement before a resident can be moved into a CCDI unit or facility. (II, III)

b. Safety policies and procedures which state the actions to be taken by staff in the event of a fire, natural disaster, emergency medical or catastrophic event. Safety procedures shall also explain steps to be taken when a resident is discovered to be missing from the unit or facility and when hazardous cleaning materials or potentially dangerous mechanical equipment is being used in the unit or facility. The facility shall identify its method for security of the unit or facility and the manner in which the effectiveness of the security system will be monitored. (II, III)

c. Program and service policies and procedures which explain programs and services offered in the unit or facility including the rationale. (III)

d. Policies and procedures concerning staff which state minimum numbers, types and qualifications of staff in the unit or facility. (II, III)

e. Policies about visiting which suggest times and ensure the residents' rights to free access to visitors. (II, III)

f. Quality assurance policies and procedures which list the process and criteria which will be used to monitor and to respond to risks specific to the residents. This shall include, but not be limited to, drug use, restraint use, infections, incidents and acute behavioral events. (II, III)

58.54(5) Preadmission assessment of physical, mental, social and behavioral status shall be completed to determine whether the applicant meets admission criteria. This assessment shall be completed by a registered nurse and a staff social worker or social work consultant and shall become part of the permanent record upon admission of the resident. (II, III)

58.54(6) All staff working in a CCDI unit or facility shall have training appropriate to the needs of the residents. (II, III)

a. Upon assignment to the unit or facility, everyone working in the unit or facility shall be oriented to the needs of people with chronic confusion or dementing illnesses. They shall have special training appropriate to their job description within 30 days of assignment to the unit or facility. (II, III) The orientation shall be at least six hours. The following topics shall be covered:

(1) Explanation of the disease or disorder; (II, III)

(2) Symptoms and behaviors of memory-impaired people; (II, III)

(3) Progression of the disease; (II, III)

(4) Communication with CCDI residents; (II, III)

(5) Adjustment to care facility residency by the CCDI unit or facility residents and their families; (II, III)

(6) Inappropriate and problem behavior of CCDI unit or facility residents and how to deal with it; (II, III)

(7) Activities of daily living for CCDI residents; (II, III)

(8) Handling combative behavior; (II, III) and

(9) Stress reduction for staff and residents. (II, III)

b. Licensed nurses, certified aides, certified medication aides, social services personnel, housekeeping and activity personnel shall have a minimum of six hours of in-service training annually. This training shall be related to the needs of CCDI residents. The six-hour training shall count toward the required annual in-service training. (II, III)

58.54(7) There shall be at least one nursing staff person on a CCDI unit at all times. (I, II, III)

58.54(8) The CCDI unit or facility license may be revoked, suspended or denied pursuant to Iowa Code chapter 135C and Iowa Administrative Code 481—Chapter 50.

This rule is intended to implement 1990 Iowa Acts, chapter 1016.

481—58.55(135C) Another business or activity in a facility. A facility is allowed to have another business or activity in a health care facility or in the physical structure of the facility, if the other business or activity meets the requirements of applicable state and federal laws, administrative rules, and federal regulations.

To obtain the approval of the department and the state fire marshal, the facility must submit to the department a written request for approval which identifies the service(s) to be offered by the business and addresses the factors outlined in paragraphs *"a"* through *"f"* of subrule 58.55(1). (I, II, III)

58.55(1) The following factors will be considered by the department in determining whether a business or activity will interfere with the use of the facility by residents, interfere with services provided to residents, or be disturbing to residents:

a. Health and safety risks for residents;

b. Noise created by the proposed business or activity;

c. Odors created by the proposed business or activity;

d. Use of the facility's corridors or rooms as thoroughfares to the business or activity in regard to safety and disturbance of residents and interference with delivery of services;

e. Proposed staffing for the business or activity; and

f. Sharing of services and staff between the proposed business or activity and the facility.

58.55(2) Approval of the state fire marshal shall be obtained before approval of the department will be considered.

58.55(3) A business or activity conducted in a health care facility or in the same physical structure as a health care facility shall not reduce space, services or staff available to residents below minimums required in these rules and 481—Chapter 61. (I, II, III)

481—58.56(135C) Respite care services. Respite care services means an organized program of temporary supportive care provided for 24 hours or more to a person in order to relieve the usual caregiver of the person from providing continual care to the person. A nursing facility which chooses to provide respite care services must meet the following requirements related to respite services and must be licensed as a nursing facility.

58.56(1) A nursing facility certified as a Medicaid nursing facility or Medicare skilled nursing facility must meet all Medicaid and Medicare requirements including CFR 483.12, admission, transfer and discharge rights.

58.56(2) A nursing facility which chooses to provide respite care services is not required to obtain a separate license or pay a license fee.

58.56(3) Rule 481—58.40(135C) regarding involuntary discharge or transfer rights, does not apply to residents who are being cared for under a respite care contract.

58.56(4) Pursuant to rule 481—58.13(135C), the facility shall have a contract with each resident in the facility. When the resident is there for respite care services, the contract shall specify the time period during which the resident will be considered to be receiving respite care services. At the end of that period, the contract may be amended to extend that period of time. The contract shall specifically state the resident may be involuntarily discharged while being considered as a respite care resident. The contract shall meet other requirements under 481—58.13(135C), except the requirements under subrule 58.13(7).

58.56(5) Respite care services shall not be provided by a health care facility to persons requiring a level of care which is higher than the level of care the facility is licensed to provide.

481—58.57(135C) Training of inspectors.

58.57(1) Subject to the availability of funding, all nursing facility inspectors shall receive 12 hours of annual continuing education in gerontology, wound care, dementia, falls, or a combination of these subjects.

58.57(2) An inspector shall not be personally liable for financing the training required under subrule 58.57(1).

58.57(3) The department shall consult with the collective bargaining representative of the inspector in regard to the training required under this rule.

[**ARC 8433B**, IAB 12/30/09, effective 2/3/10]

These rules are intended to implement Iowa Code sections 10A.202, 10A.402, 135C.6(1), 135C.14, 135C.25, 135C.32, 135C.36 and 227.4 and 1990 Iowa Acts, chapter 1016.

[Filed 8/6/76, Notice 4/19/76—published 8/23/76, effective 9/27/76]
[Filed without Notice 10/4/76—published 10/20/76, effective 11/24/76]
[Filed emergency 12/21/76—published 1/12/77, effective 1/12/77]
[Filed without Notice 2/4/77—published 2/23/77, effective 3/30/77]
[Filed 8/18/77, Notice 3/9/77—published 9/7/77, effective 10/13/77]
[Filed emergency 9/30/77—published 10/19/77, effective 9/30/77]
[Filed without Notice 10/14/77—published 11/2/77, effective 12/8/77]
[Filed 1/20/78, Notice 12/14/77—published 2/8/78, effective 3/15/78]
[Filed 5/26/78, Notice 3/8/78—published 6/14/78, effective 7/19/78]
[Filed 7/7/78, Notice 5/31/78—published 7/26/78, effective 9/1/78]
[Filed 10/13/78, Notice 9/6/78—published 11/1/78, effective 12/7/78]
[Filed 11/9/78, Notice 6/28/78—published 11/29/78, effective 1/3/79]
[Filed emergency 11/22/78—published 12/13/78, effective 1/3/79]
[Filed 5/20/82, Notice 12/23/81—published 6/9/82, effective 7/14/82]
[Filed without Notice 7/16/82—published 8/4/82, effective 9/8/82]
[Filed 3/11/83, Notice 1/5/83—published 3/30/83, effective 5/4/83]
[Filed 1/10/86, Notice 11/6/85—published 1/29/86, effective 3/5/86][1]
[Filed 5/16/86, Notice 1/1/86—published 6/4/86, effective 7/9/86]
[Filed emergency 7/1/86—published 7/16/86, effective 7/1/86][2]
[Filed 6/27/86, Notice 3/26/86—published 7/16/86, effective 8/20/86]
[Filed emergency 9/19/86—published 10/8/86, effective 9/19/86]
[Filed 2/6/87, Notice 10/22/86—published 2/25/87, effective 4/1/87]
[Filed 2/6/87, Notice 11/5/86—published 2/25/87, effective 4/1/87]
[Filed 3/12/87, Notice 1/28/87—published 4/8/87, effective 5/13/87]
[Filed emergency 6/25/87—published 7/15/87, effective 7/1/87]
[Filed 10/26/87, Notice 8/26/87—published 11/18/87, effective 12/23/87]
[Filed 2/5/88, Notice 10/7/87—published 2/24/88, effective 3/30/88][◊]
[Filed 4/28/88, Notice 12/16/87—published 5/18/88, effective 6/22/88]
[Filed 5/26/88, Notice 4/20/88—published 6/15/88, effective 7/20/88]
[Filed 9/30/88, Notice 8/24/88—published 10/19/88, effective 11/23/88][◊]
[Filed 1/5/89, Notice 10/5/88—published 1/25/89, effective 3/1/89]
[Filed 6/23/89, Notice 5/17/89—published 7/12/89, effective 8/16/89]
[Filed 7/20/89, Notice 6/14/89—published 8/9/89, effective 9/13/89]
[Filed 8/16/89, Notices 4/19/89, 7/12/89—published 9/6/89, effective 10/11/89]
[Filed emergency 5/11/90—published 5/30/90, effective 5/11/90]
[Filed 3/14/91, Notice 9/19/90—published 4/3/91, effective 5/8/91]
[Filed emergency 5/10/91—published 5/29/91, effective 5/10/91]
[Filed emergency 7/17/91—published 8/7/91, effective 7/19/91]

[Filed 1/31/92, Notice 11/13/91—published 2/19/92, effective 7/1/92]
[Filed 3/12/92, Notice 12/11/91—published 4/1/92, effective 5/6/92]
[Filed 1/15/93, Notice 11/25/92—published 2/3/93, effective 3/10/93]
[Filed 3/11/94, Notice 9/15/93—published 3/30/94, effective 5/4/94]
[Filed 5/16/95, Notice 3/15/95—published 6/7/95, effective 7/12/95]
[Filed 7/11/97, Notice 4/23/97—published 7/30/97, effective 9/3/97]
[Filed emergency 7/25/97—published 8/13/97, effective 7/25/97]
[Filed emergency 11/14/97—published 12/3/97, effective 11/14/97]
[Filed 11/14/97, Notice 8/13/97—published 12/3/97, effective 1/7/98]
[Filed 3/31/98, Notice 12/3/97—published 4/22/98, effective 5/27/98]
[Filed 7/9/98, Notice 4/22/98—published 7/29/98, effective 9/2/98]
[Filed 1/21/99, Notice 10/7/98—published 2/10/99, effective 3/17/99]
[Filed 11/12/99, Notice 10/6/99—published 12/1/99, effective 1/5/00]
[Filed 7/17/03, Notice 6/11/03—published 8/6/03, effective 9/10/03]
[Filed 1/15/04, Notice 10/1/03—published 2/4/04, effective 3/10/04]
[Filed 1/15/04, Notice 12/10/03—published 2/4/04, effective 3/10/04]
[Filed 3/12/04, Notice 1/7/04—published 3/31/04, effective 5/5/04]
[Filed 3/12/04, Notice 2/4/04—published 3/31/04, effective 5/5/04]
[Filed 9/9/04, Notice 8/4/04—published 9/29/04, effective 11/3/04]
[Filed 7/13/05, Notice 6/8/05—published 8/3/05, effective 9/7/05]
[Filed 9/20/06, Notice 8/2/06—published 10/11/06, effective 11/15/06]
[Filed 11/15/06, Notice 10/11/06—published 12/6/06, effective 1/10/07][◊]
[Filed 7/9/08, Notice 1/30/08—published 7/30/08, effective 9/3/08]
[Filed ARC 8433B (Notice ARC 8190B, IAB 10/7/09), IAB 12/30/09, effective 2/3/10]
[Filed ARC 0663C (Notice ARC 0513C, IAB 12/12/12), IAB 4/3/13, effective 5/8/13]
[Filed ARC 0766C (Notice ARC 0601C, IAB 2/6/13), IAB 5/29/13, effective 7/3/13]
[Filed ARC 0903C (Notice ARC 0776C, IAB 5/29/13), IAB 8/7/13, effective 9/11/13]
[Filed ARC 1048C (Notice ARC 0923C, IAB 8/7/13), IAB 10/2/13, effective 11/6/13]
[Filed ARC 1050C (Notice ARC 0907C, IAB 8/7/13), IAB 10/2/13, effective 11/6/13]
[Filed ARC 1205C (Notice ARC 1082C, IAB 10/2/13), IAB 12/11/13, effective 1/15/14]
[Filed ARC 1204C (Notice ARC 1083C, IAB 10/2/13), IAB 12/11/13, effective 1/15/14]
[Filed ARC 1398C (Notice ARC 1313C, IAB 2/5/14), IAB 4/2/14, effective 5/7/14]

◊ Two or more ARCs

1 Effective date of 470—58.15(2)*"c"* delayed 70 days by the Administrative Rules Review Committee, IAB 2/26/86.
Effective date of 470—58.15(2)*"c"* delayed until the expiration of 45 calendar days into the 1987 session of the General Assembly pursuant to Iowa Code section 17A.8(9), IAB 6/4/86.

2 See IAB, Inspections and Appeals Department.

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641—41.1(136C) X-rays in the healing arts.

41.1(1) *Scope.* This rule establishes requirements, for which a registrant is responsible, for use of X-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine.

a. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 9, 2008.

41.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapters 38 and 40 may also apply. The following are specific to 641—Chapter 41.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also "Phototimer"). (Includes devices such as phototimers and ion chambers.)

"Base density" means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

"Base plus fog density" means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"C-arm X-ray system" means an X-ray system in which the image receptor and X-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cassette" means a light-tight case, usually made of thin, low X-ray absorption plastic, for holding X-ray film. One or two intensifying screens for the conversion of X-rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

"Certified components" means components of X-ray systems which are subject to regulations promulgated under Public Law 90-602, the "Radiation Control for Health and Safety Act of 1968," the Food and Drug Administration.

"Certified system" means any X-ray system which has one or more certified component(s).

"Coefficient of variation" or *"C"* means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = \frac{s}{\overline{x}} = \frac{1}{\overline{x}} \left[\sum_{i=1}^{n} \frac{(x_i - \overline{x})^2}{n-1} \right]^{1/2}$$

where:
s = Estimated standard deviation of the population.
$\overline{X}$ = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of X-ray transmission data.

"Control chart" means a chart used to record (and control) the results of quality control testing as a function of time.

"Control limit" means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

"Control panel" (see X-ray control panel).

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (see "Computed tomography").

"Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Densitometer" means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

"Detents" means mechanical settings that limit or prevent the motion or rotation of an X-ray tube, cassette assembly, or image receptor system.

"Developer" means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

"Developer replenishment" means the process, occurring as film travels past a certain point in the processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

"Diagnostic mammography" means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (see "X-ray equipment").

"Field emission equipment" means equipment which uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Fixer" means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

"Fixer retention" means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical

interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot (actual)" means the area projected on the anode of the X-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"Focal spot size" means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

"Fog" means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, chemical, or heat exposure during storage, handling, and processing.

"General purpose radiographic X-ray system" means any radiographic X-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Healing arts screening" means the use of radiation on human beings for the detection or evaluation of health indicators for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under 41.1(3)*"a"*(7), or
2. An individual licensed as a physician in Iowa and listed as an authorized user on an NRC or agreement state radioactive materials license.

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp × mA × second.

"Image contrast" means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attentuation difference or light exposure difference.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

"Image noise" See "Radiographic noise."

"Image quality" means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Image sharpness" means the overall impression of detail and clarity in a radiographic image.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Kilovolts peak" (see "Peak tube potential").

"kVp" (see "Peak tube potential").

"kWs" means kilowatt second.

"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

"Linear attenuation coefficient" or "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

"Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n - V_l)/V_l$

where

V_n = No-load line potential and

V_l = Load line potential.

"mAs" means milliampere second.

"Maximum line current" means the root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

"Mobile X-ray equipment" (see "X-ray equipment").

"PBL" (see "Positive beam limitation").

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see "Automatic exposure control").

"PID" (see "Position indicating device").

"Portable X-ray equipment" (see "X-ray equipment").

"Position indicating device" means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Positive beam limitation" means the automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Processor" means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur.

"Protective apron" means an apron made of radiation-absorbing materials used to reduce radiation exposure.

"Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure.

"Quality assurance" means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

"Quality control" means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

"Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

"Radiographic contrast" means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amount of X-ray or visible light exposure.

"Radiographic noise" means unwanted fluctuations in optical density on the screen-film image.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from X-ray photons.

"Repeat (or reject) analysis" means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

"Replenishment rate" means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Safelight" means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

"Screen" means microscopic phosphor crystals on a plastic support used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X-radiation, creating a latent image on X-ray film.

"Screen-film combination" means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

"Screen-film contact" means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

"Sensitometer" means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

"Sensitometric strip" means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

"Sensitometry" means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

"SID" (see "Source-image receptor distance").

"Source" means the focal spot of the X-ray tube.

"Source-image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Spot check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot-film device" means a device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"Stationary X-ray equipment" (see "X-ray equipment").

"Technique factors" means the following conditions of operation:

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

c. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or the product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

d. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Tomogram" means the depiction of the X-ray attenuation properties of a section through the body.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the X-ray field size at a given SID.

"Viewbox" means a device by which a uniform field of white light is transmitted through an X-ray so that the image on the film may be seen.

"Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

"X-ray control panel" means a device which controls input power to the X-ray high-voltage generator and the X-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X-ray exposure.

"X-ray equipment" means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

a. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried.

c. "Stationary X-ray equipment" means X-ray equipment which is installed in a fixed location.

"X-ray exposure control" means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

41.1(3) *Administrative controls.*

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control, for ensuring that the requirements of these rules are met in the operation of the X-ray system(s), and for having the following minimum tests performed by a registered service facility according to the following schedule:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X-ray field alignment as set forth in 41.1(6) every two years.

2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7) every four years.

3. Fluoroscopic: entrance exposure rate (41.1(5)*"c"*), and minimum SSD (41.1(5)*"f"*) annually.

4. Veterinary systems are exempt from the above testing requirements.

All service and installation shall be performed by persons registered under 641—subrule 39.3(3). The registrant or the registrant's agent shall ensure that the requirements of these rules are met in the operation of the X-ray system(s).

(1) An X-ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

(2) Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

1. Operators in medical facilities shall meet the requirements of 641—Chapter 42, as applicable, and shall make the permit available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

(3) A chart shall be provided in the vicinity of the diagnostic X-ray system's control panel which specifies, for all examinations performed with that system, the following information:

1. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized unless automatically set by the X-ray system;

2. Type and size of the film or film-screen combination to be used;

3. Type and focal distance of the grid to be used, if any;

4. Source to image receptor distance to be used, except for dental intra-oral radiography; and

5. Type and location of placement of human patient shielding to be used (e.g., gonad).

(4) Written safety procedures shall be provided to each individual operating X-ray equipment, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

2. The X-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam unless (1) the radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and (2) such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3)*"a"*(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)*"a"*(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3)*"a"*(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 41.1(3)*"a"*(5)"2";

4. No individual shall be used routinely to hold film or patients; and

5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule 40.36(3) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program in the state of Iowa without prior written approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. The agency shall not approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened. If any information submitted to the agency becomes invalid or outdated, the applicant shall notify the agency in writing within five calendar days.

(12) Rescinded IAB 3/31/04, effective 5/5/04.

b. Information and maintenance record and associated information. Records in 41.1(3)*"b"*(1) and (3) below shall be maintained until the X-ray system is removed from the facility. There shall be two cycles of records on file for items in 41.1(3)*"b"*(2) below. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

(1) User's manual for the X-ray system;

(2) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;

(3) A copy of all correspondence with this agency regarding that X-ray system.

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient's name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. These records shall be kept until the facility is inspected by this agency or until all films listed on the utilization log have been purged.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X-ray film processing facilities and practices (except for mammography). Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion-resistant material; and

2. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom. Deviations from the manufacturer's recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer.

2. Processing deviations from the requirements of 41.1(3)*"f"* shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

3. All processing equipment shall be in good mechanical working order.

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records shall be maintained to verify that the items in 41.1(3)*"f"* are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

g. Retention of films. Record retention of films shall be seven years for patients 18 years of age or older and seven years plus the difference between the patient's age and 18 for minors.

(1) If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period.

(2) If the facility is currently utilizing computer media and also storing images in a hard-copy format, it may continue to use this method of retention throughout the retention period. If the images are also on computer media, the data should be backed up, or refreshed, at appropriate intervals as defined by the facility.

(3) If the facility is solely utilizing computer media to store study information for which a report is generated, the recording media is to be stored in conditions that will ensure that deterioration will not occur for the period required by this policy. The facility must maintain either retrieval or access or both to the stored images.

(4) If a patient's medical images are identified as being involved in a legal case, the records should immediately be coded appropriately, and maintained for the required time frame defined in this paragraph. At the time the records have reached the end of the appropriate time frame for retention, the previously identified responsible individuals involved in the legal action should be contacted for further instruction.

(5) If records are temporarily transferred to any party, appropriate information relating to location, date of release, and individual having custody of the records should be maintained.

(6) A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal.

41.1(4) *General requirements for all diagnostic X-ray systems.* In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC/kg) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 μC/kg) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

e. Beam quality.

(1) Half-value layer.

1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. and 3. Rescinded IAB 4/8/98, effective 7/1/98.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)*"e"* shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)*"e"*(1)"1" is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)*"h"*(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer's standards.

i. Rescinded IAB 3/30/05, effective 5/4/05.

41.1(5) *Fluoroscopic X-ray systems except for computed tomography X-ray systems.* All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5)*"a"*(2)"1" apply.

4. Other requirements for fluoroscopic beam limitation:

- Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;
- All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;
- If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;
- For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;
- For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X-ray field size adjustments required in 41.1(5)*"a"*(2) and 41.1(5)*"a"*(3), that means:

1. Shall be designed for use only in the event of system failure;

2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

3. Shall have a clear and durable label as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except

- During recording of fluoroscopic images; or
- When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

3. Compliance with the requirements of 41.1(5)*"c"* shall be determined as follows:

- If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle;
- If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

- All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

4. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activitation of high level controls shall be required. The high level control shall only be operable when continuous manual activitation is provided by the operator. A continuous signal audible to the fluroscopist shall indicate that the high level control is being employed.

5. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 5 roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 10 roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high level control is activated.

6. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

- The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)*"c"*(1)"3";
- The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;
- The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of 41.1(5)*"c"*(1)"3."

(2) Reserved.

d. Barrier transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 μC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

f. Source-to-skin distance. The SSD shall not be less than:

(1) 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974,

(2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974,

(3) 30 centimeters on all mobile fluoroscopes, and

(4) 20 centimeters for mobile fluoroscopes used for specific surgical application.

(5) The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in 41.1(3)*"a"*(4).

g. Fluoroscopic timer.

(1) Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.

h. Control of scattered radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)*"a"*(5).

(3) The agency may grant exemptions to 41.1(5)*"h"*(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

i. Spot-film exposure reproducibility. Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements of 41.1(6)*"d"* when operating in the spot-film mode.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)*"a," "c," "d,"* and *"g"* provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

(2) Systems which do not meet the requirements of 41.1(5)*"g"* are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

k. Dose-area-product monitor requirements.

(1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (e.g., pacemaker implantation, diagnostic cardiac procedures (catheterization), and therapeutic cardiac procedures (angioplasty-balloon; stent; directional coronary atherectomy; rotational atherectomy; laser atherectomy; radio frequency ablation; and intravascular brachytherapy)) shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used. Equipment used and installed prior to July 1, 2002, shall be retrofitted with the radiation exposure device by January 1, 2004.

(2) Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for agency review the patient radiation exposure received per procedure. Adult doses that exceed 300 rad and doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee. The review must document the reason why a dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If

a facility does not have a radiation safety committee, the facility must provide the agency, within 30 days of the event, documentation stating why the patient's dose exceeded 300 rad for adults or 100 rad for children. Also, if the patient doses noted above are exceeded, the patient's physician must do a follow-up examination of the patient to determine if there is any evidence of dose recorded reaction and to ensure that proper treatment is rendered.

(3) All fluoroscopic radiation detection devices in this subrule shall be calibrated annually or after repair or replacement.

l. Equipment operation.

(1) All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

(2) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(3) Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

m. Additional requirements for stationary fluoroscopic systems used for cardiac catheterization procedures.

(1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s). If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

(2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient). Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22(136C).

n. Supervision of fluoroscopy. The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner or an advanced registered nurse practitioner (ARNP), pursuant to 655—subrule 7.2(2), for the purpose of localization to obtain images for diagnostic or therapeutic purposes. The use of fluoroscopy by radiologist assistants shall be as defined in 641—42.6(136C).

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, veterinary, or computed tomography X-ray systems.*

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of 41.1(6)*"h"*(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X-ray systems and veterinarian systems (other than portable) installed after July 1, 1998.

1. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X-ray field.

- Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.
- The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)*"a"*(1)"1" and "2" provided the registrant makes a written application for such exemption and in that application

demonstrates it is impractical to comply with 41.1(6)*"a"*(1)"1" and "2"; and the purpose of 41.1(6)*"a"*(1)"1" and "2" will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)*"a"*(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:

1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems designed for or provided with special attachments for mammography. Rescinded IAB 4/8/98, effective 7/1/98.

(5) X-ray systems other than those described in 41.1(6)*"a"*(1), (2), and (3), and veterinary systems installed prior to July 1, 1998, and all portable veterinary X-ray systems.

1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

3. 41.1(6)*"a"*(5)"1" and "2" may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)*"a"*(1) or, when alignment means are also provided, may be met with either:

- An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
- A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

(1) Timers.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if

either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(2) X-ray control.

1. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures; and mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6)*"b"*(2)"2"; or
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure. Stationary podiatric systems which do not meet the above requirements shall be provided with a 9-foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

3. The X-ray control shall provide visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic exposure controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. If the X-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

3. The minimum exposure time for all equipment other than that specified in 41.1(6)*"b"*(3)"2" shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

4. Either the product of peak X-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X-ray tube potential is less than 50 kVp, the product of X-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

5. A visible signal shall indicate when an exposure has been terminated at the limits required by 41.1(6)*"b"*(3)"4," and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four timer tests are performed:

$$\overline{T} \geq 5\ (T_{max} - T_{min})$$

(5) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

c. Source-to-skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters except for veterinary systems.

d. Exposure reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 μC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product (C $kg^{-1}mAs^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of mR/mAs (or C $kg^{-1}mAs^{-1}$), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

h. Additional requirements applicable to certified systems only. Diagnostic X-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam limitation for stationary and mobile general purpose X-ray systems.

1. There shall be provided a means of stepless adjustment of the X-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less.

The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(2) Beam limitation and alignment on stationary general purpose X-ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of X-rays when

- Either the length or width of the X-ray field in the plane of the image receptor differs, except as permitted by 41.1(6)*"h"*(3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or
- The sum of the length and width differences as stated in 41.1(6)*"h"*(2)"1" above without regard to sign exceeds 4 percent of the SID;

2. Compliance with 41.1(6)*"h"*(2)"1" shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

4. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 41.1(6)*"h"*(2)"1," then any change of image receptor size or SID must cause the automatic return.

(3) Beam limitation for portable X-ray systems. Beam limitation for portable X-ray systems shall meet the beam limitation requirements of 41.1(6)*"a"* or 41.1(6)*"h"*(2).

i. Tube stands for portable X-ray systems. A tube stand or other mechanical support shall be used for portable X-ray systems, so that the X-ray tube housing assembly need not be handheld during exposures.

j. Systems used in a clinical (nonsurgical) setting shall be restricted to one room within a location or suite which meets the requirements of 41.1(3)*"d."*

41.1(7) *Intraoral dental radiographic systems.* In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used.

a. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

b. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

(1) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) If the minimum SSD is less than 18 centimeters, the X-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(3) The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements of 41.1(4)*"c."*

c. Exposure control.

(1) Exposure initiation.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

2. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in X-ray systems that cannot be altered to meet this requirement.

(3) Exposure termination.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

2. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

3. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (½) second or less.

(4) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-2}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values.

(5) Each X-ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3)*"a"*(4) must instruct the operator to remain in the protected area during the entire exposure.

2. Mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7)*"c"*(5)"1."
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 9 feet (2.7 meters) from the tube housing assembly while making exposure.

3. Portable or hand-held dental X-ray systems designed with a backscatter shield may be used without the additional protective barrier, but the operator must wear a protective apron. The operator must stand directly behind the unit to allow the shield to function as designed.

d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

e. mA/mS linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of X-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X-ray tube manufacturer.

f. *Accuracy.* Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. *kVp limitations.* Dental X-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. *Administrative controls.*

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand-held during an exposure.

(3) The X-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7)*"b"*(1).

(4) Dental fluoroscopy without image intensification shall not be used.

i. *Portable or hand-held dental X-ray systems.* Portable or hand-held dental X-ray systems designed with a backscatter shield shall:

(1) Be used only where it is impractical to us a portable dental system;

(2) Be used as the manufacturer indicates;

(3) Not be used with the backscatter shield removed, if applicable; and

(4) Be exempted from 41.1(4)*"g."*

41.1(8) Rescinded IAB 6/4/97, effective 7/9/97.

41.1(9) *Bone densitometry units.*

a. No additional shielding for the room is required.

b. Film badges, OSL devices, or TLDs must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months and another request for discontinuance submitted to the agency.

c. Rescinded IAB 2/6/13, effective 3/13/13.

d. Specific operating procedures must be prepared and made available at the operator's position.

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer's specifications. Records of maintenance shall be kept for inspection by the agency.

41.1(10) *Veterinary medicine radiographic installations.*

a. Equipment.

(1) The protective tube housing shall be equivalent to the requirements of 41.1(4)*"c."*

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. Operator protection.

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with 641—40.15(136C) and 40.21(136C) and subrule 40.26(1).

(2) All stationary, mobile or portable X-ray systems shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. Operating procedures. Veterinary medicine radiographic installations are exempt from the requirements of 641—41.1(136C) except for 641—subrules 41.1(3) and 41.1(10).

(1) No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required, and

(2) The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures, or

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) *Computed tomography X-ray systems.*

a. Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

"Computed tomography dose index" means the integral from –7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{\text{CTDI}} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.

D(z)= Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

$\overline{CTN}_x$ = of the material of interest.

$\overline{CTN}_w$ = of water.

"CS" (see "Contrast scale").

"CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

"CTDI" (see "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (see "CT number").

"CT number" means the number used to represent the X-ray attenuation associated with each elemental area of the CT image.

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.)

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted (see also "Picture element").

"Multiple tomogram system" means a computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuation in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_s) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

$\overline{CS}$ = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting X-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

"Single tomogram system" means a CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

b. Requirements for equipment.

(1) Termination of exposure.

1. Means shall be provided to terminate the X-ray exposure automatically by either deenergizing the X-ray source or shuttering the X-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X-ray exposure has been terminated through the means required by 41.1(11)*"b"*(1)"1."

3. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under CT X-ray system control, of greater than one-half second duration.

(2) Tomographic plane indication and alignment.

1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy 41.1(11)*"b"*(2)"1" or "2," the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam-on and shutter status indicators and control switches.

1. The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT conditions of operation. The CT X-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 41.1(4)*"c."*

(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

2. If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

c. Facility design requirements.

(1) Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

1. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

d. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

1. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

(2) Radiation calibrations.

1. The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

2. The calibration of a CT X-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

3. The calibration of the radiation output of a CT X-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

4. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X-ray system. Such phantom(s) shall meet the following specifications and conditions of use: CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode; CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided; any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

5. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the CTDI[3] along the two axes specified in 41.1(11)*"d"*(2)"4" shall be measured. (For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)*"d"*(3) shall be made.

7. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

(3) Spot checks.

1. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

2. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

3. All spot checks shall be included in the calibration required by 41.1(11)*"d"*(2) and at time intervals and under system conditions specified by a qualified expert.

4. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 41.1(11)*"d"*(2). The images shall be retained, until a new calibration is performed, in two forms as follows: photographic copies of the images obtained from the image display device; and images stored in digital form on a storage medium compatible with the CT X-ray system.

5. Written records of the spot checks performed shall be maintained for inspection by the agency.

(4) Operating procedures.

1. The CT X-ray system shall not be operated except by a licensed practitioner or an individual who has been specifically trained in its operation and holds a current permit to practice as a general radiologic technologist as defined under the provisions of 641—Chapter 42.

41.1(12) *X-ray machines used for mammography.* Rescinded IAB 4/8/98, effective 7/1/98.

[**ARC 8659B**, IAB 4/7/10, effective 5/12/10; **ARC 0577C**, IAB 2/6/13, effective 3/13/13]

641—41.2(136C) Use of radionuclides in the healing arts.

41.2(1) *Purpose and scope.*

a. This rule establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, the applicable portions of 641—Chapters 38 to 40. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

b. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of September 15, 2010.

41.2(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapters 38 to 40 may also apply. As used in 41.2(136C), the following definitions apply:

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

"Authorized medical physicist" means an individual who:

a. Meets the requirements of 41.2(74) and 41.2(77); or

b. Is identified as an authorized medical physicist or teletherapy physicist on:

1. A specific medical use license issued by this agency, the NRC, or an agreement state;
2. A medical use permit issued by an NRC master material licensee;
3. A permit issued by an NRC or agreement state broad scope medical use licensee; or
4. A permit issued by an NRC master material license broad scope medical use permittee.

"Authorized nuclear pharmacist" means a pharmacist who:

a. Has met the appropriate requirements of 41.2(77) and 41.2(78), or before May 3, 2006, meets the requirements in 10 CFR 35.980(a) and 10 CFR 35.59; or:

b. Is identified as an authorized nuclear pharmacist on:

1. A specific license issued by the agency, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;
2. A permit issued by an NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;
3. A permit issued by the NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
4. A permit issued by an NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

c. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

d. Is designated as an authorized nuclear pharmacist in accordance with 641—39.4(29)*"j"*(2)"3."

"Authorized user" means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67)*"a,"*41.2(68)*"a,"*41.2(69)*"a,"*41.2(70)*"a,"*41.2(72)*"a,"*41.2(73)*"a,"*41.2(81)*"a,"* or 41.2(82)*"a,"* or before May 3, 2006, meets the requirements in 10 CFR 35.910(a), 35.920(a), 35.930(c), 35.940(a), 35.950(a), or 35.960(a) and 10 CFR 35.59; or who is identified on:

1. A current Iowa, NRC, or agreement state license that authorizes the medical use of radioactive material;
2. A permit issued by an NRC master material licensee that is authorized to permit the medical use of radioactive material;
3. A permit issued by an NRC, agreement state, or Iowa-specific licensee of broad scope that is authorized to permit medical use of radioactive material; or
4. A permit issued by an NRC master material license broad scope permittee that is authorized to permit medical use of radioactive material.

"Dedicated check source" means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Management" means the chief executive officer or that individual's designee.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

"Radiation safety officer" means an individual who, in addition to the definition in 641—38.2(136C), meets the requirements of 41.2(77) and 41.2(65)*"a,"* or 41.2(65)*"c"*(1), or before May 3, 2006, meets the requirements in 10 CFR 35.900(a) and 10 CFR 35.59; or is identified as a radiation safety officer on a specific medical use license issued by Iowa, the NRC, or agreement state or a medical use permit issued by an NRC master material licensee.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an agency license.

"Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) *License required.*

a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

c. An individual may prepare unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user as provided in 41.2(11) unless prohibited by license condition.

d. A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Nothing in this subrule relieves the licensee from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

e. An applicant that satisfies the requirements of 641—paragraph 39.4(28)*"b"* may apply for a Type A specific license of broad scope.

41.2(4) *License amendments.* A licensee shall apply for and receive a license amendment:

a. Before using radioactive material for a method or type of medical use not permitted by the license issued under this rule;

b. Before permitting anyone, except a visiting authorized user described in 41.2(12), to work as an authorized user or authorized nuclear pharmacist under the license;

c. Before changing a radiation safety officer or teletherapy physicist;

d. Before receiving radioactive material in excess of the amount authorized on the license;

e. Before adding to or changing the address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

41.2(5) *Notifications.*

a. A licensee shall provide to the agency a copy of the board certification, the NRC or agreement state license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as a visiting authorized user or a visiting authorized nuclear pharmacist.

b. A licensee shall notify the agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

c. The licensee shall mail the documents required in this subrule to the Iowa Department of Public Health, Des Moines, Iowa.

d. Exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provision of 41.2(4)*"b"*;

(2) The provisions of 41.2(4)*"e"* regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provision of 41.2(5)*"a"*;

(4) The provisions of 41.2(5)*"b"*(1) for authorized user or an authorized nuclear pharmacist.

41.2(6) *Maintenance of records.*

a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.

c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6)*"a"* and *"b."*

41.2(7) *ALARA program.*

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(3).

b. To satisfy the requirement of 41.2(7)*"a"*:

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9)*"b"*(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) *Radiation safety officer.*

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

1. Authorizing the purchase of radioactive material;
2. Receiving and opening packages of radioactive material;
3. Storing radioactive material;

4. Keeping an inventory record of radioactive material;
5. Using radioactive material safely;
6. Taking emergency action if control of radioactive material is lost;
7. Performing periodic radiation surveys;
8. Performing checks and calibrations of survey instruments and other safety equipment;
9. Disposing of radioactive material;
10. Training personnel who work in or frequent areas where radioactive material is used or stored; and
11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

41.2(9) *Radiation safety committee.* Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the radiation safety officer and the management's representative.

(4) The minutes of each radiation safety committee meeting shall include:

1. The date of the meeting;
2. Members present;
3. Members absent;
4. Summary of deliberations and discussions;
5. Recommended actions and the numerical results of all ballots; and
6. Document any reviews required in 41.2(7)*"c"* and 41.2(9)*"b."*

(5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review:

1. Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;

2. Review on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;

(5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

41.2(10) *Authority and responsibilities for the radiation protection program.*

a. In addition to the radiation protection program requirements of 641—40.10(136C), a licensee's management shall approve in writing:

(1) Requests for a license application, renewal, or amendment before submittal to this agency;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment.

b. A licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the radiation safety officer, shall ensure that the radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

c. For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer under 41.2(65) or 41.2(75) to function as a temporary radiation safety officer to perform the functions of radiation safety officer, as provided in 41.2(10)*"g,"* if the licensee takes the actions required in 41.2(10)*"b," "e," "g,"* and *"h"* and notifies this agency in accordance with 41.2(5).

d. A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with 41.2(10)*"c"* if needed to ensure that the licensee has a temporary radiation safety officer who satisfies the requirements to be a radiation safety officer for each of the different types of by-product material permitted on the license.

e. A licensee shall establish the authority, duties, and responsibilities of the radiation safety officer in writing.

f. Licensees that are authorized for two or more different types of uses of radioactive materials or two or more types of units under this rule shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license.

g. A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective solutions;

(3) Verify implementation of corrective actions; and

(4) Stop unsafe operations.

h. A licensee shall retain a record of actions taken under 41.2(10) in accordance with 641—40.80(136C).

41.2(11) *Supervision.*

a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules of this chapter, and license conditions appropriate to that individual's use of radioactive material;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals certified and issued a current permit to practice in accordance with 641—Chapter 42 as a nuclear medicine technologist or a radiation therapist, as applicable, or an Iowa-licensed physician and designated by the authorized user, shall be permitted to administer radionuclides (sealed sources only for radiation therapists) or radiation to patients or human research subjects. For a nuclear medicine technologist or a radiation therapist, the individual's permit to practice shall be made available at the individual's place of employment. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:

(1) Follow the instructions of the supervising authorized user for the medical uses of by-product material;

(2) Follow the written radiation protection and written directive procedures established by the radiation safety officer; and

(3) Comply with these rules and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 41.2(3)*"c,"* shall, in addition to the requirements in 641—40.111(136C):

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written procedures for maintaining written directives, as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

41.2(12) *Visiting authorized user and visiting authorized nuclear pharmacist.*

a. A licensee may permit any visiting authorized user or visiting authorized nuclear pharmacist to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user or visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of an agency, agreement state, licensing state or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user or visiting authorized nuclear pharmacist by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user or visiting authorized nuclear pharmacist is specifically authorized by an agency (agreement state, licensing state or U.S. Nuclear Regulatory Commission) license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user or visiting authorized nuclear pharmacist to use licensed material as described in 41.2(12)*"a."*

c. A licensee shall retain copies of the records specified in 41.2(12)*"a"* for five years from the date of the last visit.

41.2(13) *Mobile nuclear medicine service administrative requirements.*

a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material and clearly delineates the authority of the licensee and client.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

e. Mobile nuclear medicine service licensees shall also perform the following:

(1) Check instruments used to measure the activity of unsealed radioactive material for proper function before use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this rule must include a constancy check;

(2) Check survey instruments for proper operation with a dedicated check source before use at each client's address;

(3) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements of 641—Chapters 40 and 41.

41.2(14) *Records and reports of misadministrations and reportable medical events.*

a. When a misadministration or reportable medical event, as defined in 641—38.2(136C), occurs, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient's or human research subject's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration or reportable medical event. If the referring physician, patient or human research subject, or the patient's or human research subject's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient's or human research subject's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this notification requirement including remedial care as a result of the misadministration or reportable medical event because of any delay in notification.

b. Written reports.

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration or reportable medical event. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event, why the event occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, actions taken to prevent recurrence, whether the licensee notified the patient or the human research subject or the patient's or the human research subject's responsible relative or guardian (this individual will subsequently be referred to as "the patient or the human research subject"), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(2) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration or reportable medical event, a written report to the patient or the human research subject and the referring physician by sending either:

1. A copy of the report that was submitted to the agency; or

2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. Rescinded IAB 4/4/01, effective 5/9/01.

d. Each licensee shall retain a record of each misadministration for ten years and each reportable medical event for three years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14)*"a"* to 41.2(14)*"d"* shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Report and notification of a dose to an embryo/fetus or a nursing child.

(1) A licensee shall report any dose to an embryo/fetus that is greater than 5 rem (50 mSv) dose equivalent that is a result of an administration of by-product material or radiation from by-product material to a pregnant individual unless the embryo/fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of by-product material to a breast-feeding individual that:

1. Is greater than 5 rem (50 mSv) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify this agency by telephone no later than the next calendar day after a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)*"f"*(1) or (2).

(4) The licensee shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 41.2(14)*"f"*(1) or (2).

1. The written report must include:

- The licensee's name;
- The name of the prescribing physician;
- A brief description of the event;
- Why the event occurred;
- The effect, if any, on the embryo/fetus or the nursing child;
- What actions, if any, have been taken or are planned to prevent recurrence; and
- Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 41.2(14)*"f"*(1) or (2), unless the referring physician personally informs the licensee either that the physician will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

1. Annotate a copy of the report provided to the agency with the:

- Name of the pregnant individual or the nursing child who is the subject of the event; and

- Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

41.2(15) *Suppliers.* A licensee shall use for medical use only:

a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and

b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration;

c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

41.2(16) *Quality control of imaging equipment.* Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) *Possession, use, calibration, and check of dose calibrators.*

a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

b. A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on frequently used settings with a sealed source of not less than 10 microcuries (370 kBq) of radium-226 or 50 microcuries (1.85 MBq) of any other photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium-226 and 50 microcuries (1.85 MBq) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 30 microcuries (1.1 megabequerels) and the highest dosage that will be administered; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

d. A licensee shall also perform checks and tests required by 41.2(17)*"b"* following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by 41.2(17) for three years. The records required by 41.2(17)*"b"* shall include:

(1) For 41.2(17)*"b"*(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For 41.2(17)*"b"*(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the individual performing the test, and the signature of the radiation safety officer;

(3) For 41.2(17)*"b"*(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer; and

(4) For 41.2(17)*"b"*(4), the model and serial number of the dose calibrator, the configuration calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer.

41.2(18) *Calibration and check of survey instruments.*

a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of 41.2(18)*"a,"* the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18)*"b,"* the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in 41.2(18)*"a"* for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18)*"a," "b,"* and *"c,"* the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18)*"e"* shall be maintained by the licensee.

g. Rescinded IAB 8/1/07, effective 9/5/07.

41.2(19) *Assay of radiopharmaceutical dosages.* A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains a photon-emitting radionuclide;

b. Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements;

c. Not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent unless otherwise directed by the authorized user; and

d. Retain a record of the assays required by 41.2(19)*"a"* for three years. To satisfy this requirement, the record shall contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's or human research subject's name and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);

(4) Date and time of the assay and administration; and

(5) Initials of the individual who performed the assay.

41.2(20) *Authorization for calibration and reference sources.* Any person authorized by 41.2(3) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the U.S. Nuclear Regulatory Commission, agreement state or licensing state and that do not exceed 15 millicuries (555 MBq) each;

b. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);

c. Any radioactive material listed in 41.2(31) or 41.2(33) with a half-life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and

d. Technetium-99m in individual amounts not to exceed 50 millicuries (1.85 GBq).

41.2(21) *Requirements for possession of sealed sources and brachytherapy sources.*

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall ensure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of 41.2(21)*"b,"* the licensee shall ensure that:

(1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the "off" position.

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becquerels), a description of the method used to measure each test sample, the date of the test, and the signature of the radiation safety officer.

e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and

(2) File a report with the agency within five days of receiving the leak test results. The report shall describe the equipment involved, the model and serial number of the leaking source, the radionuclide and its estimated activity, the test results, the date of the test, and the action taken.

f. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half-life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material; [and]

(4) Seeds of iridium-192 encased in nylon ribbon; and

(5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the radiation safety officer.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in 41.2(21)*"h"* for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) *Syringe shields.*

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. Unless otherwise approved by this agency, a licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

41.2(23) *Syringe labels.* Unless utilized immediately, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

41.2(24) *Vial shields.* A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

41.2(25) *Vial shield labels.* A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

41.2(26) *Surveys for contamination and ambient radiation dose rate.*

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by 41.2(26)*"a"* and *"b"* so as to be able to measure dose rates as low as 0.1 millirem (1 μSv) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26)*"a"* and *"b"* and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by 41.2(26)*"e"* so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26)*"e"* and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by 41.2(26)*"a," "b,"* and *"e"* for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

i. A licensee does not need to perform the surveys required in this subrule in an area where the patient or human research subject is confined and cannot be released under 41.2(27).

41.2(27) *Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.*

a. The licensee may authorize the release from its control of any individual who has been administered unsealed radioactive materials or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv). (NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).)

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast feeding, and

(2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered,

(2) Using an occupancy factor less than 0.25 at 1 meter,

(3) Using the biological or effective half-life, or

(4) Considering the shielding by tissue.

d. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). IDPH Regulatory Guide, Release of Patients Administered Radioactive Materials describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

41.2(28) *Mobile nuclear medicine service technical requirements.* A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in 41.2(17)*"b"*(1)*"d"* and *"e"* and 41.2(18)*"d"* and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

f. Retain a record of each survey required by 41.2(28)*"e"* for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) *Storage of volatiles and gases.*

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) *Decay-in-storage.*

a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

(1) Holds radioactive material for decay a minimum of ten half-lives;

(2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with 41.2(30)*"a,"* the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

41.2(31) *Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements or from a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24)*"h"* or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69) and has work experience in eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(31)*"b"*(1) or the physician who is an authorized user in 41.2(31)*"b"*(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(32) *Possession of survey instrument.* A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 μSv) per hour to 50 millirems (500 μSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(33) *Use of unsealed by-product material for imaging and localization studies for which a written directive is not required.* Except for quantities that require a written directive under 41.2(87), a licensee may use for imaging and localization studies any unsealed by-product material prepared for medical use that:

a. Is obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements or a PET radioactive drug producer licensed pursuant to 641—paragraph 39.4(24)*"h"* or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in 41.2(68) or 41.2(69);

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(33)*"b"*(1) or the physician who is an authorized user in 41.2(33)*"b"*(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

41.2(34) *Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.*

a. A licensee shall not administer to humans a radiopharmaceutical that contains:

(1) More than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m); or

(2) More than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-82 per megabecquerel rubidium-82 chloride); or more than 0.02 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel strontium-85 per megabecquerel rubidium-82 chloride).

b. A licensee preparing:

(1) Technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract; or

(2) Rubidium-82 radiopharmaceuticals from strontium-82/rubidium-82 generators shall measure the strontium-82 and strontium-85 concentration before the first patient use of the day.

c. A licensee who must measure molybdenum-99, strontium-82, or strontium-85 concentration shall retain a record of each measurement for three years. The record shall include:

(1) For each elution or extraction of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

(2) For each elution or extraction of rubidium-82, the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (kilobecquerels of strontium-82 per megabecquerel of rubidium-82), microcuries of strontium-85 per millicurie of rubidium-82 (kilobecquerels of strontium-85 per millicurie of rubidium-82), the date of the test, and the initials of the individual who performed the test.

d. A licensee shall report immediately to the agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 41.2(34)*"a"*(1) and strontium-82 or strontium-85 concentration exceeding the limits specified in 41.2(34)*"a"*(2).

41.2(35) *Control of aerosols and gases.*

a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—40.15(136C) and 641—40.26(136C) of these rules.

b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in 41.2(35)*"a"* at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

g. A copy of the calculations required in 41.2(35)*"d"* shall be recorded and retained for the duration of the license.

41.2(36) *Possession of survey instruments.* A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(37) *Use of unsealed by-product material for which a written directive is required.* A licensee may use any unsealed by-product material prepared for medical use and for which a written directive is required that:

a. Is obtained from:

(1) A manufacturer or preparer licensed under 641—paragraph 39.4(29)*"j"* or equivalent NRC or agreement state requirements; or

(2) A PET radioactive drug producer licensed under 641—paragraph 39.4(24)*"h"* or equivalent NRC or agreement state requirements; or

b. Excludes production of PET radionuclides, prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements of 41.2(68) or 41.2(69); or

(3) An individual under the supervision, as specified in 41.2(11), of the authorized nuclear pharmacist in 41.2(37)*"b"*(1) or the physician who is an authorized user in 41.2(37)*"b"*(2); or

c. Is obtained from and prepared by an NRC or agreement state licensee for use in research in accordance with the Investigational New Drug (IND) protocol accepted by FDA; or

d. Is prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

41.2(38) *Safety instruction.*

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 41.2(27). Refresher training shall be provided at intervals not to exceed one year.

b. To satisfy 41.2(38)*"a,"* the instruction shall describe the licensee's procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control;

(5) Notification of the radiation safety officer, radiation safety officer designee, or authorized user in case of the patient's or human research subject's death or medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) and adopted by reference and included herein.

c. A licensee shall keep a record of individuals receiving instruction required by 41.2(38)*"a,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

41.2(39) *Safety precautions.*

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:

(1) Provide a private room with a private sanitary facility or a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under 41.2(27);

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.26(1) which is adopted by reference and included herein and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) Provide the patient or human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;

(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 during the period which starts the first day after administration and ends the fourth day after administering the dosage, and retain for the period required by 641—paragraph 40.82(2)*"c"* which is adopted and included herein a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(40) *Possession of survey instruments.* A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(41) *Use of sealed sources for diagnosis.* A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

41.2(42) *Availability of survey instrument.* A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(43) *Use of sources for brachytherapy.* A licensee shall use only brachytherapy sources for therapeutic medical uses:

a. As approved in the Sealed Source and Device Registry; or

b. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(44) *Safety instruction.*

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

b. To satisfy 41.2(44)*"a,"* the instruction shall describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient or human research subject control;

(4) Procedures for visitor control, to include routine visitation of hospitalized individuals in accordance with 641—40.26(136C) and visitation authorized in accordance with 641—40.26(136C);

(5) Procedures for notification of the radiation safety officer, radiation safety officer designee, or authorized user if the patient or human research subject dies or has a medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) as adopted by reference and included herein.

c. A licensee shall maintain a record of individuals receiving instruction required by 41.2(44)*"a,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

41.2(45) *Safety precautions.*

a. For each patient or human research subject receiving implant therapy a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—40.26(136C) as adopted by reference and included herein at a distance of 1 meter from the implant;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—40.26(136C) as adopted by reference and included herein; and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant; and

(6) Have applicable emergency response equipment available near each treatment room to respond to a source dislodged from the patient or lodged within the patient following removal of the source applicators.

b. A licensee shall notify the radiation safety officer, radiation safety officer designee, or authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(46) *Brachytherapy sources inventory.*

a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use and patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation

survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in 41.2(46)*"b"* and *"c"* for three years.

e. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

41.2(47) *Release of patients or human research subjects treated with temporary implants.*

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed and, for remote afterloaders, returned to the safe shielded position. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 41.2(47)*"a"* for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

41.2(48) *Possession of survey instruments.* A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(49) *Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.* A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses as approved in the Sealed Source and Device Registry or in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 41.2(15) are met.

41.2(50) *Installation, maintenance, adjustment, and repair.*

a. Only a person specifically licensed by the NRC or an agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), or reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

b. Except for low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

c. For low-dose-rate remote afterloader units, only a person specifically licensed by the NRC or an agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units for three years. The record must include the date, description of the service, and the name of the individual who performed the work.

41.2(51) *Amendments.* In addition to the requirements specified in 41.2(4), a licensee shall apply for and receive a license amendment before:

a. Making any change in the treatment room shielding;

b. Making any change in the location of the teletherapy unit within the treatment room;

c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

d. Relocating the teletherapy unit; or

e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

41.2(52) *Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma sterotactic radiosurgery units.*

a. A licensee shall:

(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

(2) Permit only individuals approved by the authorized user, radiation safety officer, or authorized medical physicist to be present in the treatment room during treatment with the source;

(3) Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or to remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by 41.2(52)*"a"*(4) must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

(1) The location of the procedures required by 41.2(52)*"a"*(4); and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

d. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, appropriate to the individual's assigned duties, in:

(1) The procedures identified in 41.2(52)*"a"*(4); and

(2) The operating procedures for the unit.

e. The licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures, initially and at least annually.

f. A licensee shall retain a record for three years of individuals receiving instruction required by 41.2(52)*"d,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. A copy of the procedures required in 41.2(52)*"a"*(4) and 41.2(52)*"d"*(2) shall be retained for three years.

41.2(53) *Safety precautions for remote afterloader units, teletherapy units, and gamma sterotactic radiosurgery units.*

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam "on-off" control is reset at the console.

c. A licensee shall require any individual entering the treatment room to ensure, through the use of appropriate monitors, that radiation levels have returned to ambient levels.

d. Except for low-dose-rate remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or human research subject from the treatment console during irradiation.

e. For licensed activities where sources are placed within the patient's or human research subject's body, the licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

f. In addition to the requirements specified in 41.2(53)*"a"* through *"e,"* a licensee shall:

(1) For medium-dose-rate and pulsed-dose-rate remote afterloader units, require:

1. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation of and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who have been trained to remove the source applicator in the event of an emergency involving the unit to be immediately available during continuation of all patient treatments involving the unit.

(2) For high-dose-rate remote afterloader units, require:

1. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

2. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who have been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this subparagraph, "physically present" means to be within hearing distance of normal voice.

(4) Notify the radiation safety officer, or the radiation safety officer designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

g. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment.

41.2(54) *Possession of survey instrument.* A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(55) *Radiation monitoring device.*

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by 41.2(55)*"d"* for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a

dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55)*"e."*

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

41.2(56) *Viewing system.* A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

41.2(57) *Dosimetry equipment.*

a. Except for low-dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The results of the intercomparison must indicate that the calibration factor of the licensee's system has not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, if applicable, and sources of the same radionuclide as the source used at the licensee's facility.

b. The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57)*"a."* This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 41.2(57)*"a."*

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57)*"a"* and *"b,"* the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) *Full calibration measurements on teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.*

a. Teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements for each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output of the last full calibration corrected mathematically for radioactive decay;
- Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
- Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

(2) To satisfy the requirements of 41.2(58)*"a"*(1), full calibration measurements must include determination of:

1. The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;

2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. The accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)*"a"*(2)"1" may be made using the dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)*"a"* in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)*"a"*(2)"1" for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1 percent of all other radionuclides.

(6) Full calibration measurements required by 41.2(58)*"a"*(1) and physical decay corrections required in 41.2(58)*"a"*(5) must be performed by the authorized medical physicist.

(7) A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration; the manufacturer's name, model number, and serial number for both the unit and the source; tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the measured timer accuracy for a typical treatment time; the calculated "on-off" error; the estimated accuracy of each distance measuring or localization device; and the signature of the authorized medical physicist.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements for each unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

- Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
- Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one quarter of a year for high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding one year for low-dose-rate remote afterloader units.

(2) To satisfy the requirements of 41.2(58)*"b"*(1), full calibration measurements must include, as applicable, determination of:

1. The output within ±5 percent;

2. Source positioning accuracy to within ±1 millimeter;

3. Source retraction with backup battery upon power failure;

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output.

(4) A licensee shall make full calibration measurements required by 41.2(58)*"b"*(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low-dose-rate remote afterloader units in 41.2(58)*"b"*(2), a licensee shall perform an autoradiograph of the source to verify inventory and source arrangement at intervals not exceeding one quarter of a year.

(6) For low-dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 41.2(58)*"b."*

(7) A licensee shall mathematically correct the outputs determined in 41.2(58)*"b"*(2)"1" for physical decay intervals consistent with 1 percent physical decay.

(8) Full calibration measurements required by 41.2(58)*"b"*(1) and physical decay corrections required by 41.2(58)*"b"*(7) must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with 41.2(58)*"a"*(7).

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;
2. Before medical use under the following conditions:

- Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
- Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
- Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of 41.2(58)*"c"*(1), full calibration measurements must include determination of:

1. The output within ±3 percent;
2. Relative helmet factors;
3. Isocenter coincidence;
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)*"c"*(2)"1" may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by 41.2(58)*"c"*(1) in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in 41.2(58)*"c"*(2)"1" at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(6) Full calibration measurements required by 41.2(58)*"c"*(1) and physical decay corrections required in 41.2(58)*"c"*(5) must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with 41.2(58)*"a"*(7).

41.2(59) *Periodic spot checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.*

a. Teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57); and

6. The difference between the measurement made in 41.2(59)*"a"*(1)"5" and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by 41.2(59)*"a"*(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the result of each spot check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility once in each calendar month and after each source installation to ensure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;

2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

4. Viewing and intercom systems;

5. Treatment room doors from inside and outside the treatment room; and

6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the spot checks required in 41.2(59)*"a"*(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)*"a."* The record must include:

1. The date of the spot check;

2. The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

3. An assessment of timer linearity and constancy;

4. The calculated on-off error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

6. The determined accuracy of each distance measuring and localization device;

7. The difference between the anticipated output and the measured output;

8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical source exposure indicator light, and the viewing and intercom system and doors; and

9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required by 41.2(59)*"a"*(2) until the licensee no longer possesses the teletherapy unit.

b. Remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot checks of each remote afterloader facility and on each unit:

1. Before the first use of a high-dose-rate, medium-dose-rate, or pulsed-dose-rate remote afterloader unit on a given day;

2. Before each patient treatment with a low-dose-rate remote afterloader unit; and

3. After each source installation.

(2) A licensee shall perform the measurements required by 41.2(59)*"b"*(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(4) To satisfy the requirements of 41.2(59)*"b"*(1), spot checks must, at a minimum, ensure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high-dose-rate, medium-dose-rate, and pulsed-dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

(5) If the results of the spot checks required in 41.2(59)*"b"*(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or spot check the malfunctioning system.

(6) A licensee shall retain for three years a record of each spot check required in 41.2(59)*"b"*(4). The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
3. An assessment of timer accuracy;
4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
5. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(7) A licensee shall retain a copy of the procedures required in 41.2(59)*"b"*(2) until the licensee no longer possesses the remote afterloader unit.

c. Gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot checks for the gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

(2) A licensee shall:

1. Perform the measurements required by 41.2(59)*"c"*(1) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.
2. Have the authorized medical physicist review the results of each spot check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(3) To satisfy the requirements of 41.2(59)*"c"*(1)"1," spot checks must, at a minimum:

1. Ensure proper operation of treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; helmet microswitches; emergency timing circuits; and stereotactic frames and localizing devices (trunnions).
2. Determine:

- The output for one typical set of operating conditions measured with the dosimetry system described in 41.2(57);
- The difference between the measurement made in the above bulleted point and the anticipated output expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
- Source output against computer calculation;
- Timer accuracy and linearity over the range of use;
- On-off error; and
- Trunnion centricity.

(4) To satisfy the requirements of 41.2(59)*"c"*(1)"2" and "3," spot checks must ensure proper functioning of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

(5) A licensee shall arrange as soon as possible for the repair of any system identified in 41.2(59)*"c"*(3) that is not operating properly.

(6) If the results of the spot checks required in 41.2(59)*"c"*(4) indicate the malfunction of any system, the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(7) A licensee shall retain for three years a record of each spot check required by 41.2(59)*"c"*(3) and (4). The record must include:

1. The date of the spot check;
2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the survey instrument used to measure the output of the unit;
3. An assessment of timer linearity and accuracy;
4. The calculated on-off error;
5. A determination of trunnion centricity;
6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, on-off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
9. The name of the individual who performed the periodic spot check and the signature of the authorized medical physicist who reviewed the record of the spot check.

(8) A licensee shall retain a copy of the procedures required in 41.2(59)*"c"*(2) until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

41.2(60) *Radiation surveys for teletherapy facilities.*

a. In addition to the survey requirements in 641—40.36(136C), a person licensed under 641—41.2(136C) shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

b. The licensee shall make the survey required in 41.2(60)*"a"* at installation of a new source, and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the source.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason

the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) *Safety spot checks for teletherapy facilities.*

a. A licensee shall promptly check all systems listed in 41.2(59)*"g"* for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61)*"a"* indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program, the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);

b. Perform the survey required by 41.2(60) again; and

c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62)*"a,"* and the results of the second survey; or

d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Five-year inspection.*

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the agency, an agreement state, or the U.S. Nuclear Regulatory Commission.

c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and gamma stereotactic radiosurgery unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) *Training for radiation safety officer.* Except as provided in 41.2(75), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by this agency, NRC, or an agreement state and who meets the requirements in 41.2(65)*"d"* and *"e."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall:

(1) Require all candidates for certification to:

1. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

2. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

3. Pass an examination administered by diplomats of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

(2) Require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two years of either full-time practical training or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state, or in clinical nuclear medicine facilities providing either diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 41.2(68), 41.2(69), or 41.2(75); and

3. Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. Has completed a structured educational program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Radiation dosimetry; and

(2) One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on an agency, NRC, or agreement state license or permit issued by the NRC master material licensee that authorizes similar types of use of radioactive material involving the following:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

3. Securing and controlling radioactive material;

4. Using administrative controls to avoid mistakes in the administration of radioactive material;

5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

6. Using emergency procedures to control radioactive material; and

7. Disposing of radioactive material; or

c. (1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state under 41.2(74) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as a radiation safety officer and who meets the requirements in 41.2(65)*"d"* and *"e"*; or

(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities; and

d. Has obtained written attestation, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in 41.2(65)*"e"* and 41.2(65)*"a"*(1)"1" and "2" or 41.2(65)*"a"*(2)"1" and "2" or 41.2(65)*"b"*(1) or 41.2(65)*"c"*(1), and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; and

e. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee is seeking approval. This training requirement may be satisfied by completing training that is supervised by a radiation safety officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type of use for which the licensee is seeking approval.

41.2(66) *Training for experienced radiation safety officer.* Rescinded IAB 3/29/06, effective 5/3/06.

41.2(67) *Training for uptake, dilution, and excretion studies.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(31) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(67)*"c."* (The names of specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in 41.2(67)*"c"*(1)"1" and "2"; and

(2) Pass an examination administered by diplomats of the specialty board that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(68) or 41.2(69) or meets equivalent NRC or agreement state requirements; or

c. (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

1. Classroom and laboratory training in radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity, chemistry of radioactive material for medical use, and radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(67), 41.2(68), 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(67)*"a"*(1) or 41.2(67)*"c"*(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized in 41.2(31).

41.2(68) *Training for imaging and localization studies.* Except as provided in 41.2(75), the licensee shall require the authorized user of unsealed radioactive material for the uses authorized under 41.2(33) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(68)*"c."* (The names of specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on

the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 41.2(68)*"c"*(1)"1" and "2"; and

(2) Pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under 41.2(69) and meets the requirements in 41.2(68)*"c"*(1)"2," seventh bulleted paragraph, or equivalent NRC or agreement state requirements; or

c. (1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use;
- Radiation biology, and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(68); 41.2(68)*"c"*(1)"2," seventh bulleted paragraph, and 41.2(69); 41.2(75); or equivalent NRC or agreement state requirements, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Administering dosages of radioactive drugs to patients or human research subjects; and
- Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(68); 41.2(69) and 41.2(68)*"c"*(1)"2," seventh bulleted paragraph; 41.2(75); or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(68)*"a"*(1) or 41.2(68)*"c"*(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(31) and 41.2(33).

41.2(69) *Training for use of unsealed by-product material for which a written directive is required.* Except as provided in 41.2(75), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 41.2(37) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, and 41.2(69)*"b"*(2). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in 41.2(69)*"b"*(1)"1" through 41.2(69)*"b"*(1)"2,"

fifth bulleted paragraph. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

b. (1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

1. Classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity;
- Chemistry of radioactive material for medical use; and
- Radiation biology; and

2. Work experience, under the supervision of an authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)*"b"*(1)"2," seventh bulleted paragraph) as the individual requesting authorized user status. The work experience must involve:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient or human research subject dosages;
- Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- Reserved.
- Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

– Oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required;

– Oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 (experience with at least three cases in this category also satisfies the requirement in the above category);

– Parenteral administration of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; or

– Parenteral administration of any other radionuclide for which a written directive is required; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(69)*"a"*(1) and 41.2(69)*"b"*(1)"2," seventh bulleted paragraph, or 41.2(69)*"b"*(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69) or 41.2(75) or equivalent NRC or agreement state requirements. The preceptor authorized user who meets the requirements in 41.2(69)*"b"* must have experience in administering dosages in the same dosage category or categories (i.e., 41.2(69)*"b"*(1)"2," seventh bulleted paragraph) as the individual requesting authorized user status.

c. For training only for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) or quantities greater than 33 millicuries (1.22 gigabecquerels), see 41.2(81) or 41.2(82).

41.2(70) *Training for use of manual brachytherapy sources.* Except as provided in 41.2(75), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 41.2(43) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state, and who meets the requirements in 41.2(70)*"b"*(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

b. (1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;
- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements at a medical institution, involving:

- Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- Checking survey meters for proper operation;
- Preparing, implanting, and removing brachytherapy sources;
- Maintaining running inventories of material on hand;
- Using administrative controls to prevent a medical event involving the use of radioactive material; and
- Using emergency procedures to control radioactive material; and

(2) Has completed three years of supervised clinical experience in radiation oncology under an authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in 41.2(70)*"b"*(1)"2"; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(70)*"a"*(1) or 41.2(70)*"b"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 41.2(43).

41.2(71) *Training for ophthalmic use of strontium-90.* Except as provided in 41.2(75), the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under 41.2(70) or equivalent NRC or agreement state requirements; or

b. (1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

(2) Has completed supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

1. Examination of each individual to be treated;
2. Calculation of the dose to be administered;
3. Administration of the dose; and
4. Follow-up and review of each individual's case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 41.2(70), 41.2(71) or 41.2(75) or equivalent NRC or agreement state requirements, that the individual has satisfactorily completed the requirements in 41.2(71)*"b"*(1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

41.2(72) *Training for use of sealed sources for diagnosis.* Except as provided in 41.2(75), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 41.2(41) to be a physician, dentist, or podiatrist who:

a. Is certified by a specialty board whose certification process includes all of the requirements in 41.2(72)*"b"* and *"c"* and whose certification has been recognized by the agency, NRC, or an agreement state. (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

b. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

(1) Radiation physics and instrumentation;
(2) Radiation protection;
(3) Mathematics pertaining to the use and measurement of radioactivity; and
(4) Radiation biology; and

c. Has completed training in the use of the device for the uses requested.

41.2(73) *Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.* Except as provided in 41.2(75), the licensee shall require an authorized user of a sealed source for a use authorized under 41.2(49) to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the agency, NRC, or an agreement state, and who meets the requirements in 41.2(73)*"b"*(3) and 41.2(73)*"c."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and

(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

b. (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

1. 200 hours of classroom and laboratory training in the following areas:

- Radiation physics and instrumentation;
- Radiation protection;

- Mathematics pertaining to the use and measurement of radioactivity; and
- Radiation biology; and

2. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements at a medical institution, involving:

- Reviewing full calibration measurements and periodic spot checks;
- Preparing treatment plans and calculating treatment doses and times;
- Using administrative controls to prevent a medical event involving the use of radioactive material;
- Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
- Checking and using survey meters; and
- Selecting the proper dose and how it is to be administered; and

(2) Has completed three years of supervised clinical experience in radiation therapy under an authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by 41.2(73)*"b"*(1)"2"; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(73)*"a"*(1) or 41.2(73)*"b"*(1) and (2), and 41.2(73)*"c,"* and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(73) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and

c. Has received training in device operation, safety procedures, and clinical use for the type of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type of use for which the individual is seeking authorization.

41.2(74) *Training for an authorized medical physicist.* Except as provided in 41.2(75), the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(74)*"b"*(2) and 41.2(74)*"c."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(2) Have two years of either full-time practical training or supervised experience in medical physics:

1. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state; or

2. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 41.2(70), 41.2(73), or 41.2(75); and

(3) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

b. (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;
2. Performing decay corrections;
3. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and
4. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units, as applicable; and

(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(74)*"a"*(1) and (2) and 41.2(74)*"c"* or 41.2(74)*"b"*(1) and 41.2(74)*"c,"* and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 41.2(74) or 41.2(75) or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

c. Has training for the type of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist who is authorized for the type of use for which the individual is seeking authorization.

41.2(75) *Training for experienced radiation safety officer, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, authorized users and teletherapy or medical physicists.*

a. (1) An individual identified as a radiation safety officer, teletherapy or medical physicist, or nuclear pharmacist on an agency, NRC or agreement state license or a permit issued by an NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before January 1, 2003, does not need to comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).

(2) An individual identified as a radiation safety officer, an authorized medical physicist, or an authorized nuclear pharmacist on the agency, NRC, or agreement state license or permit issued by the agency, NRC, or agreement state broad scope licensee or issued by master material license permit or issued by a master material license permittee of broad scope between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(65), 41.2(74), or 41.2(78).

b. (1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the agency, the NRC, or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee before January 1, 2003, who perform only those medical uses for which they were authorized before that date need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material issued by the agency, the NRC, or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope licensee, or a permit issued by an NRC master material license broad scope permittee who perform only those medical uses for which they were authorized between January 1, 2003, and May 3, 2006, need not comply with the training requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), 41.2(73), 41.2(81), 41.2(82), or 41.2(89).

c. Individuals who need not comply with training requirements as described in this subrule may serve as preceptors for, and supervisors of, applicants seeking authorization on an agency license for the same uses for which these individuals are authorized.

41.2(76) *Physician training in a three-month program.* Rescinded IAB 8/1/07, effective 9/5/07.

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(78) and 41.2(81), 41.2(82), and 41.2(89) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

41.2(78) *Training for an authorized nuclear pharmacist.* Except as provided in 41.2(75), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements of 41.2(78)*"b."* (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:

(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

(2) Hold a current, active license to practice pharmacy;

(3) Provide evidence of having acquired at least 4,000 hours of combined training and experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience; and

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

b. Has completed 700 hours in a structured education program consisting of both:

(1) 200 hours of classroom and laboratory training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
4. Using administrative controls to avoid medical events in the administration of by-product material; and
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

c. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78)*"a"*(1), (2), and (3), or 41.2(78)*"b"*(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

41.2(79) *Training for experienced nuclear pharmacists.* Rescinded IAB 8/1/07, effective 9/5/07.

41.2(80) *Training for nuclear medicine technologists.* Rescinded IAB 4/2/03, effective 5/7/03.

41.2(81) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a

written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(81)*"c"*(1) and (2) and whose certification process has been recognized by the agency, NRC, or an agreement state and who meets the requirements in 41.2(81)*"c"*(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

b. Is an authorized user under 41.2(69)*"a"* or *"b"* for uses in the oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 for which a written directive is required, or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or 41.2(82) or equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)*"a"* or *"b,"*41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of less than or equal to 33 millicuries (1.22 Gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(81)*"c"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75), 41.2(81) or 41.2(82) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in administering dosages as follows: oral administration of less than or equal to 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131, for which a written directive is required; or oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131.

41.2(82) *Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels).* Except as provided in 41.2(75), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels) to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in 41.2(82)*"c"*(1) and (2), and whose certification has been recognized by the agency, NRC, or agreement state, and who meets the requirements in 41.2(82)*"c"*(3). (The names of the specialty boards that have been recognized by the agency, NRC, or agreement state must be posted on the NRC's Web page.); or

b. Is an authorized user under 41.2(69)*"a"* or *"b"* for oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131 or meets equivalent NRC or agreement state requirements; or

c. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69)*"a"* or *"b,"*41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements. A supervising authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of radioactive material;
5. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects that include at least three cases involving the oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(82)*"c"*(1) and (2), and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized in 41.2(37). The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(82) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69)*"b"* must also have experience in oral administration of greater than 33 millicuries (1.22 gigabecquerels) of sodium iodide I-131.

41.2(83) *Provisions for the protection of human research subjects.*

a. A licensee may conduct research involving human research subjects only if the licensee uses the radioactive materials authorized on its specific license for the uses authorized on its license.

b. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and

receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

d. Nothing in this subrule relieves a licensee from complying with the other requirements of these rules.

41.2(84) *Calibration measurements of brachytherapy sources.*

a. Before the first medical use of a brachytherapy source on or after January 1, 2003, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of 41.2(57);

(2) Determined the source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 41.2(84)*"a."*

b. A licensee may use measurements that are provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine and that are made in accordance with 41.2(84)*"a"*(1) and (2).

c. A licensee shall mathematically correct the outputs or activities determined in 41.2(84)*"a"* for physical decay at intervals consistent with 1 percent physical decay.

d. A licensee shall retain a record of each calibration for three years after the last use of the source. The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

41.2(85) *Decay of strontium-90 sources for ophthalmic treatment.*

a. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(84).

b. A licensee shall retain a record of the activity of each strontium-90 source in accordance with 41.2(84).

41.2(86) *Therapy-related computer systems.* The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance must include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine sealed source positions from radiographic images; and

e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of unsealed by-product material or any therapeutic dose of radiation from by-product material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable.

(2) The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

b. Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate setting per treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, dose per fraction, number of fractions and total dose; or

(6) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radioisotope, number of sources, and source strengths and dose; and

2. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, equivalently, the total dose);

(7) For therapeutic use of radiation machines, see 41.3(14).

c. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive.

d. The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives.

e. Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41.

f. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

g. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed by-product material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable.

(2) The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user with 48 hours of the oral revision.

h. A copy of the written directive in auditable form shall be retained for three years after the date of administration.

41.2(88) *Other medical uses of by-product material or radiation from by-product material.* A licensee may use by-product material or a radiation source approved for medical use which is not specifically addressed in 641—41.2(136C)(e.g., Y-90 microspheres, liquid brachytherapy, intravascular brachytherapy) if:

a. The applicant or licensee has submitted the information required by the agency; and

b. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with the regulations and specific conditions the agency considers necessary for the medical use of the material.

41.2(89) *Training for the parenteral administration of unsealed by-product material requiring a written directive.* Except as provided in 41.2(75), the licensee shall require an authorized user for the parenteral administration requiring a written directive to be a physician who:

a. Is an authorized user under 41.2(69) for parenteral administration of either any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required or equivalent NRC or agreement state requirements; or

b. Is an authorized user under 41.2(70) or 41.2(73) or equivalent NRC or agreement state requirements, and who meets the requirements in 41.2(89)*"d"*; or

c. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an agreement state under 41.2(70) or 41.2(73) and who meets the requirements in 41.2(89)*"d"*; or

d. (1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of radioactive material for medical use; and
5. Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements, in the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in 41.2(69) must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or parenteral administration of any other radionuclide for which a written directive is required. The work experience must involve:

1. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
2. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
3. Calculating, measuring, and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
5. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
6. Administering dosages to patients or human research subjects, that include at least three cases involving the parenteral administration for which a written directive is required, of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in 41.2(89)*"b"* or *"c,"* and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed by-product material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in 41.2(69), 41.2(75) or 41.2(89) or equivalent NRC or agreement state requirements. A preceptor authorized user who meets the requirements in 41.2(69) must have experience in administering dosages of either any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required.

[**ARC 7983B**, IAB 7/29/09, effective 9/2/09; **ARC 8982B**, IAB 8/11/10, effective 9/15/10; **ARC 0577C**, IAB 2/6/13, effective 3/13/13]

641—41.3(136C) Therapeutic use of radiation machines.

41.3(1) Scope and applicability.

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(5).

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), the following definitions are specific to 641—41.3(136C).

"Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

"Beam-scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Contact therapy system" means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than 5 centimeters.

"Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Field flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Megavolt (MV) (mega electron volt (MeV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

"Monitor unit (MU)." See "Dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams

with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"Radiation field." See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation therapy physicist" means an individual qualified in accordance with 41.3(6).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Target" means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Tenth-value layer (TVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

"Virtual source" means a point from which radiation appears to originate.

41.3(3) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 39.4(136C).

41.3(4) General administrative requirements for facilities using therapeutic radiation machines.

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of 41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) Training for external beam radiation therapy authorized users. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5)*"b"* above, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4)*"b"* above, training shall be under the supervision of an authorized user and shall include:

(1) Reviewing the full calibration measurements and periodic quality assurance checks;

(2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Postadministration follow-up and review of case histories.

f. Notwithstanding the requirements of 41.3(5)*"b,"* the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

g. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant.

41.3(6) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

a. Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen-ray and gamma-ray physics; or

(3) X-ray and radium physics; or

(4) Radiological physics; or

c. Be certified by the American Board of Medical Physics in radiation oncology physics; or

d. Be certified by the Canadian College of Physicists in Medicine; or

e. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16)*"a,"*41.3(17)*"c"* and *"d,"* and 41.3(18)*"e"* and *"f"* under the supervision of a radiation therapy physicist during the year of work experience.

f. Rescinded IAB 4/3/02, effective 5/8/02.

41.3(7) Qualifications of operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and hold a current permit to practice in radiation therapy as a radiation therapist under the provisions of 641—Chapter 42.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing arts purposes.

41.3(10) Records of visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under the following conditions:

a. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

b. The visiting authorized user meets the requirements of 41.3(5); and

c. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the agency:

a. Report of acceptance testing;

b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 41.3(136C), as well as the name(s) of person(s) who performed such activities;

c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;

d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) Records retention. All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 41.3(136C). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

41.3(13) Form of records. Rescinded IAB 4/5/00, effective 5/10/00.

41.3(14) Written directives. Each registrant shall meet the following:

a. A written directive must be dated and signed by an authorized user prior to the administration of radiation.

(1) If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

(2) The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(3) A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose, or the next fractional dose.

(4) The registrant shall retain a copy of the written directive for three years.

b. Procedures for administration. The registrant shall have written procedures that provide the following information:

(1) Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(2) Each administration is in accordance with the written directive;

(3) External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by:

1. Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive; and

2. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(4) Any unintended deviation from the written directive is identified, evaluated and appropriate action is taken; and

(5) The registrant retains a copy of the procedures for administrations for the duration of the registration.

41.3(15) Reports and notifications of misadministrations.

a. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of external beam radiation results, or will result, in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

b. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of an external beam radiation therapy dose results in:

(1) A dose that differs from the prescribed dose by more than 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin, and either:

1. The total dose delivered differs from the prescribed dose by 20 percent or more; or

2. The fractionated dose delivered differs from the prescribed dose for a single fraction by 50 percent or more.

(2) A dose that exceeds 5 rem (0.05 sievert) effective dose equivalent, 50 rem (0.5 sievert) to an organ or tissue, or 50 rem (0.5 sievert) shallow dose equivalent to the skin from either of the following:

1. An administration of the wrong treatment modality;

2. An administration to the wrong individual or human research subject.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 sievert) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

c. The registrant shall notify the agency by telephone no later than the next calendar day after the discovery of a misadministration.

d. The registrant shall submit a written report to the agency within 15 days after the discovery of a misadministration. The written report shall include:

(1) The registrant's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

(4) Why the event occurred;

(5) The effect, if any, on the individual or individuals who received the misadministration;

(6) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(7) Certification that the registrant notified the individual or the individual's responsible relative or guardian, and if not, why not.

e. The report to the agency shall not contain the individual's name or any other information that could lead to the identification of the individual.

f. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that the referring physician will inform the individual or that, based on medical judgment, the physician's telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that

individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

g. Aside from the notification requirement, nothing in this subrule affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to individuals' responsible relatives or guardians.

h. A copy of the record required in this subrule shall be provided to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration.

i. Records of misadministrations. A registrant shall retain a record of misadministrations reported in this subrule for three years. The record must contain the following:

(1) The registrant's name and the names of the individuals involved;

(2) The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

(3) A brief description of the event; why it occurred; and the effect, if any, on the individual;

(4) The actions, if any, taken or planned to prevent recurrence; and

(5) Whether the registrant notified the individual or the individual's responsible relative or guardian, and, if not, whether such failure to notify was based on guidance from the referring physician.

41.3(16) General technical requirements for facilities using therapeutic radiation machines.

a. Protection surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.15(1); and

2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraphs 40.26(1)*"a"* and *"b."*

(2) In addition to the requirements of 41.3(16)*"a"*(1), a radiation protection survey shall also be performed prior to any subsequent medical use and:

1. After making any change in the treatment room shielding;

2. After making any change in the location of the therapeutic radiation machine within the treatment room;

3. After relocating the therapeutic radiation machine; or

4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(4) If the results of the surveys required by 41.3(16)*"a"*(1) or (2) indicate any radiation levels in excess of the respective limit specified in 41.3(16)*"a"*(1), the registrant shall lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

2. Until the registrant has received a specific exemption in writing from the agency.

b. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 41.3(16)*"a"* indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—paragraphs 40.26(1)*"a"* and *"b,"* before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b"*;

(2) Perform the survey required by 41.3(16)*"a"* again; and

(3) Include in the report required by 41.3(16)*"d"* the results of the initial survey, a description of the modification made to comply with 41.3(5)*"b"*(1), and the results of the second survey; or

(4) Request and receive written authorization from the agency that authorizes radiation levels in unrestricted areas greater than those permitted by 641—paragraphs 40.26(1)*"a"* and *"b."*

c. Dosimetry equipment.

(1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16)*"c"*(1). This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16)*"c"*(1).

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16)*"c"*(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16)*"a"* and *"b"* to the agency within 30 days following completion of the action that initiated the record requirement.

41.3(17) Therapeutic radiation machines of less than 500 kV.

a. Equipment requirements.

(1) Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5-50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)*"a"*(1)"1" and 41.3(17)*"a"*(1)"2" for the

specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

(2) Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam-limiting devices.

1. All adjustable or removable beam-limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X-ray tube is possible;

2. An indication of whether X-rays are being produced;

3. Means for indicating X-ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Multiple tubes. When a control panel may energize more than one X-ray tube:

1. It shall be possible to activate only one X-ray tube at any time;

2. There shall be an indication at the control panel identifying which X-ray tube is activated; and

3. There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the treatment room shall meet the following design requirements:

(1) Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

(2) Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(3) Additional requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;

2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in 41.3(17)*"b"*(3)"3" is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

c. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(17) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. At intervals not exceeding one year; and

3. Before medical use under the following conditions:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and
- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

4. Notwithstanding the requirements of 41.3(17)*"c"*(1):

- Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and
- If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 41.3(17)*"b"*(3).

(2) To satisfy the requirement of 41.3(17)*"c"*(1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

d. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to 41.3(17), which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 41.3(17)*"d"*(1), quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 41.3(17)*"c"*(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 41.3(17)*"c"*(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in 41.3(17)*"c"*(1);

(5) The registrant shall use the dosimetry system described in 41.3(16)*"c"*(2) to make the quality assurance check required in 41.3(17)*"d"*;

(6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 41.3(17) are performed at intervals not to exceed one month;

(8) Notwithstanding the requirements of 41.3(17)*"d"*(6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 41.3(17)*"d"*(6) and (7) have been performed within the 30 days prior to administration;

(9) To satisfy the requirement of 41.3(17)*"d"*(7), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. The "BEAM-ON" and termination switches;

3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(17)*"d"*(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine,

the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

e. Operating procedures.

(1) Therapeutic radiation machines shall not be left unattended unless secured by means identified in 41.3(17)*"a"*(9)"5";

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—40.26(136C).

(6) The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of 41.3(17)*"c"* and *"d"* have been met.

f. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(17) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

41.3(18) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

a. Equipment requirements.

(1) Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 41.3(18)*"a"*(1)"1," the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 41.3(18)*"a"*(1)"1" to "3" for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the agency.

(2) Leakage radiation through beam-limiting devices.

1. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the

area shielded by the beam-limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10-centimeter by 10-centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and
- A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of leakage radiation.

1. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters;

2. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector with an area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.

(4) Filters/wedges.

1. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 41.3(18)*"a"*(9) relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such filter or foil shall be removable only by the use of tools;

3. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

- Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
- An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and interchangeable beam-scattering foil(s) in use; and
- An interlock shall be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

(5) Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 (most current revision).

(6) Beam monitors. All therapeutic radiation machines subject to 41.3(18) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated shall meet the following requirements:

- Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
- Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
- Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

3. For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that the:

- Malfunctioning of one system shall not affect the correct functioning of the other system(s); and
- Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

4. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

- Maintain a reading until intentionally reset;
- Have only one scale and no electrical or mechanical scale multiplying factors;
- Utilize a design such that increasing dose is displayed by increasing numbers; and
- In the event of power failure, the beam monitoring information required in 41.3(18)*"a"*(6)"4" displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

(7) Beam symmetry.

1. Bent-beam linear accelerators with beam-flattening filter(s) subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 41.3(18)*"a"*(7)"1" shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

(8) Selection and display of dose monitor units.

1. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

2. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

3. For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

4. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

(9) Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 41.3(18)*"a"*(6) may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 41.3(18)*"a"*(7)"2" and "3" for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

4. For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

- An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value;
- Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;
- An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;
- An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.
- Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18)*"a"*(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

- Occurs during stationary beam radiation therapy; or
- Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 41.3(136C), the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced; and

4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b,"* interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18)*"a"*(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18)*"e"* and protection surveys required by 41.3(16)*"a"*;

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18)*"f"*(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by 41.3(18)*"d"* shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16)*"a,"*41.3(18)*"e,"* and 41.3(18)*"f"* have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Acceptance testing, commissioning, and full calibration measurements.

(1) Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45, and the manufacturer's contractual specifications and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41 and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

3. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

- Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and
- Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)*"e"*(1)"3."

(2) The registrant shall use the dosimetry system described in 41.3(16)*"c"* to measure the radiation output for one set of exposure conditions.

(3) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals as specified in Appendix D of 641—Chapter 41;

(2) To satisfy the requirement of 41.3(18)*"f"*(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been intercompared within the previous 12 months with the dosimetry system described in 41.3(16)*"c"*(1) to make the periodic quality assurance checks required in 41.3(18)*"f"*(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18)*"f"*(1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week;

(7) To satisfy the requirement of 41.3(18)*"f"*(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the "BEAM-ON," interrupt and termination switches;

3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

4. Viewing systems;

5. Aural systems;

6. Electrically operated treatment room door(s) from inside and outside the treatment room;

7. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(8) Rescinded IAB 4/11/07, effective 5/16/07.

(9) The registrant shall promptly repair any system identified in 41.3(18)*"f"*(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)*"f"*(1) and 41.3(18)*"f"*(7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) Shielding and safety design requirements.

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic

radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

41.3(20) Calibration of survey instruments.

a. The registrant shall ensure that the survey instruments used to show compliance with 645—41.3(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

b. To satisfy the requirements of 41.3(20), the registrant shall:

(1) Calibrate all required scale readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

(2) Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full scale;

(3) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(4) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

c. The registrant shall retain a record of each calibration required in 41.3(20) for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

d. The registrant may obtain the services of individuals licensed by this agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in 41.3(20) shall be maintained by the registrant.

[**ARC 0577C**, IAB 2/6/13, effective 3/13/13]

641—41.4(136C) Radiation safety requirements for analytical X-ray equipment. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.5(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.6(136C) X-ray machines used for screening and diagnostic mammography.

41.6(1) *Definitions.* In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

"Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities.

"Action limits" or *"action levels"* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

"Adverse event" means an undesirable experience associated with mammography activities. Adverse events include but are not limited to:

1. Poor image quality;

2. Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

3. Use of personnel who do not meet the applicable requirements of this chapter.

"Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gray of absorbed dose is delivered by 114 roentgens (R) of exposure.

"Annually" means within 10 to 14 months of previous occurrence.

"Artifact" means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

"Automatic exposure control systems" means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X-ray intensity after passage through the patient and image receptor.

"Average glandular dose" means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X-ray beam quality (half-value layer), and compressed breast thickness. For a 50 percent-50 percent adipose and glandular 4.2 centimeter breast, the average glandular dose shall not exceed 300 millirad (3 mGy). See also: "Dose."

"Breast implant" means a prosthetic device implanted in the breast.

"Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

"Category 1" means medical education activities that have been designated as Category 1 by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

"Certificate" means the certificate described in 41.6(2)*"a"*(2).

"Certification" means the process of approval of a facility by the FDA or this agency to provide mammography services.

"Clinical image" means a mammogram.

"Compression device" means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

"Computed radiography mammography" means a type of digital mammography in which the digital image receptor must be removed from the X-ray unit for the image to be read and processed by a separate image receptor reader.

"Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

"Contact hour" means an hour of training received through direct instruction.

"Continuing education unit" or *"continuing education credit"* means one contact hour of training.

"Craniocaudal view" means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X-ray beam is directed from cranial to caudad (downward) through the breast.

"Dedicated mammography equipment" means X-ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Direct detector technology" means a digital mammogram captured using a material which converts the X-ray energies directly to an electric signal.

"Direct instruction" means:

1. Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

2. The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

"Direct supervision" means that:

1. During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

2. During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

"Dose" means the amount of energy deposited per unit mass of tissue due to X-radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

"Exposure" means the amount of X-radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen=2.58 × 10E-4 Coulombs of charge per kilogram of air.

"Facility" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

"FDA" means the Food and Drug Administration.

"First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

"Full field digital mammography" means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

"Image noise." See "Radiographic noise."

"Image receptor support device" means, for mammography X-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

"Interpreting physician" means a licensed radiologist who interprets mammograms and who meets the requirements set forth in 41.6(3)*"a."*

"Kerma" means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

"Laterality" means the designation of either the right or left breast.

"Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of this chapter. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

"Mammogram" means a radiographic image produced through mammography.

"Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography, xeromammography, and digital mammography.

"Mammography" means radiography of the breast but, for the purposes of 641—41.6(136C), does not include:

1. Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

2. Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA investigational device exemption regulations; or

3. Radiography of the breast performed as part of either a breast localization procedure or a post-stereotactic clip placement localization procedure.

"Mammography equipment evaluation" means an on-site assessment of the mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards.

"Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

"Mammography unit(s)" means an assemblage of components for the production of X-rays for use during mammography including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

"Mean optical density" means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

"Medical physicist" means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 41.6(3)*"c."*

"Mediolateral view" means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X-ray beam is directed from medial to lateral aspect through the breast.

"MQSA" means the Mammography Quality Standards Act of 1992.

"Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram. A radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Oblique mediolateral view" means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30-60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X-ray beam is directed from the supero-medial to the infero-lateral aspect of the breast.

"Patient" means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

"Phantom" means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Phantom image" means a radiographic image of a phantom.

"Physical science" means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

"Provisional certification" means the six-month certification time period in which a facility has to complete the accreditation/certification process.

"Qualified instructor" means individuals whose training and experience adequately prepare them to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 41.6(3) would be considered qualified instructors in their respective areas of mammography. Radiological technologists who meet the requirements of 41.6(3) and have passed a state-approved mammography examination such as the examination given by the American Registry of Radiography Technologists would be considered qualified instructors in their respective areas of mammography. The examination would include, but not necessarily be limited to: breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this chapter include, but are not limited to, instructors in a post-high school training institution and manufacturers' representatives.

"Quality control technologist" means an individual meeting the requirements of 41.6(5)*"a"*(4) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

"Radiographic equipment" means X-ray equipment used for the production of static X-ray images.

"Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and in the positioning of patients for radiographic examinations and who meets the requirements set forth in 41.6(3)*"b."*

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Reinstatement" means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

"Screen-film mammography" means mammography performed with high-detailed intensifying screen(s) in close contact with the film.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Serious adverse event" means an adverse event that may significantly compromise clinical outcomes or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

"Serious complaint" means a report of a serious adverse event.

"Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

"Supplier" means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

"Survey" means an on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

"Time cycle" means the film development time.

"Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

"Written report" means interpreting physician's technical narrative of a mammography evaluation.

"Written statement" means interpreting physician's description of a mammography examination written in lay terms.

41.6(2) *Registration and application standards and requirements.*

a. Registration and certificates.

(1) Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

(2) A certificate issued by the FDA or this agency is required for lawful operation of all mammography facilities subject to the provisions of this subrule. To obtain a certificate from the FDA or this agency, facilities are required to meet the quality standards in 641—41.6(136C) and to be accredited and approved by an approved accreditation body.

b. Each facility wishing to perform mammography shall apply for agency approval by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for agency-approved mammography accreditation bodies.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated at least annually by a medical physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

(8) Provisional or reinstatement certification. A new facility beginning operation after September 30, 1994, is eligible to apply for provisional or reinstatement certification. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive provisional or reinstatement certification, a facility must meet the requirements of 641—41.6(136C). Provisional or reinstatement certification shall be effective for up to six months from the date of issuance and cannot be renewed. The facility may apply for one 90-day extension.

c. Suspension, revocation, or denial of mammography certification.

(1) Mammography certification may be suspended or revoked with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the certification.

(2) The facility shall have opportunity for a hearing in connection with a denial, suspension or revocation of mammography certification in accordance with 641—Chapter 173.

(3) An emergency order suspending or revoking certification may be issued in accordance with 641—173.31(17A) if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If certification is revoked, the radiation machine shall not be used for mammography until reinstated.

(5) If a facility's certification is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility in Iowa within two years of the date of revocation.

d. Reinstatement of mammography certification after revocation.

(1) An application for reinstatement shall be submitted and processed as an initial application. Appropriate corrective actions must be submitted with the application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A full certificate shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial mammography certification and at least annually thereafter.

f. The authorization of facilities is included in the accreditation process for facilities accredited by the state of Iowa. Determination of the quality of the mammograms produced by facilities accredited by the state of Iowa will be made. To make the determination, each facility will:

(1) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria for the clinical image review process by the agency:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly fatty breast tissue,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with predominantly glandular breast tissue, and

3. Each mammography examination must have been interpreted as a "negative" or "benign" examination.

(2) Provide randomly, at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2)*"f"*(1).

(3) Provide at the time of initial accreditation, new unit installation, or reaccreditation (at least every three years) thereafter, a phantom image taken with the unit being accredited within six months of the submission date for review by the agency.

(4) Be billed the fee for the quality review process as set forth in 641—subparagraph 38.8(1)*"b"*(2).

(5) Be provided with a written explanation of the results of the quality review process which will accompany the returned mammograms referred to in 41.6(2)*"f"*(3).

g. Facilities accredited by an approved accrediting body other than the state of Iowa must be authorized by the agency. Quality determination for these facilities will be made by the agency through a phantom image provided at the time of initial authorization, new unit authorization, or reauthorization (at least every three years) thereafter, taken with the unit being accredited within six months of the submission date.

h. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Part 900 which has an effective date of April 28, 1999. Persons certified to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

i. Soft copy review workstation requirements.

(1) Soft copy review workstations used for final interpretation of mammogram images must be a configuration of two monitors that meet one of the following criteria:

1. Have 5 megapixel resolution; or

2. Be approved by the United States Food and Drug Administration 510K process and be intended for digital mammography use.

(2) The workstation must have a quality control program substantially the same as that outlined by the image receptor manufacturer's quality control manual or that outlined by the image receptor manufacturer's designated soft copy review workstation quality control manual.

41.6(3) *Mammography personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

a. Interpreting physicians. All radiologists interpreting mammograms shall meet the following qualifications:

(1) Initial qualifications. Unless the exemption in 41.6(3)"a"(3)"1" applies, before beginning to interpret mammograms independently, the interpreting radiologist shall:

1. Be licensed to practice medicine in Iowa;

2. Either:

- Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or
- Have had at least three months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a radiologist who meets the requirements of 41.6(3)"a"; and

3. Have a minimum of 60 hours of documented medical education in mammography, which shall include: instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, and physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be Category 1 and at least 15 of the Category 1 hours shall have been acquired within the 36 months immediately prior to the date that the radiologist qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category 1 continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution;

4. Unless the exemption in 41.6(3)"a"(3)"2" applies, have interpreted or multi-read at least 240 mammographic examinations within the six-month period immediately prior to the date that the

radiologist qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician; and

5. Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality other than the modality in which the initial training was received, the interpreting physician shall have at least 8 hours of Category 1 continuing medical education credits in the new mammographic modality or at least 8 hours of training in the new mammographic modality provided by a vendor manufacturing the new mammographic modality equipment. An interpreting physician previously qualified to interpret a new mammographic modality in another state will have six months to complete this requirement. The six-month time frame begins when the interpreting physician commences Iowa new mammographic modality interpretation.

(2) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

1. Following the second anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"a"*(1) were completed, the interpreting physician shall have read or multi-read at least 960 mammographic examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"a"*(1) were completed, the interpreting physician shall have taught or completed at least 15 Category 1 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

3. Units earned through teaching a specific course can be counted only once towards the 15 required by 41.6(3)*"a"*(2)"2" even if the course is taught multiple times during the previous 36 months.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever mammography interpretations are performed by the physician.

(3) Exemptions.

1. Those physicians who qualified as interpreting physicians under 41.6(3)*"a"* or FDA interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 41.6(3)*"a."* They may continue to interpret mammograms provided they continue to meet the licensure requirements of 41.6(3)*"a"*(1)"1" and the continuing experience and education requirements of this subrule.

2. Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six-month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from 41.6(3)*"a"*(1)"4."

(4) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

1. Interpreting physicians who fail to meet the continuing experience requirements of 41.6(3)*"a"*(2)"1" shall:

- Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or
- Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total to at least 960 examinations for the prior 24 months, whichever is less. The interpretations required under 41.6(3)*"a"*(4)"1" shall be done within the six months immediately prior to resuming independent interpretation. Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

2. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)*"a"*(2)"2" shall obtain a sufficient number of additional Category 1 continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

b. Radiologic technologists. All mammographic examinations shall be performed by general radiographers who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(1) General requirements. Be permitted to operate as a general radiographer in Iowa; and

(2) Mammography requirements. Have qualified as a radiologic technologist under 41.6(3)*"b"* before April 28, 1999, or have completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor after successful completion of at least a two-year radiography program. The hours of documented training shall include, but not necessarily be limited to:

1. Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, and imaging of patients with breast implants;

2. The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under 41.6(3)*"b"*; and

3. Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under 41.6(3)*"b"*(2)"3," the technologist shall have at least 8 hours of continuing education units in the new modality. The 8 hours may not be derived from the supervised examination of patients; and

(3) Continuing education requirements.

1. Following the third anniversary date of the end of the calendar quarter in which the requirements of 41.6(3)*"b"*(1) and (2) were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility will choose one of these dates to determine the 36-month period.

2. Units earned through teaching a specific course can be counted only once towards the 15 required in 41.6(3)*"b"*(3)"1" even if the course is taught multiple times during the previous 36 months.

3. Requalification. A radiologic technologist who fails to meet the continuing education requirements of 41.6(3)*"b"*(3)"1" shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 36 months. The continuing education for requalification cannot be obtained by performing supervised mammography examinations. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

4. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

5. Only 50 percent of the total required mammography continuing education hours may be obtained through presenting, or acting as a trainer for, a continuing education or training program.

(4) Continuing experience requirements.

1. Following the second anniversary date on which the requirements of 41.6(3)*"b"*(1) and (2) were completed, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility will choose one of these dates to determine the 24-month period.

2. Requalification. Radiologic technologists who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

3. Continuing qualifications must be met and an Iowa permit to practice radiography must be in effect whenever mammogram procedures are performed by the radiologic technologist.

(5) Consecutive or back-to-back requalification of mammography personnel, due to failure to meet continuing education or experience requirements, will be allowed once without proof of extenuating circumstances. This agency will determine the validity of such proof and render a decision after review of all pertinent information. Those individuals who are denied requalification will be allowed to resubmit for requalification following a 90-day waiting period.

c. Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 41.6(3)*"c"*(2) shall meet the following:

(1) Initial qualifications.

1. Be Iowa approved; and

2. Have a master's degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or 30 quarter hours of college undergraduate or graduate level physics;

3. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

4. Have experience conducting surveys in at least one mammography facility and have a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of this subrule; or

(2) Alternative initial qualifications.

1. Have qualified as a medical physicist under FDA interim regulations and have retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

2. Prior to April 28, 1999, have:

- A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics.
- Forty contact hours of documented specialized training in conducting surveys of mammography facilities.
- Experience conducting surveys in at least one mammography facility and have a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.
- At least eight hours of training in surveying units of the new mammographic modality before independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received training to qualify under this subrule.

(3) Continuing qualifications.

1. Continuing education. Following the third anniversary date on which the requirements of 41.6(3)*"c"*(1) or (2) were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the prior 36 months, during the 36-month period ending on the last day of the previous calendar quarter, or during any 36-month period between the two. The facility shall choose one of these dates to determine the 36-month period. Units earned through teaching a specific course shall be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

2. Continuing experience. Following the second anniversary date on which the requirements of this subrule were completed, the medical physicist shall have surveyed at least two mammography facilities and a total of at least 6 mammography units during the prior 24 months, during the 24-month period ending on the last day of the previous calendar quarter, or during any 24-month period between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days shall be counted towards this requirement.

3. Continuing qualifications must be met whenever medical physics services are provided by the medical physicist.

(4) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows:

1. Medical physicists who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous three years.

2. Medical physicists who fail to meet the continuing experience requirements of this subrule shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring their total surveys up to the required two facilities and 6 units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. *Retention of personnel records.* Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, general radiographers, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the agency has determined that the facility is in compliance with the MQSA personnel requirements.

41.6(4) *Obtaining and preserving records.*

a. The facility performing the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from other facilities, for comparison with the current mammography records.

b. The facility must make, for each patient, a written report of each mammography examination performed. This report shall include:

(1) The date the mammography procedure was performed.

(2) The date of the interpretation.

(3) The name of the interpreting physician.

(4) The name of the patient and an additional patient identifier.

(5) A description of the procedures performed.

(6) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(7) The date the interpreting physician's written report was sent to the appropriate physician or patient.

(8) A separate and distinct section entitled, "Assessment" with the appropriate assessment term. One of the following terms in quotations or an approved equivalent must be included in the assessment:

1. "Negative": Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign": Also a negative assessment.

3. "Probably benign": Finding(s) has a high probability of being benign.

4. "Suspicious": Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy": Finding(s) has a high probability of being malignant.

6. "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment in cases where no final assessment category can be assigned due to incomplete workup, and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

c. Preservation of records.

(1) The facility must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the facility or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the facility must be retained for at least 60 calendar months following the date of service, as long as the patient continues consecutive mammograms. If no additional mammograms of the patient are performed, the records must be retained for at least ten years.

(3) If the facility should cease to exist before the end of the retention period, the records must be transferred to the patient or patient's physician or other mammographic facility.

(4) The facility shall upon request by, or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patient for providing the services in subparagraph (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated in lay terms to each patient in a time period not to exceed 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4)*"e"*(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including all of the items listed in 41.6(4)*"b,"* to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible or, if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by the FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and ZIP code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

41.6(5) *Quality assurance program.*

a. The facility shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system to ensure consistently high-quality images with minimum patient exposure. Responsibility for the quality assurance program and for each of its

elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5)*"e"* through *"k."*

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. Under the direction of the lead interpreting physician, the medical physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting or training others to conduct equipment performance monitoring functions.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d. Calibration of equipment. All variable parameters of the equipment shall be calibrated:

(1) When the equipment is first installed.

(2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored for film-screen mammography shall include but not be limited to:

(1) Processor performance (through daily sensitometric-densitometric means).

(2) Half-value layer.

(3) Output reproducibility and linearity.

(4) Automatic exposure control reproducibility and linearity.

(5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

(6) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor.

(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammography facility shall be the ability to observe the image of at least four 0.75-mm fibriles, three 0.32-mm speck groups, and three 0.75-mm masses from an FDA-approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

(1) Processor performance shall be accomplished daily before processing patient films.

(2) Image quality shall be monitored at least weekly with a phantom and every time the unit is altered including the replacement of parts.

(3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results. Full field digital mammography units must comply with the quality control test requirements outlined by the performance criteria in the appropriate manufacturer's quality control manual.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.2 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 millirad for film-screen units with no grids, 300 millirad for film-screen units with grids, or 300 millirad for full field digital units.

(2) The monitoring results shall be compared routinely by the facility staff to the standards of image quality in 41.6(5)*"k."* If the results fall outside the acceptable range, the test shall be repeated. For film-screen mammography, if the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted. For full field digital mammography, if any test results fall outside the performance criteria range listed for the unit, specific actions as directed in the appropriate quality control manual shall be followed.

h. Retake analysis program—film-screen and full field digital.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first. If more than 250 mammograms are performed in one week, weekly analysis is acceptable.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow-up on the disposition of positive mammograms and correlation of surgical biopsy results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and pathology results, or both, and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the facility's records.

(2) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and notifying other interpreting

physicians of the results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up. The reviewing physician shall sign the medical audit as proof of the evaluation of the data.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

k. Quality assurance—equipment.

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be below plus 0.03 of the established operating level.
2. The mid-density shall be within plus or minus 0.15 of the established operating level.
3. The density difference shall be within plus or minus 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.
2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.
3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by the FDA.
4. The density difference between the background of the phantom and an added test object used to assess image contrast shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

- Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeter.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for two minutes while such film is placed on the countertop emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.
2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.
3. Compression device performance. The maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 45 pounds (200 newtons).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

- The AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6

centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

- The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

- The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.
- At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Facilities shall evaluate focal spot condition only by determining the system resolution.

- Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.
- The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.
- When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.
- When more than one SID is provided, the test shall be performed at the SID most commonly used clinically.
- Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.
- Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode-cathode axis) and width (dimension perpendicular to the anode-cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal Spot Tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50	
Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

- All systems shall have beam-limiting devices that allow the entire chest wall edge of the X-ray field to extend to the chest wall edge of the image receptor and provide means to ensure that the X-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.
- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than 1 percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 800 milliRoentgen (mR) per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector.
- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5)*"k"*(5)"6."

(7) Use of test results.

1. After completion of the tests specified in 41.6(5)*"k,"* the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside the action limits, the source of the problem shall be identified, and corrective actions shall be taken before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5)*"k."*

3. Full field digital unit corrective actions shall be made as prescribed in the appropriate manufacturer's quality control manual or in accordance with the appropriate FDA-approved alternative requirements.

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5)*"k"*(5) and (6), the weekly phantom image quality test described in 41.6(5)*"k"*(2) and the quarterly retake analysis results described in 41.6(5)*"h."*

2. The results of all tests conducted by the facility in accordance with 41.6(5)*"k"*(1) through (7) for film-screen units, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey. Surveys of full field digital mammography units shall be conducted as described in the appropriate manufacturer's quality control manual. The results of the tests, any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors or any other applicable mammography system ancillary parts shall be conducted at new installations, at disassembly, at reassembly, at the same or a new location, or when major components are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5) and 41.6(6). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa-approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and viewbox cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

l. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body and any other appropriate regulatory entity if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with rule 641—41.6(136C) and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

41.6(6) *Equipment standards.* The equipment used to perform mammography shall meet the following standards:

a. Design: Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments for mammography.

b. Performance standards: Meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

c. Image receptor systems: Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 × 24 centimeters and 24 × 30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

d. Light fields: For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

e. Magnification:

(1) Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

f. Tube-image receptor assembly:

(1) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with this subrule shall not fail in the event of power interruption.

g. Film/screen contact: Shall check film/screen contact when cassettes are first placed into use and semiannually thereafter.

h. Focal spot: The focal spot size, magnification factor and source to image receptor distance (SID) shall be appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
> 65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< 50 cm	< or = to 0.4 mm

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material or focal spot, or both, is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material or focal spot, or both, actually used during the exposure.

i. Compression devices: Shall have compression devices parallel to the imaging plane and able to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds. Effective October 28, 2002, each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression"), may be provided. Such compression paddles for special purposes are not subject to 41.6(6)*"i"*(6) and (7).

(4) Except as provided in 41.6(6)*"i"*(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design not to be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

j. Grids: Shall have the capability for using antiscatter grids.

k. AEC: Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

- The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
- The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

l. Control panel: Shall have a control panel that:

(1) Gives a positive indication when X-rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Has manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) or time, or both).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure.

m. mAs: Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

n. Viewboxes: Shall have a viewbox that is checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

o. X-ray film: Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

p. Intensifying screens: Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

q. Chemicals: Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

r. Hot-lights: Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

s. Masking devices: Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

t. Mobile units and vans—film-screen.

(1) A phantom image shall be produced, processed, and evaluated after each relocation and prior to examinations being conducted.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be recalibrated as necessary to maintain quality of phantom image.

u. Mobile units and vans—full field digital. Appropriate manufacturer's quality control manual procedures and criteria shall be met.

41.6(7) *Safety standards for mammography equipment.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall be monitored in accordance with 641—40.37(136C).

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

RULE 641—41.6(136C)—APPENDIX I
Rescinded IAB 4/5/00, effective 5/10/00

RULE 641—41.6(136C)—APPENDIX II
Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
4.5-cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

	Mo/Mo Target Filter X-Ray Voltage (kVp)											W/Al Target Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.23	109											
0.24	113	116										
0.25	117	120	122									
0.26	121	124	126	128								
0.27	126	128	130	132	134							
0.28	130	132	134	136	138	139						
0.29	135	137	139	141	142	143	144					
0.30	139	141	143	145	146	147	148	149				170
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36-mm aluminum yields an average glandular dose of (0.50 R) × (174 mrad/R) = 87 mrad or 0.87 mGy.

*Wu X. Breast dosimetry in screen-film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical

Physics Publishing; 159-175, 1991. W/Al conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577-584.
[**ARC 1401C**, IAB 4/2/14, effective 5/7/14]

641—41.7(136C) X-ray machines used for stereotactically guided breast biopsy.

41.7(1) *Definitions.* In addition to the definitions provided in rules 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon (under 41.7(3)*"a"* or 41.7(3)*"c"*) are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient's benefit.

"Procedure" means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

"Qualified training physician" means a physician who is qualified under 41.7(3) to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

"Stereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

41.7(2) *Registration and application standards and requirements.*

a. Each radiation machine used to perform stereotactically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform stereotactically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The stereotactically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform stereotactically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire stereotactically guided breast biopsy system is evaluated annually by a medical physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Suspension, revocation, or denial of authorization.

(1) Authorization may be suspended or revoked with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial,suspension, or revocation of authorization.

(3) An emergency order suspending or revoking authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within 20 working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is revoked, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application. If the reinstatement is after a revocation, appropriate corrective action shall be submitted with the application.

(3) A full reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 14 months after initial authorization and at least annually thereafter.

41.7(3) *Physicians.* Physicians must be qualified according to the setting and their role in performing stereotactically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)*"a."*

2. Shall have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsies under a physician who is qualified under 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in 41.7(3)*"a"*(1)"2" above and be experienced in the specific recommendations for each biopsy and lesion identification at time of each biopsy performed by that physician.

5. Shall be responsible for the supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year. If experience is not maintained, the physician must requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever procedures are performed independently by the physician.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be licensed to practice medicine in Iowa.

2. Must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy which includes instruction on triangulation for lesion location.

3. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified to perform stereotactic biopsy procedures according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

4. Shall be responsible for post-biopsy management of the patient.

5. Shall be responsible for supervision of the radiologic technologist during the procedure.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency–approved manufacturer applications specialist before resuming unsupervised procedures.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

c. Requirements for a radiologist performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)*"a."*

2. Initially, must have at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 stereotactically guided breast biopsies prior to July 1, 1998, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient which may include referral to a surgeon for a follow-up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

2. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months which includes post-biopsy management of the patient. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. These CMEs cannot be obtained by the performance of supervised procedures.

3. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3)*"c"*) performing stereotactically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be licensed to practice medicine in Iowa.

2. Must have evaluated at least 480 mammograms in the prior 24 months in consultation with a physician who is qualified according to 41.6(3)*"a."*

3. Initially, must have at least 15 hours of Category 1 CME or 15 hours of training approved by the agency in stereotactically guided breast imaging and biopsy or three years' experience having performed at least 36 stereotactically guided breast biopsies.

4. Must have four hours of Category 1 CME in medical radiation physics.

5. Must have performed at least 12 stereotactically guided breast biopsies prior to May 9, 2001, or at least 3 hands-on stereotactically guided breast biopsy procedures under a physician who is both qualified according to 41.7(3) and has performed at least 24 stereotactically guided breast biopsies.

6. Must be responsible for patient selection.

7. Must be responsible for the supervision of the radiologic technologist during the procedure.

8. Must be responsible for post-biopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480 mammograms every 24 months in consultation with a physician who is qualified according to 41.6(3)*"a."*

2. Perform at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 procedures under direct supervision of a qualified training physician or an agency-approved manufacturer applications specialist.

3. Obtain at least three hours of Category 1 CME or three hours of training approved by the agency in stereotactically guided breast biopsy every 36 months. If education is not maintained, the physician must requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months before resuming unsupervised procedures. The CME credits for requalification cannot be obtained by performing procedures.

4. Continuing qualifications must be met and a current state of Iowa medical license must be in effect whenever unsupervised procedures are performed by the physician.

41.7(4) *Medical physicist.*

a. Must be qualified according to 41.6(3)*"c."*

b. Must have performed three hands-on stereotactically guided breast biopsy system physics surveys prior to July 1, 1998; or one hands-on stereotactically guided breast biopsy system physics survey under the guidance of a medical physicist qualified through 41.7(4)*"a"* and 41.7(4)*"b."*

c. Maintenance of proficiency and continuing education requirements.

(1) Have performed at least one stereotactically guided breast biopsy system physics survey per year after the initial qualifications are met or requalify by performing one survey supervised by a qualified medical physicist; and

(2) Following the third anniversary in which the requirements of this subrule were met, have obtained at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months.

41.7(5) *Radiologic technologist.*

a. Must be qualified according to 41.6(3)*"b."*

b. Must meet the following initial requirements:

(1) Five hands-on stereotactically guided breast biopsy procedures on patients under the supervision of a physician or technologist qualified under rule 641—41.7(136C).

(2) Three hours of continuing education in stereotactically guided breast biopsy. The required continuing education cannot be obtained through the performance of supervised stereotactically guided breast biopsy procedures.

c. Maintenance of proficiency and continuing education and experience requirements.

(1) Following the first anniversary in which the requirements of this subrule were met, have performed at least 12 stereotactically guided breast biopsies per year or requalify by performing 3 stereotactically guided breast biopsies under the supervision of a physician or radiologic technologist qualified under 41.7(3) or 41.7(5).

(2) Following the third anniversary in which the requirements of this subrule were met, have at least three hours of continuing education in stereotactically guided breast biopsy system physics during the previous 36 months or requalify by obtaining additional CME credits to reach 3 CME credits in the prior 36 months. The CMEs cannot be obtained by the performance of supervised procedures.

(3) If a stereotactic radiologic technologist performs only stereotactic procedures, the radiologic technologist must perform at least 100 stereotactic procedures during the prior 24 months.during the 24-month period ending on the last day of the previous calendar quarter, or any 24-month period between the two. In this case, all requirements for radiologic technologists must be met with the exception of 41.6(3)*"b"*(4)"1."

(4) Only 50 percent of the total required stereotactic continuing education hours may be obtained through presenting or acting as a trainer for a continuing education or training program.

41.7(6) *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

(1) The date of the procedure.

(2) The name of the patient and one additional patient identifier.

(3) The name of the radiologic technologists and physicians performing the procedure.

(4) A description of the service provided.

(5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to stereotactically guided breast biopsy systems and covering all components of the system to ensure high-quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified medical physicist who is capable of establishing and conducting the program.

c. The facility shall name a supervising stereotactic biopsy physician who shall be responsible for:

(1) Quality assurance activities including the medical audit,

(2) Oversight of the quality control program, and

(3) Supervision of the radiologic technologist(s) and the medical physicist.

d. Under the direction of the supervising physician, the medical physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, initially and then at least annually, to include:

1. Evaluation of biopsy unit assembly. Any failed items must be corrected within 30 days of the survey unless the medical physicist deems that the failure poses a serious injury risk to the patient, at which time the failure needs to be corrected before further procedures are performed.

2. Collimation.

- Digital – X-ray field must not extend beyond the image receptor by more than 5 mm on any side.
- Film-screen – On all sides other than the chest wall side, the X-ray field must be within the image receptor. The chest wall side must not extend beyond the image receptor by more than 2 percent.
- Any failures must be corrected within 30 days of the survey.

3. Evaluation of focal spot.

- Digital – Focal spot must not degrade from initial measurement. If reduction in lp/mm is found, focal spot must be corrected within 30 days of survey.
- Film-screen – Film-screen must show 13 lp/mm parallel to the anode-cathode axis and 11 lp/mm perpendicular to the anode-cathode axis. Failure to meet the performance criteria must be corrected within 30 days of survey.

4. kVp accuracy/reproducibility. kVp accuracy/reproducibility must be accurate to within +/- 5% of nominal kVp setting. Failures must be corrected before further procedures are performed.

5. Half-value layer measurement. HVL shall be greater than kVp/100 (in units of mm Al). Failures must be corrected before further procedures are performed.

6. Exposure reproducibility. Exposure must be reproducible to within +/- 15% of mean exposure. Failures must be corrected before further procedures are performed.

7. Breast entrance exposure, average glandular dose. Average glandular dose must be less than 300 millirad (3 milliGray) per exposure of a 50 percent glandular/50 percent adipose 4.5 centimeter breast. Failures must be corrected before further procedures are performed.

8. Image quality evaluation.

- Digital – Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer.
- Film-screen – Phantom image must meet the criteria of 4 fibers, 3 speck groups and 3 masses for the ACR phantom or 2 fibers, 2 speck groups and 2 masses for the mini phantom unless otherwise stated by the phantom manufacturer. The background density must be within +/- .20 of the established aim, and the density differences must be within +/- .05 of the established aim.
- Failures must be corrected before further procedures are performed.

9. Artifact evaluation. Any significant black or white artifacts seen in the image detector field must be corrected within 30 days of the survey.

10. Digital field uniformity. For units with region of interest (ROI) capability, the SNR in each corner must be within +/- 15% of the SNR in the center. Failures must be corrected within 30 days of the survey.

11. Localization simulation (gelatin phantom) test. Localization accuracy must be within 1 mm of target, and the test must include a portion of the test "lesion" in the sample chamber. Failures must be corrected before further procedures are performed.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

e. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily before use and before using the localization unit after it is adjusted). Each coordinate must be within manufacturer specifications for the intended target value. Failures must be corrected before further procedures are performed.

(2) Visual checklist (monthly). Any failed items must be corrected within 30 days.

(3) Phantom image (weekly). Phantom image must meet the criteria of 5 fibers, 4 speck groups and 3 masses for the ACR accreditation phantom or 3 fibers, 3 speck groups and 2.5 masses for the mini phantom unless otherwise stated by the phantom manufacturer. Failures must be corrected before further procedures are performed.

(4) Compression (semiannually). The maximum auto drive compression force shall not exceed 45 pounds. Failures must be corrected within 30 days.

(5) Any additional quality control testing indicated by the stereotactic breast biopsy unit manufacturer must be completed as outlined in the quality control manual applicable to the unit.

f. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging-pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure. The program must include the number of biopsies performed, the number of cancers found, the number of benign lesions found, and the number of biopsies repeated.

g. Additional medical physicist evaluations of stereotactic units shall be conducted whenever a new unit is installed, a unit is disassembled and reassembled at the same or a new location, or major components of a stereotactic unit are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.7(7). All problems shall be corrected before the new or changed equipment is put into service for examinations. The stereotactic equipment evaluation shall be performed by a medical physicist qualified under 41.7(4) or by an individual under the direct supervision of a medical physicist qualified under 41.7(4).

41.7(8) *Equipment standards.*

a. Be specifically designed for stereotactically guided breast biopsy.

b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) *Safety standards.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to monitor their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

[**ARC 1401C**, IAB 4/2/14, effective 5/7/14]

CHAPTER 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X-ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X-ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X-ray control placement:

The X-ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows or mirrors.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X-ray" warning sign that will be lighted anytime the rotor of the X-ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m^2).

(2) Regardless of size or shape, at least 0.09 m^2 (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

CHAPTER 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.
2. Diseases or conditions for which the X-ray examinations are to be used in diagnoses.
3. A detailed description of the X-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over age 45 or men over age 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.
6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the X-ray examination procedures to be used.
9. The qualifications of each individual who will be operating the X-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.
11. The name and address of the physician who will interpret the radiograph(s) and a copy of the physician's license to practice in Iowa.
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.
14. An indication of the frequency of screening and the duration of the entire screening program.
15. Documentation justifying the reason for the screening. The applicant must submit data which supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data which will be acceptable to the department includes, but is not limited to, the following: (1) the recommendation of a nationally recognized certifying medical or government body; (2) the recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or (3) medical literature from peer-reviewed journals supporting the screening.
16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.
17. The dates of the screening to include beginning and ending dates.
18. A copy of IRB for a research project or information justifying the research project.

CHAPTER 41—APPENDIX D

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	Safety	
	Door interlocks	functional
	Audiovisual monitors	functional
Monthly	Dosimetry	
	X-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and electron symmetry	3%
	Safety Interlocks	
	Wedge, electron cone interlocks	functional
	Mechanical	
	Light/radiation field coincidence	2mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 degree
	Wedge position	2mm (or 2% change in transmission factor)
	Tray position	2mm
	Applicator position	2mm
	Field size indicators	2mm
	Cross-hair centering	2mm diameter
	Treatment couch position indicators	2mm/1deg
	Latching of wedges, blocking tray	functional
	Jaw symmetry[e]	2mm
	Field Light intensity	functional
Annual	Dosimetry	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[b] All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

[c] A constancy check with a field instrument using temperature pressure corrections.

[d] Whichever is greater. Should also be checked after change of light field source.

[e] Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

Frequency	Procedure	Tolerance[a]
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturer's test procedures	functional
	Mechanical	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

[f] Most wedges' transmission factors are field size and depth dependent.

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

CHAPTER 41—APPENDIX E

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerator" (1984).

D. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).

These rules are intended to implement Iowa Code chapter 136C.

[Filed 4/7/80, Notice 2/6/80—published 4/30/80, effective 7/1/80]
[Filed 5/17/85, Notice 2/27/85—published 6/5/85, effective, see rule 41.7]
[Filed 11/24/86, Notice 10/8/86—published 12/17/86, effective 1/21/87]
[Filed 11/6/87, Notice 9/23/87—published 12/2/87, effective 1/6/88]
[Filed 7/16/92, Notice 5/27/92—published 8/5/92, effective 9/9/92]

[Filed emergency 9/14/92 after Notice 7/22/92—published 9/30/92, effective 10/1/92]
[Filed 11/5/92, Notice 9/30/92—published 11/25/92, effective 1/13/93]◊
[Filed 1/15/93, Notice 11/25/92—published 2/3/93, effective 3/10/93]
[Filed 3/10/93, Notice 12/23/92—published 3/31/93, effective 5/5/93]
[Filed emergency 7/16/93—published 8/4/93, effective 7/16/93]
[Filed emergency 11/15/93—published 12/8/93, effective 11/15/93]
[Filed 7/14/94, Notice 6/8/94—published 8/3/94, effective 9/7/94]
[Filed 5/15/95, Notice 3/29/95—published 6/7/95, effective 7/12/95]
[Filed 1/11/96, Notice 10/11/95—published 1/31/96, effective 3/6/96]
[Filed 3/15/96, Notice 1/31/96—published 4/10/96, effective 5/15/96]
[Filed 9/16/96, Notice 7/17/96—published 10/9/96, effective 11/16/96]
[Filed 5/16/97, Notice 4/9/97—published 6/4/97, effective 7/9/97]
[Filed 3/18/98, Notice 1/14/98—published 4/8/98, effective 7/1/98]◊
[Filed 1/21/99, Notice 11/4/98—published 2/10/99, effective 4/28/99]
[Filed 4/2/99, Notice 1/13/99—published 4/21/99, effective 7/1/99]
[Filed 6/25/99, Notice 5/5/99—published 7/14/99, effective 9/15/99]
[Filed 3/15/00, Notice 1/26/00—published 4/5/00, effective 5/10/00]
[Filed 3/16/01, Notice 2/7/01—published 4/4/01, effective 5/9/01]
[Filed 5/10/01, Notice 4/4/01—published 5/30/01, effective 7/4/01]
[Filed 3/14/02, Notice 2/6/02—published 4/3/02, effective 5/8/02]
[Filed 11/15/02, Notice 10/2/02—published 12/11/02, effective 1/15/03]
[Filed 3/14/03, Notice 2/5/03—published 4/2/03, effective 5/7/03]
[Filed 3/12/04, Notice 2/4/04—published 3/31/04, effective 5/5/04]
[Filed 3/11/05, Notice 2/2/05—published 3/30/05, effective 5/4/05]
[Filed 3/9/06, Notice 2/1/06—published 3/29/06, effective 5/3/06]
[Filed 3/16/07, Notice 1/31/07—published 4/11/07, effective 5/16/07]
[Filed 7/13/07, Notice 6/6/07—published 8/1/07, effective 9/5/07]
[Filed 5/14/08, Notice 4/9/08—published 6/4/08, effective 7/9/08]
[Filed ARC 7983B (Notice ARC 7792B, IAB 5/20/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 8659B (Notice ARC 8161B, IAB 9/23/09), IAB 4/7/10, effective 5/12/10]
[Filed ARC 8982B (Notice ARC 8762B, IAB 5/19/10), IAB 8/11/10, effective 9/15/10]
[Filed ARC 0577C (Notice ARC 0381C, IAB 10/3/12), IAB 2/6/13, effective 3/13/13]
[Filed ARC 1401C (Notice ARC 1317C, IAB 2/5/14), IAB 4/2/14, effective 5/7/14]

◊ Two or more ARCs

CHAPTER 95
VITAL RECORDS: GENERAL ADMINISTRATION

[Prior to 12/12/12, see [641] Ch 96, 98.1, Chs 103, 104]

641—95.1(144) Definitions. For the purpose of 641—Chapters 95 to 100, the following definitions shall apply:

"Administrative costs" means costs for the registration, collection, preservation, modification and certification of records, including but not limited to costs related to copying, regular mailing, searching, staffing, and maintenance of systems.

"Advanced registered nurse practitioner" or *"ARNP"* means an individual licensed pursuant to Iowa Code chapter 152.

"Age of majority" means the chronological moment when a child legally assumes majority control over the child's own person and actions and decisions, thereby terminating the legal control and legal responsibilities of the child's parents over and for the child. The period of minority extends to the age of 18 years, but every minor attains majority by marriage.

"Amendment" means a change made by the state registrar upon request from an entitled person as described in 641—95.8(144) to an obvious error, omission, or transposition of letters in a word of common knowledge one year or more after the event.

"Birth center" means a facility or institution, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur following a normal, uncomplicated, low-risk pregnancy.

"Birthing institution" means a private or public hospital licensed pursuant to Iowa Code chapter 135B that has a licensed obstetric unit or is licensed to provide obstetric services.

"Burial-transit permit" means a permit which is required to assume custody of a dead body or fetus pursuant to Iowa Code section 144.32.

"Certificate" means the written or electronic legal document containing the facts of an event; also used interchangeably with the term "record."

"Certificate of birth resulting in stillbirth," pursuant to Iowa Code section 144.31A, means a noncertified copy issued based upon a properly filed fetal death certificate to record the birth of a stillborn fetus.

"Certified copy" means an official copy of a registered vital record that is authenticated by the registrar in whose jurisdiction the record is registered. A certified copy contains a statement certifying the facts are true and accurate as recorded, is printed on security paper, and has authentication seals and signatures. A certified copy excludes all entries indicated as confidential or for statistical information.

"Commemorative certificate," pursuant to Iowa Code section 144.45A, means a commemorative abstract of an Iowa birth or marriage record that has been properly filed.

"Confidential information" means data or information that is on a vital record, is not considered public information, and is restricted as to its release pursuant to Iowa Code chapter 144 or other provision of federal or state law.

"Correction" means a change made by the state registrar upon observation, upon query, or upon request from an entitled person as described in 641—95.8(144) to an obvious error, omission, or transposition of letters in a word of common knowledge within one year and prior to the first anniversary of the event.

"County registrar" means the county recorder with the authority to record vital records and issue certified copies. The county registrar operates under the state vital records laws and rules and the guidance of the state registrar pursuant to Iowa Code sections 144.5 and 144.9. Pursuant to Iowa Code section 331.601(4), if the office of the county recorder has been abolished, "county registrar" means the office to which the duties are assigned by the county board of supervisors.

"County resident copy" means a properly filed, clearly marked working copy of a decedent's death certificate which is sent to and recorded by the county registrar of the county of the decedent's residence in the event the death occurred outside the county of the decedent's residence.

"Court of competent jurisdiction" means the appropriate court for the type of action. When used to refer to inspection of an original certificate of birth based upon an adoption, "court of competent jurisdiction" means the court in which the adoption was ordered.

"Custody" means guardianship or control of vital records, including both physical possession, referred to as physical custody, and legal responsibility, referred to as legal custody, unless one or the other is specified. The state registrar shall not transfer legal custody of vital records to another agency for purposes of granting public access until all the records have been purged of all confidential information.

"Day" means calendar day.

"Dead human body" means a lifeless human body or parts or bones of a body, if, from the state of the body, parts, or bones, it may reasonably be concluded that death recently occurred.

"Death" means the condition as defined in Iowa Code section 702.8.

"Declaration of paternity registry" means a registry for a putative father to declare paternity pursuant to Iowa Code section 144.12A. The declaration does not constitute an affidavit of paternity filed pursuant to Iowa Code section 252A.3A.

"Delayed birth record" means the registration of a live birth event occurring in Iowa one or more years after the date of birth which is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Delayed death record" means the registration of a death event occurring in Iowa one or more years after the date of death which is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Delayed marriage record" means the registration of a marriage event occurring in Iowa one or more years after the event which is clearly marked as delayed and shall show on its face the date of the delayed registration.

"Department" means the Iowa department of public health.

"Disinterment permit" means a permit which allows the removal of a dead human body or fetus from its original place of burial, entombment or interment for the purpose of autopsy or reburial.

"Emancipated minor" means a person younger than 18 years of age who has obtained the age of majority by court order.

"Fetal death" means a death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy which is not an induced termination of pregnancy. The death is indicated by the fact that, after such expulsion or extraction, the fetus does not breathe or show any other evidence of life such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles. In determining a fetal death, heartbeats shall be distinguished from transient cardiac contractions, and respirations shall be distinguished from fleeting respiratory efforts or gasps.

"Filing" means the presentation of a certificate, report, or other record of a live birth, death, fetal death, adoption, marriage, dissolution, or annulment for registration pursuant to Iowa Code chapter 144.

"Final disposition" means the burial, interment, cremation, removal from the state, or other disposition of a dead body or fetus.

"Foundling" means a living infant of unknown parentage whose place of birth is where the infant is found and whose date of birth shall be determined by approximation.

"Funeral director" means a person licensed in Iowa to practice mortuary science pursuant to Iowa Code chapter 156.

"Gestational surrogate arrangement" or *"surrogate mother arrangement,"* as defined in Iowa Code section 710.11, means an arrangement whereby a female agrees to be artificially inseminated with the sperm of a donor, to bear a child, and to relinquish all rights regarding that child to the donor or donor couple.

"Health care provider" means an individual licensed under Iowa Code chapter 148, 148C, 148D, or 152 or any individual who provides medical services under the authorization of the licensee.

"Induced termination of pregnancy" means the use of any means to terminate the pregnancy of a woman known to be pregnant with the intent other than to produce a live birth or to remove a dead fetus as defined in Iowa Code section 144.29A(8).

"Institution" means a facility as defined in Iowa Code section 144.1(10), including "hospital" as defined in Iowa Code section 135B.1(3) but not including "birth center" as defined in Iowa Code section 135.61(2).

"Institutional health facility" means a hospital as defined in Iowa Code section 135B.1, including a facility providing medical or health services that is open 24 hours per day, seven days per week and that is a hospital emergency room or a health care facility as defined in Iowa Code section 135C.1.

"Jurisdiction" means the state or county to which legal authority for the system of vital statistics has been granted by statute.

"Last name" means surname.

"Lineal consanguinity" means the existence of a line of descent in which one person is descended in a direct lineal relationship to another: as between the registrant and the registrant's parent, grandparent, great-grandparent, and so upward, in the direct ascending line; or between the registrant and the registrant's child, grandchild, great-grandchild and so downward in the direct descending line; or any siblings of the registrant.

"Live birth" means the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which after such expulsion or extraction, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. In determining a live birth, heartbeats shall be distinguished from transient cardiac contractions, and respirations shall be distinguished from fleeting respiratory efforts or gasps.

"Marriage license valid date" means the day on which the marriage license becomes valid and on or after which the parties are authorized to marry. When the marriage license valid date is computed, the date of application shall be excluded. The marriage license shall become valid after the expiration of three calendar days after the date of application, unless earlier validated by a court of competent jurisdiction.

"Medical certification" means a statement which attests that the medical information reported on the certificate of death or fetal death is accurate to the best of the medical certifier's knowledge.

"Medical certifier" means an Iowa-licensed physician, physician assistant, advanced registered nurse practitioner, or medical examiner who attests that the death event has taken place and who determines the cause and manner of death.

"Medical examiner" means the medical legal officer who makes the determination of the cause of death in nonroutine deaths such as non-natural, sudden, or unattended deaths or other deaths which affect the public interest.

"Modification" means any change made to a record that has been accepted and registered, such as a correction, an amendment, a change after adoption or paternity determination, or any other change.

"Mutual consent voluntary adoption registry" means a registry which authorizes adult adopted children, adult siblings, and the biological parents of adult adoptees to register to obtain identifying birth information.

"Natural cause of death" means a death due to a disease or the aging process and not due to external causes.

"Newborn safe haven registration" means the registration of the birth of a living infant of unknown parentage who has been abandoned or left at some unknown time after birth in a location other than the place of delivery.

"Non-birthing institution" means a private or public hospital licensed pursuant to Iowa Code chapter 135B that does not have a licensed obstetric unit or is not licensed to provide obstetric services but may provide obstetric services on an emergency basis.

"Non-institution birth" means a live birth that occurs outside of an institution and not en route to an institution.

"Non-natural cause of death," pursuant to Iowa Code section 144.28(1)*"a,"* means the death is a direct or indirect result of physical, chemical, thermal, or electrical trauma, or drug or alcohol intoxication or other poisoning.

"Notification of record search" means the document issued to the applicant when the record requested cannot be located through a search of registered records. The document contains a certification statement, is printed on security paper, and has authentication seals and signatures.

"Officiant" means (1) a judge of the Iowa supreme court, court of appeals, or district court, including a district associate judge, an associate juvenile judge, or a judicial magistrate, and including a senior judge as defined in Iowa Code section 602.9202(3), or (2) a person ordained or designated as a leader of the person's religious faith.

"Physician" means an individual licensed pursuant to Iowa Code chapter 148.

"Physician assistant" means an individual licensed pursuant to Iowa Code chapter 148C.

"Presumptive death" means a death event presumed to have occurred in Iowa where no human body is found and a court of competent jurisdiction has determined the death has occurred.

"Putative father" means a man who is alleged to be or who claims to be the biological father of a child born to a woman to whom the man is not married at the time of the conception or birth of the child or at any time during the period between the conception and birth of the child.

"Record of death" means the compilation of those entries of a death, whether electronic or paper, which are contained in indexed systems which record the death event occurring in Iowa. "Record of death" shall include the certificate of death.

"Record of fetal death" means the compilation of those entries of a fetal death, whether electronic or paper, which are contained in indexed systems which record a fetal death event occurring in Iowa. "Record of fetal death" shall include the certificate of fetal death.

"Record of foreign born adoption" means the compilation of those entries of a live birth event for a child born in a foreign country and adopted by an Iowa resident. "Record of foreign born adoption" shall include the certificate of foreign birth and shall not constitute U.S. citizenship.

"Record of live birth" means the compilation of those entries of a live birth event, whether electronic or paper, which are contained in indexed systems which record a live birth event occurring in Iowa. "Record of live birth" shall include the certificate of live birth.

"Record of marriage" means the compilation of those entries of a marriage event, whether electronic or paper, which are contained in indexed systems which record a marriage event occurring in Iowa. "Record of marriage" shall include the certificate of marriage.

"Registrant" means the person named on the certificate as the person who was born, died, or was married.

"Registration" means the process by which vital statistics records are completed, filed, and incorporated by the state registrar in the official records.

"Report of dissolution or annulment" means the statistical report of dissolution or annulment, whether electronic or paper, excluding all entries indicated as confidential or for statistical information only.

"Report of termination of pregnancy" means the aggregated compilation of the information received by the department on terminations of pregnancies for each information item listed, with the exception of the report tracking number, the health care provider code, and any set of information for which the number is so small that the confidentiality of any person to whom the information relates may be compromised.

"Research" means the systematic investigation designed primarily to develop or contribute to scientific, medical, public health or psychosocial disciplines and generalized knowledge and not for private gain.

"Sealed" means the removal from inspection of any copy of an original certificate in the custody of the county registrar and the state registrar.

"Security paper" means standardized paper for issuing certified copies of vital record events that meets, at a minimum, national requirements for security features embedded within the paper to deter

tampering, counterfeiting, photocopying, or imaging in order to help prevent fraudulent use of the certified copy and prevent identity theft.

"Single parent birth" means any record of live birth for which there is a reference or statement on the certificate or entry which directly indicates "no" regarding "born in wedlock" or "married"; or any record of live birth for which there is reference or statement on the certificate or entry that either parent is "unknown" or "anonymous"; or any certificate or entry which reflects the omission or absence of the name of the father of the child.

"Spontaneous termination of pregnancy" means the occurrence of an unintended termination of pregnancy at any time during the period from conception to 20 weeks' gestation and is not a spontaneous termination of pregnancy at any time during the period from 20 weeks or greater which is reported to the department as a fetal death under Iowa Code section 144.29.

"Standard birth registration" means a vital record of a live birth event that occurred in Iowa which was submitted and accepted for registration within one year of the event.

"State registrar" means the director of the department or the director's designee.

"Stillbirth" means an unintended fetal death occurring after a gestation period of 20 completed weeks or more or an unintended fetal death of a fetus with a weight of 350 or more grams.

"System of vital statistics" or *"system"* means the registration, collection, preservation, amendment, and certification of vital statistics records, and activities and records related thereto including the data processing, analysis, and publication of statistical data derived from such records.

"Uncertified copy" means an unofficial copy of a registered vital record which is not printed on security paper and which does not contain any authentication by the issuing jurisdiction. Uncertified copies shall contain an overstamp such as: "Not for Legal Purposes," "Administrative Use Only," "Deceased," "For Genealogical Purposes Only," "Working Copy," or any other overstamp as authorized by the state registrar.

"Vital records" means certificates or reports of birth, death, fetal death, marriage, dissolution, annulment, and related data.

"Vital statistics" means data derived from reports, certificates, and records of live birth, death, fetal death, induced termination of pregnancy, marriage, dissolution of marriage or annulment, and data related thereto.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.2(144) Vital records and statistics. There is established a division in the department which shall install, maintain, and operate the system of vital statistics throughout the state. No system for the registration of births, deaths, fetal deaths, adoptions, marriages, dissolutions, and annulments shall be maintained in the state or any of its political subdivisions other than the one provided for in Iowa Code chapter 144, including, but not limited to, a system maintained by any agency or private entity.

95.2(1) No person shall prepare or issue any certificate which purports to be an original certified copy or a copy of a certificate of birth, death, fetal death, adoption, marriage, dissolution, or annulment or any subset of the data items taken from a certificate except as provided for in Iowa Code chapter 144 and authorized by the state registrar.

95.2(2) A vital record, index, or subset of data shall not be maintained in any other system or manner except as provided for in Iowa Code chapter 144 and authorized by the state registrar.

95.2(3) The state registrar and the county registrar shall not maintain or issue copies of any vital record of an event occurring outside the state registrar's or county registrar's jurisdiction except as provided for in Iowa Code chapter 144 and authorized by the state registrar.

95.2(4) To protect the integrity of vital records and to ensure their proper use, no vital record, index, or subset of data shall be posted to the World Wide Web or published in any other manner except as provided for in Iowa Code chapter 144 and pursuant to subrule 95.10(3) or as authorized by the state registrar.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.3(144) Forms—property of department. All forms, certificates and reports pertaining to the registration of vital events are the property of the department and shall be surrendered to the state registrar upon demand.

95.3(1) The forms supplied or approved for reporting vital events shall be used for official purposes as provided for by law, rules and instructions of the state registrar.

95.3(2) No forms, except those furnished or approved by the state registrar, shall be used in the reporting of vital events or the making of copies of vital records.

95.3(3) Security paper used to report vital events shall be maintained in a secure location accessible only to the state and county registrars and their employees for administrative purposes.

95.3(4) Security paper shall be used to issue certified copies of Iowa vital records and shall be maintained in a secure location accessible only to the state and county registrars and their employees for administrative purposes.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.4(144) Information by others.

95.4(1) Any person having knowledge of the facts shall furnish information that the person possesses regarding any birth, death, fetal death, adoption, marriage, dissolution, or annulment, upon demand of the state registrar.

95.4(2) Every person in charge of an institution, or the person's designee, shall maintain a record of personal particulars and data concerning each person admitted or confined to the institution pursuant to Iowa Code section 144.47. This record shall include information required by the standard certificate of birth, death, and fetal death forms issued under the direction of the state registrar. The record shall be made at the time of admission based on the information provided by such person, but when information cannot be obtained from the person, it shall be obtained from the most knowledgeable relative or person acquainted with the facts. The name and address of the person providing the information shall be a part of the record.

95.4(3) Records maintained under this rule shall be retained for a period of not less than ten years and shall be made available for inspection by the state registrar upon demand.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.5(144) Handling of vital records.

95.5(1) State equipment and state vital records shall not be handled or accessed except by the state registrar, the state registrar's employees, or other authorized personnel for administrative purposes.

95.5(2) The county registrar shall provide assistance to the public in accessing vital records designated as public records in the custody of the county registrar.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.6(144) Fees.

95.6(1) *Fees for services provided by state registrar or county registrar.* The following fees shall be charged and remitted for the various services provided by the state registrar or the county registrar.

a. The state registrar or county registrar, as applicable, shall charge a fee of $20 to conduct a search for a record. On and after July 1, 2019, this fee will revert to $15.

(1) The search fee shall include one certified copy of the record.

(2) For each additional certified copy of the same record, a $20 fee shall be charged. On and after July 1, 2019, this fee will revert to $15.

(3) If, following a search, no record is found, the $20 fee shall be retained. On and after July 1, 2019, this fee will revert to $15.

b. The state registrar shall charge a fee of $20 to prepare an adoption certificate, to amend a certificate, to amend a certificate of live birth to reflect a legal change of name, to prepare a delayed certificate, to process other administrative or legal actions, or for the search and preparation of copies of supporting documents on file in the state registrar's office. On and after July 1, 2019, this fee will revert to $15. No fee shall be charged for establishment of paternity.

c. The state registrar shall charge a fee of $25 to file a completed application for the mutual consent voluntary adoption registry.

d. The state registrar shall charge a fee of $5 to update applicant information maintained in the mutual consent voluntary adoption registry and the declaration of paternity registry.

e. The state registrar shall charge a fee of $20 to amend an abstract or other legal documentation in support of the preparation of a new certificate. On and after July 1, 2019, this fee will revert to $15.

f. The state registrar shall charge a fee of $35 to conduct a search for a record for the purpose of issuing a commemorative copy of a certificate of birth or a certificate of marriage pursuant to Iowa Code section 144.45A. Fees collected shall be deposited in the emergency medical services fund established in Iowa Code section 135.25.

g. The state registrar shall charge a fee of $20 to conduct a search for a certificate of fetal death for the purpose of issuing an uncertified copy of a certificate of birth resulting in stillbirth pursuant to Iowa Code section 144.31A. On and after July 1, 2019, this fee will revert to $15.

95.6(2) *Overpayments.* Any overpayment of $5 or less received by the state registrar for the copying of or search for vital records or for the preparation or amending of a certificate shall not be refunded and shall be retained by the department.

95.6(3) *Certified copy of modified vital record.* When an individual is in possession of a previously issued certified copy of a vital record and the original record is subsequently modified, the individual may request and receive a certified copy of the modified record without charge if the certified copy prior to modification is relinquished to the registrar's office that issued the certified copy, unless otherwise directed by the state registrar.

95.6(4) *Search of county registrar's records—fee for uncertified copy.* A person who is requesting an uncertified copy of a record in the custody of the county registrar shall conduct the search of the county files to locate the record. If a copy is requested, the county registrar may charge a fee of no more than $5 for an uncertified copy of the county record. The fee shall be retained by the county.

95.6(5) *Distribution of fees.*

a. All fees collected by the county registrar and the state registrar shall be distributed as follows:

(1) For fees collected by a county registrar, with the exception of the fee in subrule 95.6(4), the county registrar shall retain $4 of each $20 fee collected by that office. On and after July 1, 2019, this $20 fee will revert to $15. Fees collected shall be divided as follows:

1. For a birth certificate or a marriage certificate, the state registrar shall receive $13, and $3 shall be deposited in the general fund of the state, except for the fee collected pursuant to paragraph 95.6(1)*"f."* On and after July 1, 2019, the amount received by the state registrar will revert to $8.

2. For a death certificate, the state registrar shall receive $11, the office of the state medical examiner shall receive $3, and $2 shall be deposited in the general fund of the state. On and after July 1, 2019, the amount received by the state registrar will revert to $6.

(2) For fees collected by the state registrar, the state registrar shall retain all fees, with the exception of the fees in paragraph 95.6(1)*"a,"* of which the state registrar shall retain $14 of each $20 fee collected for the issuance of certified copies. On and after July 1, 2019, the fee collected will revert to $15 and the amount retained by the state registrar will revert to $9. The $6 balance of certified copy fees collected by the state registrar shall be divided as follows:

1. For a birth certificate or a marriage certificate, $6 shall be deposited in the general fund of the state.

2. For a death certificate, the office of the state medical examiner shall receive $3, and $3 shall be deposited in the general fund of the state.

b. All fees retained by the state registrar shall be added to the vital records fund established by the department pursuant to Iowa Code section 144.46A.

c. All fees received by the office of the state medical examiner shall be added to the operating budget established for the operation of that office.

95.6(6) *Fee for search to verify vital statistics record.* A fee shall be charged by the state registrar for each search conducted for the purpose of providing verification of vital statistics data to an agency authorized to receive such data under subrule 95.12(2).

a. The amount of the fee shall be determined in an agreement with the department and shall be dependent on the nature and scope of the project and the resources required to obtain the data requested.

b. The state registrar shall retain the full amount of all fees collected under this subrule in the vital records fund established pursuant to Iowa Code section 144.46A.

95.6(7) *Fee for researcher access to vital statistics data.* A fee shall be charged to each researcher who is provided access to vital statistics data in accordance with Iowa Code section 144.44 and the required agreement executed with the department. The amount of the fee shall be based on the nature and scope of the research project and resources required to obtain the data requested.

a. The state registrar shall allocate the fees for copies of birth, marriage, and death certificates provided to researchers pursuant to the distribution of fees set forth in subrule 95.6(5).

b. The state registrar shall retain in the vital records fund established pursuant to Iowa Code section 144.46A the full amount of fees collected from researchers for searching files or records to create a data file.

95.6(8) *Service member who died while on active duty—waiver of fee.* The certified copy fee for a birth certificate or a death certificate of a service member, as defined in Iowa Code section 29A.90, who died while on active duty shall be waived for a period of one year from the date of death. Application for the certified copy shall be made by an entitled family member as described in 641—95.8(144) of the deceased service member or the entitled family member's legal representative. Documentation shall be submitted at the time of application to substantiate the date of death and active duty status.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter; **ARC 1074C**, IAB 10/2/13, effective 1/1/14; see Delay note at end of chapter; **ARC 1402C**, IAB 4/2/14, effective 5/7/14]

641—95.7(144) General public access of vital records in the custody of the county registrar. A vital record may be in the custody of the county registrar if the event occurred in that county and the record is not excluded by statute or definition for purposes of confidentiality.

95.7(1) There shall be public access and the right to inspect in person all vital records in the custody of the county registrar after they are purged of confidential information.

95.7(2) Electronic devices, including but not limited to scanners, cameras, cell phones or laptops, shall not be used to secure information from county vital records.

95.7(3) Information inspected and copied shall not be published or used to establish an index or record of information at any other location except as authorized by Iowa Code chapter 144.

95.7(4) County registrars may issue uncertified copies of vital records held in the registrars' custody and accessible to the general public, except those records excluded by statute or at the direction of the state registrar.

a. Requests for uncertified copies shall be accepted solely through in-person application after the applicant has conducted the applicant's own search for the record at the county registrar's office.

b. Uncertified copies shall be issued on plain white paper and clearly stamped "not for legal purposes." Security paper provided by the state registrar shall not be used to produce records for uncertified copies.

95.7(5) County registrars shall not provide specific information from any vital record via telephone, fax, electronic file, Web site, written letter or verbally, except for administrative purposes with the state vital records office.

95.7(6) County registrars shall not produce lists of vital records for any agency, private business, or member of the general public.

95.7(7) Records of births prior to July 1, 1995, that have been determined to be single parent births shall not be in the custody of the county registrar or accessible to the public as a right under Iowa Code chapter 22.

95.7(8) Records of births on and after July 1, 1995, that have been determined to be single parent births shall be accessible to the public as a right under Iowa Code chapter 22.

95.7(9) For a record of death registered on or after April 5, 2012, for a decedent who died outside of the county of the decedent's residence, the state registrar shall send a clearly marked copy of the decedent's death certificate and any amendments to the county registrar of the county of the decedent's

residence. The county registrar shall incorporate the clearly marked copy of the county resident death certificate in the vital records system maintained by the county. Certified or uncertified copies of county resident death certificates shall be clearly marked as "county resident copy."
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.8(144) Direct tangible interest in and entitlement to a vital record. Certified copies of vital records may be issued by the state registrar or county registrar upon written application, payment of the required fee pursuant to paragraph 95.6(1)*"a,"* and demonstration of a verifiable, direct tangible interest and entitlement.

95.8(1) The following persons shall be considered to have a direct tangible interest and entitlement and are authorized to obtain a certified copy of a vital record:

a. The registrant, if the registrant is of legal age, has reached the age of majority, or is an emancipated minor.

b. A member of the registrant's immediate legal family, including:

(1) Current spouse or surviving spouse;

(2) Children;

(3) Mother or father if listed on the registrant's birth certificate;

(4) Sibling, if sibling has reached the age of majority;

(5) Maternal grandparents, or paternal grandparents if the father is listed on the birth certificate; or

(6) Step-parent or step-child if:

1. Legal parent and step-parent are currently married at the time of application; or

2. Step-parent is the surviving spouse of the legal parent and not remarried.

c. The documented legal representative of the registrant or the registrant's immediate legal family, including:

(1) An attorney;

(2) A court-appointed guardian;

(3) A foster parent;

(4) A funeral director, for up to one year following the decedent's date of death; or

(5) A legal executor.

d. Other persons who demonstrate a direct tangible interest and entitlement when it is shown that the certified copy is needed to determine or protect a personal or property interest.

95.8(2) The following persons shall not be deemed to have direct tangible interest and entitlement or be authorized to secure vital records:

a. Biological parents of adopted persons in the absence of a court order from the court of competent jurisdiction;

b. Biological family members of adopted persons;

c. Adopted persons requesting biological family records; or

d. Commercial firms or agencies requesting lists of vital record events, or lists of names, or lists of addresses.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.9(144) Search and issuance of a certified copy of a vital record. The search and issuance of a certified copy of a vital record shall be requested from the state registrar or county registrar.

95.9(1) Only entitled applicants as described in rule 641—95.8(144) may submit requests for certified copies of vital records.

95.9(2) A person requesting a search and issuance of a certified copy of a vital record shall provide in writing the following:

a. The name of the person or persons whose vital record is to be searched;

b. The purpose of such request;

c. The relationship to the registrant of the person making the request; and

d. The notarized signature and the address of the person making the request.

95.9(3) In addition to a completed written application, the applicant shall provide:

a. A current, legible government-issued photo identification of the applicant making the request or other identification documents acceptable to the state registrar; and

b. Payment of the required fee before the search is conducted.

95.9(4) The state registrar and county registrar shall have the authority to require additional supporting documents to prove direct tangible interest and entitlement pursuant to rule 641—95.8(144).

95.9(5) If, after the search is conducted, no record is on file, the state registrar or county registrar shall issue a "notification of record search" on certified paper, and the fee for the search shall be retained pursuant to paragraph 95.6(1)*"a."*

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.10(144) Search and issuance for genealogy or family history. The search and issuance of a vital record for genealogy may be requested from the state registrar or county registrar upon written application and payment of the required fee pursuant to paragraph 95.6(1)*"a."*

95.10(1) The county registrar may issue certified copies of a vital record for genealogy or family history to an applicant who can satisfactorily demonstrate a line of direct lineal consanguinity and to aunts, uncles, and cousins not past twice removed.

95.10(2) The county registrar may issue uncertified copies of a vital record for genealogy or family history to any member of the general public except those records excluded by statute or at the direction of the state registrar. Requests for uncertified copies shall be accepted solely through in-person application after the applicant has conducted a search for the record at the county registrar's office.

95.10(3) The state registrar may issue uncertified copies of a vital record for genealogy or family history to an applicant who is conducting genealogical research and can satisfactorily demonstrate a line of direct lineal consanguinity and to aunts, uncles, and cousins not past twice removed if the event occurred 125 years ago or more for birth records and 75 years ago or more for marriage and death records.

95.10(4) All copies issued for genealogy or family history shall be clearly marked "for genealogical purposes only."

95.10(5) No copy shall be issued for genealogy or family history if the registrant is known to be living.

95.10(6) If, after the search is conducted, no record is on file, the state registrar or county registrar shall issue a "notification of record search" on certified paper, and the fee for the search shall be retained pursuant to paragraph 95.6(1)*"a."*

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.11(144) Registrars' responsibility for maintenance of confidentiality.

95.11(1) The state registrar and county registrar shall maintain the confidentiality of the following material, records, and information:

a. Entries indicated as confidential or statistical in nature on the face of the record or otherwise confidential by law;

b. Records of fetal death or stillbirth, adoption, legal change of name, and single parent births occurring prior to July 1, 1995; and

c. Any record which is ordered sealed by the state registrar or pursuant to a court order.

95.11(2) The county registrar shall take all necessary steps to ensure that confidential information reflected on vital records has been redacted from general public access. If confidential information is included with accessible information, only accessible information shall be made available to the general public for examination.

95.11(3) The county registrar shall employ at a minimum all of the following methods to ensure confidentiality:

a. Permanently cover or remove, by appropriate means, confidential information;

b. Promptly process the notice to seal a record as directed by the state registrar; and

c. Seal and not reproduce confidential information when copies of vital records are made.

95.11(4) The county registrar may charge reasonable administrative costs to reflect the expenses for efforts required to allow general public access, examination and the assurance of confidentiality of this material and information pursuant to the authority of Iowa Code chapter 22.

a. The administrative cost is to be paid by persons who request the services provided by the county registrar, including supervising, copying or providing a suitable place for such work.

b. The county registrar shall retain all administrative costs collected to allow general public access, examination, and the assurance of confidentiality of the vital record and information pursuant to the authority of Iowa Code chapter 22.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.12(144) Disclosure of data.

95.12(1) The state registrar may disclose data from the system of vital statistics to federal, state, county or municipal agencies of government that request such data in the conduct of their official duties, subject to conditions the state registrar may impose to ensure that the use of the data is limited to official purposes.

a. The aforementioned agencies shall not provide the certified copy or a copy of the vital record, or release information contained therein, to the person named on the certificate, a member of the person's legal family, or the person's legal representative.

b. Certified copies issued to the aforementioned agencies shall be appropriately stamped, for example, "administrative purposes only" or "for veteran affairs purposes only."

95.12(2) Confidential verifications of the facts contained in vital records may be furnished by the state registrar to any federal, state, county or municipal government agency or other entity in the conduct of the agency's or entity's official duties, subject to conditions the state registrar may impose to ensure that the verification is limited to official purposes.

a. Such confidential verifications shall be on forms prescribed and furnished by the state registrar or on forms furnished by the requesting agency or entity and acceptable to the state registrar, or the state registrar may authorize the verification in other ways.

b. The aforementioned agencies and entities shall not provide the original or a copy of the verified certificate, or release information contained therein, to the person named on the certificate, a member of the person's legal family, or the person's legal representative.

95.12(3) The state registrar may permit the use of data from vital statistics for research purposes subject to conditions the state registrar may impose to ensure the use of the data is limited to such research purposes. No data shall be furnished from vital statistics for research purposes until the state registrar has prepared in writing the conditions under which the data may be used and has received an agreement signed by a responsible agent of the research organization agreeing to meet and conform to such conditions.

95.12(4) The state registrar may transmit to the county registrar data needed to produce certified copies of vital records pursuant to rule 641—95.8(144).

95.12(5) The state registrar may transmit to the statewide immunization registry information from birth certificates for the sole purpose of identifying those children in need of immunizations. The state registrar may impose conditions to ensure that the use of the information is limited to official purposes.

95.12(6) The state medical examiner or the county medical examiner may request an uncertified copy of a death certificate before the death certificate is accepted and filed at the county registrar's office.

a. The copy shall be clearly stamped "administrative purposes only."

b. The death certificate shall be for the sole use of the state medical examiner or county medical examiner and shall not be used as a legal document, be distributed, be copied or be maintained other than to be made a part of the investigatory file.

c. If the state medical examiner or any county medical examiner determines the death does not warrant further investigation, the state medical examiner or county medical examiner shall destroy the uncertified copy of the death certificate.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.13(144) Preparation of certified copies. Certified copies of vital records may be prepared and issued by the state registrar or the county registrar pursuant to rules 641—95.3(144) and 641—95.9(144).

95.13(1) Certified copies of vital records may be made by mechanical, electronic, or other reproductive processes, except for confidential information. Certified copies shall be issued using security paper that is prescribed by the state registrar.

95.13(2) When a certified copy is issued, each certification shall contain a statement certifying that the facts are the true facts recorded in the issuing office, the date issued, the name of the issuing office, the registrar's signature or an authorized copy thereof, and the seal of the issuing office.

95.13(3) No person shall prepare or issue any certificate which purports to be an original, certified copy, or copy of a certificate of birth, death, fetal death, or marriage.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.14(144) Cancellation of fraudulent records.

95.14(1) When the state registrar determines that a certificate was registered through fraud or misrepresentation, the state registrar shall give to the registrant a notice in writing of the state registrar's intention to cancel said certificate.

95.14(2) The notice of cancellation shall give the registrant an opportunity to appear and show cause why the certificate shall not be canceled.

a. The notice may be served on the registrant, or, in the case of a minor or incompetent person, on the parent or guardian, by the forwarding of the notice by certified mail to the last-known address on file in the office of the state registrar.

b. The certificate shall not be available for certification unless the registrant, parent or guardian within 30 days after the date of mailing the notice shows cause satisfactory to the state registrar why the certificate shall not be canceled.

95.14(3) Upon presentation to the state registrar of a court order stating a marriage certificate was registered through fraud or misrepresentation, the state registrar shall remove said record from the vital statistics system. The state registrar shall order the county registrar to remove any record related to the marriage.

[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.15(144) Unlawful acts.

95.15(1) *Serious misdemeanors.* Any person who reports information required under Iowa Code chapter 144 and who commits any of the following acts is guilty of a serious misdemeanor:

a. Willfully and knowingly makes any false statement in a report, record, or certificate required to be filed or in an application for an amendment or willfully and knowingly supplies false information intending that such information be used in the preparation or amendment of any such report, record, or certificate.

b. Without lawful authority and with the intent to deceive, makes, alters, amends, or mutilates any report, record, or certificate required to be filed or a certified copy of such report, record, or certificate.

c. Willfully and knowingly uses or attempts to use or furnish to another for use for any purpose of deception any certificate, record, or report or certified copy thereof.

d. Willfully and knowingly alters, amends, or mutilates any copy, certified copy, record or report.

e. Willfully, with the intent to deceive, uses or attempts to use any certificate of birth or certified copy of a record of birth knowing that such certificate or certified copy was issued based upon a record which is false in whole or in part or which relates to the birth of another person.

f. Willfully and knowingly furnishes a certificate of birth or certified copy of a record of birth with the intention that it be used by a person other than the person to whose birth the record relates.

g. Disinterring a body in violation of Iowa Code section 144.34.

h. Knowingly violates a provision of Iowa Code section 144.29A.

95.15(2) *Simple misdemeanors.* Any person committing any of the following acts is guilty of a simple misdemeanor:

a. Knowingly transports or accepts for transportation, interment, or other disposition a dead body without an accompanying permit as provided in Iowa Code sections 144.32, 144.33, and 144.34.

b. Refuses to provide information required by Iowa Code chapter 144.

c. Willfully violates any of the provisions of Iowa Code chapter 144 or refuses to perform any of the duties imposed upon the person.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

641—95.16(144) Enforcement assistance.

95.16(1) The department shall report cases of alleged violations to the proper county attorney, with a statement of the facts and circumstances, for such action as is appropriate.

95.16(2) Upon request of the department, the attorney general shall assist in the enforcement of the provisions of Iowa Code chapter 144.
[**ARC 0483C**, IAB 12/12/12, effective 1/16/13; see Delay note at end of chapter]

These rules are intended to implement Iowa Code chapter 144.

[Filed ARC 0483C (Notice ARC 0376C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13][1]
[Filed ARC 1074C (Notice ARC 0926C, IAB 8/7/13), IAB 10/2/13, effective 1/1/14][2]
[Filed ARC 1402C (Notice ARC 1294C, IAB 1/22/14), IAB 4/2/14, effective 5/7/14]

[1] January 16, 2013, effective date of the rescission of Chapter 95 and the adoption of new Chapter 95 [ARC 0483C] delayed until adjournment of the 2013 General Assembly by the Administrative Rules Review Committee at its meeting held January 8, 2013; delay lifted at the meeting held March 8, 2013.

[2] January 1, 2014, effective date of 95.6(2) [ARC 1074C, Item 2] delayed 70 days by the Administrative Rules Review Committee at its meeting held October 8, 2013.

CHAPTER 127
COUNTY MEDICAL EXAMINERS
[Prior to 7/29/87, Health Department [470] Ch 127]

641—127.1(144,331,691) Definitions.

"Autopsy" means the external and internal postmortem examination of a deceased person.

"Cause of death" means the disease or injury which sets in motion the chain of events which eventually result in the death of a person. The physician shall consider "but for" this injury or disease the person would still be living.

"County medical examiner" or *"CME"* means a medical or osteopathic physician or surgeon licensed in the state of Iowa and appointed by the board of supervisors to serve in this capacity.

"County medical examiner investigator" or *"CME-I"* means an individual appointed by a county medical examiner, with approval by the board of supervisors and the state medical examiner, to serve under the supervision of a county medical examiner to assist in death investigations.

"County of appointment" means the county which requests a medical examiner to conduct an investigation, perform or order an autopsy, or prepare a report(s) in a death investigation case. The request may be authorized by the county attorney or the county medical examiner. The county of appointment shall be the county in which the death occurred.

"Cremation" means the technical process, using heat and flame, that reduces human remains to bone fragments.

"Day" means calendar day.

"Death" means the condition as described in Iowa Code section 702.8.

"Death affecting the public interest" means any death of a human being in which the circumstances are sudden, unexpected, violent, suspicious, or unattended, including but not limited to those deaths listed at Iowa Code section 331.802(3) and described as follows:

1. Violent death. Violent death includes homicide, suicide, or accidental death resulting from physical, mechanical, thermal, chemical, electrical, or radiation injury. A medical examiner's investigation and report are required irrespective of the period of survival following injury.

2. Death caused by criminal abortion, including self-induced.

3. Death related to disease thought to be virulent or contagious which may constitute a public hazard. Any such case investigated by a medical examiner shall be reported to the department and to the local health authority.

4. Death that has occurred unexpectedly or from an unexplained cause. This term includes the following situations:

- Death without prior medical conditions accounting for the death.
- Apparently instantaneous death without obvious cause.
- Death during or following an unexplained syncope or coma.
- Death during an unexplained, acute, or rapidly fatal illness.

5. Death of a person confined in a prison, jail, or correctional institution.

6. Death of a person when unattended by a physician during the period of 36 hours immediately preceding death.

- This term includes the following situations:

— Persons found dead without obvious or probable cause.

— Death when the person was unattended by a physician during a terminal illness.

— Fetal death unattended by a physician. A fetal death is a fetus born dead after a gestation period of 20 completed weeks or greater or a fetus which weighs 350 grams or more (Iowa Code section 144.29).

- This term does not include a prediagnosed terminal or bedfast case in which a physician has been in attendance within 30 days preceding the death.
- This term does not include a terminally ill patient who was admitted to and received services from a hospice program as defined in Iowa Code section 135J.1, if a physician or registered nurse employed by the program was in attendance within 30 days preceding the death.

7. Death of a person if the body is not claimed by a relative or friend.

8. Death of a person if the identity of the deceased is unknown.

9. Death of a child under the age of two years if death results from an unknown cause or if the circumstances surrounding the death indicate that sudden infant death syndrome may be the cause of death.

"Department" means the Iowa department of public health.

"Deputy county medical examiner" or *"DCME"* means an individual appointed by a county medical examiner, with approval by the board of supervisors and the state medical examiner, to assist the county medical examiner in the performance of the county medical examiner's duties.

"External examination" means a close inspection of the exterior of a deceased human body for the purpose of locating, describing, and delineating any and all injuries or other abnormalities. External examination of a body does not constitute an autopsy, even if toxicology samples are obtained.

"Fee" means an amount to be paid to a county medical examiner's office as determined by the board of supervisors of the county of appointment for completion of an investigation, autopsy, or report(s). Fees for services provided by the state medical examiner's office are established at 641—126.3(691).

"Form ME-1" means the Preliminary Report of Investigation by Medical Examiner form.

"Form ME-2" means the Medical Examiner Embalming Certificate form.

"Form ME-3" means the Permit by Medical Examiner for Autopsy form.

"Form ME-4" means the Preliminary Report of Child/Infant Death Scene Investigation form.

"Form ME-5" means the Cremation Permit by Medical Examiner form.

"Form ME-6" means the Iowa State Medical Examiner's Office Personal Effects form.

"Form ME-7" means the Medication List form.

"Form ME-8" means the Body Identification Record form.

"Manner of death" means the circumstances under which the cause of death occurred and may be specified as follows: natural, accident, suicide, homicide, undetermined, or pending.

"Medical care provider" means an individual licensed or certified in any medical profession, including but not limited to a physician, physician assistant, nurse, emergency medical care provider, certified nurse's aide, pharmacist, physical therapist, and medical technologist.

"Medical examiner" means the state medical examiner, deputy state medical examiner, county medical examiner, or deputy county medical examiner.

641—127.2(331,691) Duties of medical examiners—jurisdiction over deaths which affect the public interest.

127.2(1) *Jurisdiction.* Upon receiving notification of a death which affects the public interest, a medical examiner shall notify any appropriate law enforcement agency not otherwise notified and shall take charge of the body of the decedent. The body shall not be disturbed or removed from the position in which it was found without authorization from the medical examiner except for the purpose of preserving the body from loss or destruction or permitting the passage of traffic on a highway, railroad, or airport, or unless the failure to remove the body might endanger life, safety, or health.

127.2(2) *Investigation.* A county medical examiner shall conduct a preliminary investigation of the cause and manner of death and shall utilize the investigative protocol outlined in the most current edition of the County Medical Examiner's Handbook, available from the state medical examiner's office. A medical examiner may perform or authorize performance of any scientific study to assist in identifying the cause, circumstances, and manner of death. A medical examiner shall cooperate with other investigating officials and agencies involved and shall share reports, information, and conclusions with these officials and agencies.

127.2(3) *Reports required.*

a. Form ME-1.

(1) Preparation and filing. A county medical examiner shall prepare a written report of the examiner's findings on the Preliminary Report of Investigation by Medical Examiner, Form ME-1. A county medical examiner shall file the original Form ME-1 with the state medical examiner's office within 14 days of the date of death and shall file a copy of the Form ME-1 with the county attorney within 14 days of the date of the death and shall retain a copy for the medical examiner's records.

(2) Content. Form ME-1 shall be completed as fully as possible in light of all available information and may be signed by either a county medical examiner or a county medical examiner investigator acting under the supervision of a county medical examiner. If the cause or manner of death, identity of the decedent, or other information is unknown or pending at the time of filing, "unknown" or "pending" may be written in the appropriate area of the form. If additional information becomes available, this information shall be forwarded to the state medical examiner in written form at such time as it becomes available to be added as a supplement to the file.

b. Jurisdiction declined or terminated. A form designated by the office of the state medical examiner shall be completed and filed in accordance with subparagraphs (1) and (2) of paragraph *"a"* above in cases reported to the county medical examiner where jurisdiction is terminated or declined.

127.2(4) *Disposition of body.* After an investigation, including an autopsy if one was performed, the body of the decedent shall be made available to the funeral home designated by a relative or friend of the decedent for burial or appropriate disposition. A medical examiner shall not use influence in favor of a particular funeral director or funeral home. If no one claims a body, it shall be disposed of as provided in Iowa Code chapter 142.

127.2(5) *Coverage.*

a. When an individual is required to report a death to a medical examiner and the county medical examiner cannot be located or is not available, the individual shall contact a county medical examiner from any adjacent Iowa county to perform those duties outlined in this chapter. The responding medical examiner shall have full authority to conduct any procedures necessary to the investigation of the cause and manner of death. If an adjacent county medical examiner is not available, the state medical examiner shall be contacted and may act in the capacity of a county medical examiner.

b. The responding county medical examiner shall be reimbursed by the county for which the service is provided for all fees and expenses at the rate which is customarily paid by the county for which the service is provided or at a rate agreed upon by the medical examiner and the board of supervisors of the county for which the service is provided.

641—127.3(331,691) Autopsies.

127.3(1) *Autopsy required.* A county medical examiner shall perform an autopsy or order that an autopsy be performed in the following cases:

a. All cases of homicide or suspected homicide, irrespective of the period of survival following injury.

b. All cases in which the manner of death is undetermined.

c. All cases involving unidentified bodies.

d. All deaths of children under the age of two when there is not a clear cause of death, including suspected cases of sudden infant death syndrome. A summary of the findings of the autopsy shall be transmitted by the physician who performed the autopsy to the county medical examiner within two days of completion of the report. Autopsies performed on children under the age of two when the circumstances surrounding the death indicate that sudden infant death syndrome may be the cause of death or the cause of death is not clearly explained by known medical history shall conform to Form ME-4.

e. All work- and farm-related deaths unless there is an obvious natural cause of death.

f. All drowning deaths.

g. All deaths of commercial vehicle drivers that occur during the performance of their job duties.

h. Deaths due to poisoning.

i. Deaths of airplane pilots who die as a result of an airplane crash. The National Transportation Safety Board and the Federal Aviation Administration should be contacted prior to the autopsy to request specimen kit(s).

j. Deaths due to a natural disaster, including tornadoes and floods.

k. Deaths in a prison, jail or correctional institution or under police custody, where there is not a natural disease process that accounts for the death.

127.3(2) *Autopsy recommended.* It is recommended that a county medical examiner should perform an autopsy or order that an autopsy be performed in the following cases:

a. Deaths of adolescents less than 18 years of age when there is not a natural cause of death.

b. All cases which involve a motor vehicle crash, unless it is a single motor vehicle accident with no potential for litigation and there is an obvious cause of death or the injuries have been clearly documented by hospitalization.

c. Rescinded IAB 3/29/06, effective 5/3/06.

d. Deaths from suicide.

e. All pedestrian, bicycle, motorcycle, snowmobile, boating, watercraft, three- or four-wheeler or all-terrain vehicle fatalities.

f. Deaths due to failure of a consumer product.

g. Deaths due to a possible public health hazard.

h. Deaths due to drug or alcohol abuse or overdose.

i. Electrical- and lightning-related deaths.

j. Deaths from burns or smoke or soot inhalation.

k. All deaths related to exposure, such as hypothermia and hyperthermia.

l. All sport-related deaths, including but not limited to deaths from auto racing and deaths resulting from injuries sustained in football, basketball, baseball, softball, soccer, or other games or sports.

127.3(3) *Other deaths.* For those deaths not listed in subrule 127.3(1) or 127.3(2), a county medical examiner shall determine whether the public interest requires an autopsy and may perform an autopsy or order that an autopsy be performed. A county medical examiner may consult with the state medical examiner to assist in determining the need for an autopsy.

127.3(4) *Performance of autopsy.*

a. *Who may authorize.* Autopsies may be authorized by the state medical examiner, the county medical examiner for the county in which the death occurred or the county where any injury contributing to or causing the death was sustained, or the county attorney who would have jurisdiction in any criminal proceeding related to the death.

b. *Who may perform.* An autopsy shall be performed by a pathologist trained or with experience in forensic pathology, licensed to practice medicine and surgery or osteopathic medicine and surgery in the state of Iowa and board-certified by the American Board of Pathology, or under the direct supervision of a physician with these qualifications. If an autopsy is performed by a physician who does not satisfy these criteria and who is not performing under the direct supervision of a physician who satisfies these criteria, the physician shall submit a supplemental report with the Permit by Medical Examiner for Autopsy, Form ME-3, which details the specific training, education, and experience which qualify the physician to perform an autopsy. The following cases/types of deaths shall be transported to the office of the state medical examiner for autopsy unless otherwise approved by the state medical examiner:

(1) Deaths of adolescents through 18 years of age when there is not a known or preexisting natural cause of death.

(2) All cases of homicide or suspected homicide, irrespective of the period of survival following injury.

(3) Deaths of children under the age of 2 years if death results from an unknown cause or if the circumstances surrounding the death indicate that Sudden Infant Death Syndrome may be the cause of death.

(4) All suspicious suicides.

(5) All high-profile deaths including, but not limited to, deaths of elected officials in municipal, state or federal government.

(6) All deaths of inmates occurring in any institutions under the department of corrections as outlined in Iowa Code section 904.102, excluding those deaths that result from a pre-existing medical condition.

c. *Permit required—Form ME-3.* A medical examiner shall complete the Permit by Medical Examiner for Autopsy, Form ME-3. All reasonable efforts shall be made to complete the Form ME-3

prior to the performance of an autopsy and to submit the form with the body of the decedent or to submit the form via facsimile to the state medical examiner.

127.3(5) *Autopsy report.* A complete record of the findings of the autopsy shall be submitted to the state medical examiner's office, the county attorney of the county where the death occurred and the county attorney of the county where the injury contributing to or causing the death was sustained within 90 days following the date of death, unless unusual circumstances requiring further investigation or testing exist. The report filed shall include all diagrams, transcriptions of the autopsy observations and opinions, and toxicology reports.

127.3(6) *Out-of-state autopsy.* The body of a decedent may be sent out of state for an autopsy or postmortem examination only if the county medical examiner certifies in writing that the out-of-state autopsy or examination is necessary for any of the following reasons:

a. A forensic pathologist practicing in the state of Iowa is unavailable;

b. Requiring an in-state autopsy would cause financial hardship; or

c. Requiring an in-state autopsy would delay the funeral or burial more than three days.

127.3(7) *Retention and disposal of tissues, organs, and bodily fluids.* The office of the state medical examiner shall retain tissues, organs, and bodily fluids as necessary to determine the cause and manner of death or as deemed advisable by the state medical examiner for medical or public health investigation, teaching, or research. Tissues, organs, and bodily fluids shall be retained at a minimum for the time periods established by the National Association of Medical Examiners and may be retained for a longer time period at the discretion of the state medical examiner. Tissues, organs, and bodily fluids retained under this subrule shall be disposed of without the specific consent or notification of the legal next of kin and in accordance with applicable federal and state regulations including but not limited to OSHA-recommended biohazard and blood-borne pathogen standards. The anatomical material shall be removed from the laboratory premises through use of a contracted, licensed, and bonded medical waste removal service to a medical waste processing center for final disposition.

641—127.4(331,691) Fees.

127.4(1) *Payment of fee and expenses.*

a. A medical examiner shall receive from the county of appointment a fee for each preliminary investigation and report submitted in a case in which a death affects the public interest. A county medical examiner shall also receive from the county of appointment the examiner's actual expenses.

b. A pathologist or other physician who performs an autopsy under medical examiner authorization shall be paid for the services by the county of appointment.

127.4(2) *Reimbursement.*

a. *County of residence different from county of appointment—Iowa resident.* The county of the decedent's residence shall reimburse the county of appointment for the fee and expenses paid by the county of appointment.

b. *Death caused by criminal defendant.* If the person's death is caused by a criminal defendant who has been convicted and sentenced for murder, voluntary manslaughter, involuntary manslaughter, or homicide by vehicle, the county of the person's residence may recover from the defendant the fee and expenses.

c. *Out-of-state resident—law enforcement involvement.* The fee and expenses of a county medical examiner who performs an investigation or autopsy of a person who dies after being brought into the state for emergency medical treatment by or at the direction of an out-of-state law enforcement officer or public authority shall be paid by the state. A claim for payment shall be filed with the state appeal board.

d. *Out-of-state resident—no law enforcement involvement.* The fee and expenses of a county medical examiner who performs an investigation or autopsy of an out-of-state resident shall be paid by the county of appointment.

e. *Child under the age of two.* Rescinded IAB 4/2/14, effective 5/7/14.

[**ARC 1403C**, IAB 4/2/14, effective 5/7/14]

641—127.5(144,331,691) Death certificates—deaths affecting the public interest.

127.5(1) *Completion.* The funeral director to whom the body is released shall complete the personal data on the death certificate. The medical examiner shall complete the manner of death and cause of death sections of the death certificate within 72 hours after determination of the cause of death. If an autopsy is performed by the state medical examiner, the death certificate shall be submitted to the state medical examiner's office for completion. All information included on the certificate shall be typewritten.

127.5(2) *Filing.* The funeral director shall file the certificate with the county registrar in the county in which the death occurred. A death certificate shall be filed prior to the issuance of a burial transit permit and prior to disposal of the body.

127.5(3) *Extension of time.* If a medical examiner is unable to complete the manner of death and cause of death sections of the death certificate within the 24-hour time period, the funeral director shall file a death certificate form completed with all available information. Such certificate shall be authority for the issuance of a burial transit permit. Within 15 days, a supplemental report shall be filed with the local registrar which provides the information missing from the original certificate.

127.5(4) *Additional standards.* Additional rules relative to death certificates may be found at 641—Chapter 101.

641—127.6(331,691) Cremation.

127.6(1) *Permit obtained prior to cremation—Form ME-5.* A permit for cremation shall be obtained from a county medical examiner prior to cremation of a body of a decedent. For purposes of this requirement, a facsimile or electronic copy of the cremation permit has the same legal effect as the original. Cremation permits shall be issued on the Cremation Permit by Medical Examiner, Form ME-5.

127.6(2) *Requirements for issuance of permit.* A county medical examiner shall direct an inquiry into the cause and manner of death and shall determine whether the death is one which affects the public interest prior to issuing a cremation permit.

a. *Death which affects the public interest.* If the death occurred in a manner specified in Iowa Code section 331.802(3) or if reasonable suspicion that the death occurred in such a manner exists, a medical examiner shall view the body, make a personal inquiry into the cause and manner of death, and complete or cause to be completed all necessary autopsy or postmortem examinations prior to issuing a cremation permit.

b. *Death which does not affect the public interest.* If, following an inquiry into the cause and manner of death, the county medical examiner determines that the death did not occur in a manner specified in Iowa Code section 331.802(3), a medical examiner is not required to view the body prior to issuing a cremation permit. A county medical examiner shall certify on the Cremation Permit by Medical Examiner, Form ME-5, that the medical examiner's inquiry into the cause and manner of death did not disclose evidence that the death occurred in a manner specified in Iowa Code section 331.802(3).

127.6(3) *Fee.* A fee for the Cremation Permit by Medical Examiner, Form ME-5, shall be paid by the family, next of kin, guardian of the decedent, or other person authorized to act on behalf of the decedent.

641—127.7(331,691) County medical examiner investigators.

127.7(1) *Appointment.* A county medical examiner may appoint one or more county medical examiner investigators upon approval by the board of supervisors and the state medical examiner.

127.7(2) *Qualifications.*

a. Prior to appointment, a CME-I should possess a minimum of two years of experience as a licensed or certified nurse or medical care provider. A certified peace officer may be appointed to the position of CME-I if a nurse or medical care provider is not available.

b. A CME-I shall satisfy the following criteria:

(1) Prior to or within two years of appointment, attend the St. Louis University School of Medicine Basic Medicolegal Death Investigation Course or its state medical examiner-approved equivalent; and

(2) Prior to or within five years of appointment, obtain certification at the registry-level as a death investigator by the American Board of Medicolegal Death Investigators.

c. A CME-I is not required to meet the requirements of paragraph *"a"* or *"b"* if the individual has functioned in the capacity of a CME-I for a period of five years as of January 1, 2002.

d. If a CME is unable to appoint a CME-I who possesses the qualifications required by paragraph *"a," "b,"* or *"c,"* the CME may request a waiver. Waiver requests shall be submitted in writing to the state medical examiner and shall include the efforts undertaken by the CME to locate a CME-I who meets the above qualifications; the qualifications of the individual willing to serve in the capacity of CME-I; and the period of time for which the waiver is requested, not to exceed two years. The state medical examiner has sole discretion to waive the requirements of this rule and may withdraw or modify a waiver request upon a finding that the CME-I has failed to adequately perform the duties of the position or for other good cause.

e. If a CME-I is unable to meet the eligibility requirements for obtaining registry certification due to the small number of cases requiring investigation in the county of appointment, then a waiver shall be obtained from the state medical examiner in order for the investigator to continue his or her duties. The county medical examiner shall submit a request for a waiver in writing with documentation of the number of deaths occurring in the county of appointment which require death investigation. The waiver must be renewed every five years if the required number of investigations has still not been achieved.

127.7(3) *Duties.* A CME-I shall assist in death investigations. A CME-I acting under the supervision of a county medical examiner may sign the Form ME-1. A CME-I shall not sign a certificate of death or a Form ME-5.

127.7(4) *Supervision.* A CME-I shall serve under the supervision of a county medical examiner. A CME-I provides services under the direction of a county medical examiner or state medical examiner's office. A CME-I shall at all times perform services in a manner which is consistent with the protocol outlined in the most current edition of the County Medical Examiner's Handbook and any policies or protocols of the supervising county medical examiner.

127.7(5) *Fees.* Fees for the services provided by a CME-I shall be paid by the county of appointment.
[**ARC 8526B**, IAB 2/10/10, effective 3/17/10]

641—127.8(331,691) Deputy county medical examiners.

127.8(1) *Appointment.* A county medical examiner may appoint one or more deputy county medical examiners upon approval by the board of supervisors and the state medical examiner.

127.8(2) *Qualifications.* A DCME shall be licensed in the state of Iowa as a medical or osteopathic physician or surgeon.

127.8(3) *Duties.* A DCME shall serve at the direction of the county medical examiner and may perform any duty of a county medical examiner which is delegated by the county medical examiner to the DCME.

127.8(4) *Fees.* Fees for the services provided by a DCME shall be paid by the county of appointment.

641—127.9(331,691) Failure to comply with rules. If a county medical examiner, deputy county medical examiner, county medical examiner investigator, pathologist, or other physician fails to comply with these rules, the state medical examiner may provide written notice of the failure to comply to that individual, the appropriate county medical examiner, and the appropriate county board of supervisors. Within 30 days of the date of the notice, the individual to whom the notice was provided shall submit a written response to the state medical examiner, outlining a proposed corrective action plan. If no response is received within the 30 days or if the proposed corrective action plan is unacceptable, the state medical examiner shall forward copies of the notice and all pertinent correspondence and information to the board of supervisors for the county which appointed the individual, notifying the board of the individual's failure to comply with these rules.

641—127.10(331,691,22) Confidentiality. Records and reports of a medical examiner may be confidential records pursuant to Iowa Code sections 22.7(2), 22.7(5), and 22.7(41) and other provisions of Iowa law. Prior to releasing a medical examiner record or report to a member of the public, a county

medical examiner may inform the appropriate law enforcement agency, the county attorney, and the state medical examiner to determine whether release is authorized under Iowa law.

641—127.11(331,691,670) Indemnification. A board of supervisors shall defend, hold harmless, and indemnify a county medical examiner and any properly appointed staff members to the extent provided in Iowa Code chapter 670.

These rules are intended to implement Iowa Code chapters 331 and 691.

[Filed May 10, 1966]
[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]
[Filed 11/19/01, Notice 10/3/01—published 12/12/01, effective 1/16/02]
[Filed 1/16/03, Notice 11/27/02—published 2/5/03, effective 3/12/03]
[Filed 3/9/06, Notice 2/1/06—published 3/29/06, effective 5/3/06]
[Filed 1/10/07, Notice 11/22/06—published 1/31/07, effective 3/7/07]
[Filed 7/10/08, Notice 5/21/08—published 7/30/08, effective 9/3/08]
[Filed ARC 8526B (Notice ARC 8162B, IAB 9/23/09), IAB 2/10/10, effective 3/17/10]
[Filed ARC 1403C (Notice ARC 1316C, IAB 2/5/14), IAB 4/2/14, effective 5/7/14]

CHAPTER 131
EMERGENCY MEDICAL SERVICES—PROVIDER EDUCATION/TRAINING/CERTIFICATION

641—131.1(147A) Definitions. For the purpose of these rules, the following definitions shall apply:

"Advanced emergency medical technician" or *"AEMT"* means an individual who has successfully completed a course of study based on the United States Department of Transportation's Advanced Emergency Medical Technician Instructional Guidelines (January 2009), has passed the NREMT practical and cognitive examinations for the AEMT, and is currently certified by the department as an AEMT.

"Automated external defibrillator" or *"AED"* means an external semiautomatic device that determines whether defibrillation is required.

"Candidate" means an individual who has successfully completed a course of study at an EMR, EMT, AEMT or paramedic or other level certified by the department and who has been recommended by a training program for NREMT certification examination.

"CECBEMS" means the continuing education coordinating board for emergency medical services.

"CEH" means continuing education hour, which is based upon a minimum of 50 minutes of training per hour.

"Certification period" means the length of time an emergency medical care provider certificate is valid. The certification period shall be for two years from initial issuance or from renewal, unless otherwise specified on the certificate or unless sooner suspended or revoked.

"Certification status" means a condition placed on an individual certificate for identification as active, deceased, denied, dropped, expired, failed, hold, idle, inactive, incomplete, pending, probation, restricted, retired, revoked, surrendered, suspended, or temporary.

"Continuing education" means department-approved training which is obtained by a certified emergency medical care provider to maintain, improve, or expand relevant skills and knowledge and to satisfy renewal of certification requirements.

"Course completion date" means the date of the final classroom session of an emergency medical care provider course.

"Course coordinator" means an individual who has been assigned by the training program to coordinate the activities of an emergency medical care provider course.

"CPR" means training and successful course completion in cardiopulmonary resuscitation, AED, and obstructed airway procedures for all age groups according to recognized national standards.

"Critical care paramedic" or *"CCP"* means a currently certified paramedic specialist who has successfully completed a critical care course of instruction approved by the department and has received endorsement from the department as a critical care paramedic.

"Current course completion" means written recognition given for training and successful course completion of CPR with an expiration date or a recommended renewal date that exceeds the current date.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"DOT" means the United States Department of Transportation.

"Emergency medical care" means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by protocol.
5. Any medical procedure authorized by subrule 131.3(3).

"Emergency medical care provider" means an individual who has been trained to provide emergency and nonemergency medical care at the EMR, EMT, AEMT, paramedic or other certification level recognized by the department before 2011 and who has been issued a certificate by the department.

"Emergency medical responder" or *"EMR"* means an individual who has successfully completed a course of study based on the United States Department of Transportation's Emergency Medical Responder Instructional Guidelines (January 2009), has passed the NREMT practical and cognitive examinations for the EMR, and is currently certified by the department as an EMR.

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

"Emergency medical technician" or *"EMT"* means an individual who has successfully completed a course of study based on the United States Department of Transportation's Emergency Medical Technician Instructional Guidelines (January 2009), has passed the NREMT practical and cognitive examinations for the EMT, and is currently certified by the department as an EMT.

"Emergency medical technician-ambulance" or *"EMT-A"* means an individual who has successfully completed the 1984 United States Department of Transportation's Emergency Medical Technician-Ambulance curriculum, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-A.

"Emergency medical technician-basic" or *"EMT-B"* means an individual who has successfully completed the current United States Department of Transportation's Emergency Medical Technician-Basic curriculum and department enhancements, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-B.

"Emergency medical technician-defibrillation" or *"EMT-D"* means an individual who has successfully completed an approved program which specifically addresses manual or automated defibrillation, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-D.

"Emergency medical technician-intermediate" or *"EMT-I"* means an individual who has successfully completed an EMT-Intermediate curriculum approved by the department, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-I.

"Emergency medical technician-paramedic" or *"EMT-P"* means an individual who has successfully completed the current United States Department of Transportation's EMT-Intermediate curriculum (1999) or the 1985 or earlier DOT EMT-P curriculum, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-P.

"EMS advisory council" means the council appointed by the director, pursuant to Iowa Code chapter 147A, to advise the director and develop policy recommendations concerning regulation, administration, and coordination of emergency medical services in the state.

"EMS evaluator" or *"EMS-E"* means an individual who has successfully completed an EMS evaluator curriculum approved by the department and is currently endorsed by the department as an EMS-E.

"EMS instructor" or *"EMS-I"* means an individual who has successfully completed an EMS instructor curriculum approved by the department and is currently endorsed by the department as an EMS-I.

"Endorsement" means an approval granted by the department authorizing an individual to serve as an EMS-I, EMS-E or CCP.

"First responder" or *"FR"* means an individual who has successfully completed the current United States Department of Transportation's first responder curriculum and department enhancements, has passed the department's approved written and practical examinations, and is currently certified by the department as an FR.

"First responder-defibrillation" or *"FR-D"* means an individual who has successfully completed an approved program that specifically addresses defibrillation, has passed the department's approved written and practical examinations, and is currently certified by the department as an FR-D.

"Good standing" means that a student or candidate is in compliance with these rules and training program requirements.

"Idle" means the status of a lower certification level when a higher certification level is held.

"Inactive" means the status of a certification level when an individual requests inactive status or moves from a higher certification level to a lower certification level that was previously idle.

"NCA" means North Central Association of Colleges and Schools.

"NREMT" means National Registry of Emergency Medical Technicians.

"Out-of-state student" means any individual participating in clinical or field experience as a student in an approved out-of-state training program.

"Out-of-state training program" means an EMS program located outside the state of Iowa that is approved by the authorizing agency of the program's home state to conduct initial EMS training for EMR, EMT, AEMT, paramedic or other level certified by the department.

"Outreach course coordinator" means an individual who has been assigned by the training program to coordinate the activities of an emergency medical care provider course held outside the training program facilities.

"Paramedic" means an individual who has successfully completed a course of study based on the United States Department of Transportation's Paramedic Instructional Guidelines (January 2009), has passed the NREMT practical and cognitive examination for the paramedic, and is currently certified by the department as a paramedic.

"Paramedic specialist" or *"PS"* means an individual who has successfully completed the current United States Department of Transportation's EMT-Paramedic curriculum (1999) or equivalent, has passed the department's approved written and practical examinations, and is currently certified by the department as a paramedic specialist.

"Patient" means an individual who is sick, injured, or otherwise incapacitated.

"Physician" means an individual licensed under Iowa Code chapter 148.

"Physician assistant" or *"PA"* means an individual licensed pursuant to Iowa Code chapter 148C.

"Physician designee" means a registered nurse licensed under Iowa Code chapter 152 or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistants. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the care provided by emergency medical care providers.

"Preceptor" means an individual who has been assigned by the training program, clinical facility or service program to supervise students while the students are completing their clinical or field experience. A preceptor must be an emergency medical care provider certified at the level at which the preceptor is providing supervision or at a higher level or must be licensed as a registered nurse, physician assistant or physician.

"Primary instructor" means an individual who is responsible for teaching the majority of an emergency medical care provider course.

"Protocols" means written directions and orders consistent with the department's standard of care that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols must be approved by the service program's medical director and address the care of both adult and pediatric patients.

"Registered nurse" or *"RN"* means an individual licensed pursuant to Iowa Code chapter 152.

"Service program" or *"service"* means any medical care ambulance service or nontransport service that has received authorization from the department.

"Service program area" means the geographic area of responsibility served by any given ambulance or nontransport service program.

"Student" means any individual enrolled in a training program and participating in the didactic, clinical, or field experience portion of the program.

"Training program" means an Iowa college approved by the North Central Association of Colleges and Schools or an Iowa hospital authorized by the department to conduct emergency medical care training.

"Training program director" means an appropriate health care professional (full-time educator or practitioner of emergency or critical care) assigned by the training program to direct the operation of the training program.

"Training program medical director" means a physician licensed under Iowa Code chapter 148 who is responsible for directing an emergency medical care training program.
[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.2(147A) Emergency medical care providers—requirements for enrollment in training programs. To be enrolled in an EMS training program course leading to certification by the department, an applicant shall:

1. Be at least 17 years of age at the time of enrollment.
2. Have a high school diploma or its equivalent if enrolling in an AEMT or paramedic course.
3. Be able to speak, write and read English.
4. Hold a current course completion card in CPR if enrolling in an EMT, AEMT or paramedic course.
5. Be currently certified, as a minimum, as an EMT if enrolling in an AEMT or paramedic course. If an applicant is currently nationally registered but not certified in Iowa, the applicant must submit an endorsement application to the department within 14 days after the course start date.
6. Be a current emergency medical care provider, RN, PA, or physician and submit a recommendation in writing from an approved EMS training program if enrolling in an EMS instructor course.
7. Be currently certified as a paramedic if enrolling in a CCP course.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.3(147A) Emergency medical care providers—authority.

131.3(1) Authority of emergency medical care personnel. An emergency medical care provider who holds an active certification issued by the department may:

a. Render, via on-line medical direction, emergency and nonemergency medical care in those areas for which the emergency medical care provider is certified as part of an authorized service program:

(1) At the scene of an emergency;
(2) During transportation to a hospital;
(3) While in the hospital emergency department;
(4) Until patient care is directly assumed by a physician or by authorized hospital personnel; and
(5) During transfer from one medical care facility to another or to a private home.

b. Function in any hospital or any other entity in which health care is ordinarily provided only when under the direct supervision of a physician when:

(1) Enrolled as a student in, and approved by, a training program;
(2) Fulfilling continuing education requirements;
(3) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician as a member of an authorized service program, or in an individual capacity, by rendering lifesaving services in the facility in which employed or assigned pursuant to the emergency medical care provider's certification and under direct supervision of a physician, physician assistant, or registered nurse. An emergency medical care provider shall not routinely function without the direct supervision of a physician, physician assistant, or registered nurse. However, when the physician, physician assistant, or registered nurse cannot directly assume emergency care of the patient, the emergency medical care provider may perform, without direct supervision, emergency medical care procedures for which certified, if the life of the patient is in immediate danger and such care is required to preserve the patient's life;
(4) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only under the direct supervision of a physician, as a member of an authorized service program, or in an individual capacity, to perform nonlifesaving procedures for which certified and designated in a written job description. Such procedures may be performed after the patient is observed by and when the emergency medical care provider is under the supervision of the physician, physician assistant, or registered nurse, including when the registered nurse is not acting in the capacity of a physician designee, and where the procedure may be immediately abandoned without risk to the patient.

131.3(2) When emergency medical care personnel are functioning in a capacity identified in 131.3(1)*"a,"* they may perform emergency and nonemergency medical care without contacting a supervising physician or physician designee if written protocols have been approved by the service program medical director which clearly identify when the protocols may be used in lieu of voice contact.

131.3(3) Scope of practice.

a. Emergency medical care providers shall provide only those services and procedures that are authorized within the scope of practice for which they are certified.

b. Scope of Practice for Iowa EMS Providers (April 2013) is hereby incorporated and adopted by reference for emergency medical care providers. For any differences that may occur between the Scope of Practice adopted by reference and these administrative rules, the administrative rules shall prevail.

c. The department may grant a variance for changes to the Scope of Practice that have not yet been adopted by reference in these rules. A variance to these rules may be granted by the department pursuant to 641—subrule 132.14(1).

d. Scope of Practice for Iowa EMS Providers is available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

131.3(4) The department may approve emergency medical pilot project(s) on a limited basis. Requests for a pilot project application shall be made to the department.

131.3(5) An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11; **ARC 0062C**, IAB 4/4/12, effective 5/9/12; **ARC 0480C**, IAB 12/12/12, effective 1/16/13; **ARC 1404C**, IAB 4/2/14, effective 5/7/14]

641—131.4(147A) Emergency medical care providers—certification, renewal standards, procedures, continuing education, and fees.

131.4(1) *Student application and candidate examination.*

a. Applicants shall complete the EMS Student Registration within 14 days after the beginning of the course. The EMS Student Registration shall be completed via the bureau of EMS Web site at www.idph.state.ia.us/ems.

b. Upon satisfactory completion of the course and all training program requirements, including payment of appropriate fees, a candidate shall be recommended by a training program to take the appropriate NREMT certification examination. A candidate is not eligible to continue functioning as a student in the clinical and field settings and must obtain state certification to perform appropriate skills.

c. A candidate shall submit an EMS Certification Application form to the department. EMS Certification Application forms are provided by the department.

d. When a student's EMS Student Registration or a candidate's EMS Certification Application is referred to the department for investigation or when a student or candidate is otherwise under investigation by the department, the individual shall not be eligible for certification, and the practical examination results will not be confirmed with the NREMT, until the individual is approved by the department.

e. The fee for certification as an emergency medical care provider is $30, payable to the Iowa Department of Public Health. This nonrefundable fee shall be paid prior to a candidate's receiving certification.

f. A candidate must successfully complete the NREMT practical and cognitive examinations to be eligible for state certification.

g. The practical examination may be conducted by an authorized training program and must be conducted according to the policies and procedures of the NREMT.

h. A candidate must meet all certification requirements within two years of the initial course completion date. If a candidate is unable to complete the requirements within two years due to medical reasons or military obligation, an extension may be granted upon submission of a signed statement from an appropriate medical or military authority and approval by the department.

i. Examination scores shall be confidential except that they may be released to the training program that provided the training or to other appropriate state agencies or released in a manner which does not permit the identification of an individual.

j. An applicant for EMS-I endorsement shall successfully complete an EMS-Instructor curriculum approved by the department.

131.4(2) *Multiple certificates and renewal.*

a. The department shall consider the highest level of certification attained to be active. Any lower levels of certification shall be considered idle.

b. A lower-level certificate may be issued if the individual fails to renew the higher level of certification or voluntarily chooses to move from a higher level to a lower level. To be issued a certificate in these instances, an individual shall:

(1) Complete all applicable continuing education requirements for the lower level during the certification period and submit a change of status request, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

(2) Complete and submit to the department an EMS Affirmative Renewal of Certification Application and the applicable fee.

(3) Complete the reinstatement process in 131.4(4)*"f"* if renewal of the higher level is requested later.

c. A citation and warning, denial, probation, restriction, suspension or revocation imposed upon an individual certificate holder by the department shall be considered applicable to all certificates issued to that individual by the department.

131.4(3) *Certification transition.*

a. An individual certified as a first responder based on the 1996 National Standard Curriculum for First Responders, an EMT-B, an EMT-I, an EMT-P or a PS shall complete the following certification transition requirements. Transition documents for each level are available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

b. FR transition to EMR.

(1) The FR shall complete training identified in the FR to EMR Documentation (January 2011).

(2) The FR shall verify completion of training on the Affirmative Renewal of Certification Application by the certification's regular expiration date prior to October 1, 2014.

(3) An FR who does not complete the transition requirements will not satisfy the renewal requirements for the certification period immediately prior to October 1, 2014.

c. EMT-B transition to EMT.

(1) The EMT-B shall complete training identified in the EMT-B to EMT Documentation (January 2011).

(2) The EMT-B shall verify completion of training on the Affirmative Renewal of Certification Application by the certification's regular expiration date prior to April 1, 2015.

(3) An EMT-B who does not complete the transition requirements will not satisfy the renewal requirements for the certification period immediately prior to April 1, 2015.

d. EMT-I transition to AEMT.

(1) The EMT-I shall submit documentation of training identified in the EMT-I to AEMT Documentation (January 2011) to the department.

(2) The EMT-I shall successfully complete the NREMT computer-based AEMT examination.

(3) A provider certified as an EMT-I who has not completed the transition to AEMT will be issued an EMT certification on April 1, 2016.

e. EMT-P transition to paramedic.

(1) The EMT-P shall submit documentation of training identified in the EMT-P to Paramedic Documentation (January 2011) to the department.

(2) The EMT-P shall successfully complete the NREMT computer-based paramedic examination.

(3) A provider certified as an EMT-P who has not completed the transition to paramedic will be issued an AEMT certification on April 1, 2018.

f. PS transition to paramedic.

(1) The PS shall complete training identified in the PS to Paramedic Documentation (January 2011).

(2) The PS shall verify completion of training on the Affirmative Renewal of Certification Application by the certification's regular expiration date prior to April 1, 2015.

(3) A PS who does not complete the transition requirements will not satisfy the renewal requirements for the certification period immediately prior to April 1, 2015.

131.4(4) *Renewal of certification.*

a. A certificate shall be valid for two years from issuance unless specified otherwise on the certificate or unless sooner suspended or revoked.

b. All continuing education requirements shall be completed during the certification period prior to the certificate's expiration date. Failure to complete the continuing education requirements prior to the expiration date shall result in an expired certification, unless the emergency medical care provider requests an extension as described in 131.4(11)*"b."*

c. An emergency medical care provider shall submit the EMS Affirmative Renewal of Certification Application to the department within 90 days prior to the expiration date. Failure to submit a renewal application to the department within 90 days prior to the expiration date (date of submission is based upon the postmark date) shall cause the current certification to expire.

d. An emergency medical care provider shall not function with an expired certification.

e. An emergency medical care provider who completes the required continuing education during the certification period but fails to submit the EMS Affirmative Renewal of Certification Application within 90 days prior to the expiration date shall be required to submit a late fee of $30 (in addition to the renewal fee) and complete the audit process pursuant to 131.4(5)*"i"* to obtain renewal of certification.

f. An emergency medical care provider who has not completed the required continuing education during the certification period or who is seeking to reinstate an expired, inactive, or retired certificate shall:

(1) Complete a refresher course or equivalent approved by the department.

(2) Meet all applicable eligibility requirements.

(3) Submit an EMS Reinstatement Application and the applicable fees to the department.

(4) Pass the appropriate practical and cognitive certification examinations.

g. An emergency medical care provider may request an inactive or retired status for a certificate. The request must be made by submitting a change of status request, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems). Reinstatement of an inactive or retired certificate shall be made pursuant to 131.4(4)*"f."* A request for inactive or retired status, when accepted in connection with a disciplinary investigation or proceeding, has the same effect as an order of revocation.

h. An emergency medical care provider shall be deemed to have complied with the continuing education requirements during periods in which the provider serves honorably on active duty in the military services or for periods in which the provider is a government employee working as an emergency medical care provider and assigned to duty outside the United States. The emergency medical care provider must submit the Affirmative Renewal of Certification Application, all appropriate fees and documentation of assignment.

131.4(5) *Continuing education renewal standards.* The following standards apply to renewal through continuing education:

a. An applicant shall sign and submit an Affirmative Renewal of Certification Application provided by the department and submit the applicable fee within 90 days prior to the certificate's expiration date.

b. An applicant shall complete the continuing education requirements, including current course completion in CPR, during the certification period for the following emergency medical care provider levels:

(1) EMR, FR, FR-D—12 hours of approved continuing education.
(2) EMT, EMT-A, EMT-B, EMT-D—24 hours of approved continuing education.
(3) AEMT, EMT-I—36 hours of approved continuing education.
(4) EMT-P—48 hours of approved continuing education.
(5) PS, paramedic—60 hours of approved continuing education.
(6) EMS-I—Attend at least one EMS-I workshop sponsored by the department.
(7) CCP—8 hours of approved CCP core curriculum topics.

c. At least 50 percent of the required hours for renewal shall be formal continuing education including, but not limited to, refresher programs, seminars, lecture programs, scenario-based programs, conferences, and Internet-delivered courses approved by CECBEMS and shall meet the criteria established in 131.4(6)*"d."*

d. Up to 50 percent of the required continuing education hours may be made up of any of the following:
(1) Nationally recognized EMS-related courses.
(2) EMS self-study courses.
(3) Medical director or designee case reviews.
(4) Clinical rounds with medical team (grand rounds).
(5) Working with students as an EMS field preceptor.
(6) Hospital or nursing home clinical performance.
(7) Skills workshops/maintenance.
(8) Community public information education projects.
(9) Emergency driver training.
(10) EMS course audits.
(11) Injury prevention or wellness initiatives.
(12) EMS service operations, e.g., management programs, continuous quality improvement.
(13) EMS system development meetings that occur at the county, regional or state level.
(14) Disaster preparedness.
(15) Emergency runs/responses as a volunteer member of an authorized EMS service program (primary attendant).
(16) EMS-Instructor development.

e. Additional hours may be allowed for any of the following (maximum):
(1) CPR—2 hours.
(2) Disaster drill—4 hours.
(3) Rescue—4 hours.
(4) Hazardous materials—8 hours.
(5) Practical examination evaluator—4 hours.
(6) Topics outside the provider's core curriculum—8 hours.

f. With training program approval, a person who is not enrolled in an emergency medical care provider course may audit the course for CEHs.

g. The certificate holder must notify the department within 30 days of a change in address.

h. The certificate holder shall maintain a file containing documentation of CEHs accrued during each certification period for four years from the end of each certification period.

i. A group of individual certificate holders will be audited for each certification period. Certificate holders to be audited will be chosen in a random manner or at the discretion of the bureau of EMS. Falsifying reports or failure to comply with the audit request may result in formal disciplinary action. Certificate holders who are audited will be required to submit an Audit Report Form provided by the department within 45 days of the request. If audited, the certificate holders must provide the following information:
(1) Date of program.
(2) Program sponsor number.
(3) Title of program.
(4) Number of approved hours.

(5) Appropriate supervisor signatures if clinical or practical evaluator hours are claimed.

j. An EMS instructor who teaches EMS initial or continuing education courses may use those courses for renewal as approved under subrule 131.4(6).

131.4(6) *Continuing education approval.* The following standards shall be applied for approval of continuing education:

a. Required CEHs identified in 131.4(5)*"c"* shall be approved by the department, CECBEMS, or an authorized EMS training program, using a sponsor number assignment system approved by the department.

b. Optional CEHs identified in 131.4(5)*"d"* and 131.4(5)*"e"* require no formal sponsor number; however, CEHs awarded shall be verified by an authorized EMS training program, a national EMS continuing education accreditation entity, a service program medical director, an appropriate community sponsor, or the department. Documentation of CEHs awarded shall include the date and title of the program or event, the number of hours approved, and the applicable signatures.

c. Courses in physical, social or behavioral sciences offered by accredited colleges and universities are approved for CEHs and need no further approval. One quarter credit equals 10 hours. One semester credit equals 15 hours.

d. Courses approved as formal education must meet the following criteria:

(1) Involve live interaction with an instructor or be an Internet-delivered course approved by CECBEMS; and

(2) Be based on the appropriate department curricula for EMS providers and include one or more of the following topic areas: airway management, patient assessment, trauma assessment and management, medical assessment and management, behavioral emergencies, obstetrics, gynecology, pediatrics, or patient care record documentation.

e. Programs developed and delivered by the department may be approved for formal education.

131.4(7) *Out-of-state continuing education.* Out-of-state continuing education courses will be accepted for CEHs if they meet the criteria in subrule 131.4(5) and have been approved for emergency medical care personnel in the state in which the courses were held. A copy of course completion certificates (or other verifying documentation) shall, upon request, be submitted to the department with the EMS Affirmative Renewal of Certification Application.

131.4(8) *Fees.* The following fees shall be collected by the department and shall be nonrefundable:

a. FR, EMR, EMT-B, EMT, EMT-I, AEMT, EMT-P, PS and paramedic certification fee—$30.

b. Certification renewal fees:

(1) FR, EMR, EMT-B, and EMT—no fee.

(2) EMT-I, AEMT—$10.

(3) EMT-P, PS and paramedic—$25.

A certification renewal fee is refundable if the applicant's certification renewal status is not posted on the bureau of EMS Web site in the certification database within ten working days from the date the department receives the completed renewal application.

c. Endorsement certification fee—$50.

d. Reinstatement fee—$30.

e. Late fee—$30.

f. Duplicate/replacement card—$10.

g. Returned check—$20.

h. Extension fee—$50.

131.4(9) *Certification through reciprocity.* An individual currently certified by the NREMT must also possess a current Iowa certificate to be considered certified in this state. The department shall contact the NREMT to verify certification or registry and good standing.

a. To receive Iowa certification, the individual shall:

(1) Complete and submit the EMS Reciprocity Application available from the department.

(2) Provide verification of current certification in another state, if applicable, and registration with the NREMT.

(3) Provide verification of current course completion in CPR.

(4) Meet all other applicable eligibility requirements necessary for Iowa certification pursuant to these rules.

(5) Submit all applicable fees to the department.

b. An individual certified through reciprocity shall satisfy the renewal and continuing education requirements set forth in subrule 131.4(4) to renew Iowa certification.

131.4(10) *National registration in lieu of continuing education.*

a. An emergency medical care provider who is certified in Iowa and is registered with the NREMT may renew certification by meeting the NREMT reregistration requirements.

b. The emergency medical care provider shall submit the NREMT Registration in Lieu of Continuing Education Application, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems), to the department, with proof of NREMT registration exceeding the current certification expiration date, within 90 days prior to the expiration date.

131.4(11) *Extension of certification.*

a. If an emergency medical care provider is unable to complete the required continuing education during the certification period due to a medical reason, an extension of certification may be issued upon submission of a signed statement from an appropriate medical provider and approval by the department. The statement must include information concerning the reason the emergency medical care provider could not complete the continuing education requirements, the time period affected, and the length of time requested for extension.

b. If an emergency medical care provider is unable to attain all continuing education requirements within the certification period, a 45-day extension may be granted. To complete the extension process, the provider shall:

(1) Submit a Request for Extension Application, available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems), at least 7 days prior to the expiration date, but no more than 90 days prior to the expiration date, and a $50 extension fee.

(2) Be given 45 days from the current expiration date to complete continuing education requirements.

(3) Submit the EMS Affirmative Renewal of Certification Application, with all applicable renewal fees, to the department prior to the extended expiration date (date of submission is based on the postmark date).

(4) Not use continuing education completed during the extension period in the subsequent renewal period.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.5(147A) Training programs—standards, application, inspection and approval.

131.5(1) *Education standards.*

a. A training program shall use the applicable United States Department of Transportation's Education Standards (January 2009) for courses leading to certification.

b. A training program shall use the EMS-Instructor curriculum approved by the department for courses leading to the EMS-I endorsement.

c. A training program shall use the Iowa CCP curriculum (November 2001) for courses leading to the CCP endorsement.

d. A training program may waive portions of the required emergency medical care provider training for individuals certified as emergency medical care providers or licensed in other health care professions including, but not limited to, nursing, physician assistant, respiratory therapist, dentistry, and military. The training program shall document equivalent training and what portions of the course have been waived for equivalency.

131.5(2) *Clinical or field experience resources.* If clinical or field experience resources are located outside the framework of the training program, written agreements for such resources shall be obtained by the training program.

131.5(3) *Facilities.*

a. A training program shall ensure adequate classroom, laboratory, and practice space to conduct the training program. A library with reference materials on emergency and critical care shall also be available.

b. A training program shall ensure opportunities for the student to accomplish the appropriate skill competencies in the clinical environment. The following hospital units shall be available for clinical experience for each training program as required in approved education standards pursuant to subrule 131.5(1):

(1) Emergency department;

(2) Intensive care unit or coronary care unit or both;

(3) Operating room and recovery room;

(4) Intravenous or phlebotomy team or other method to obtain IV experience;

(5) Pediatric unit;

(6) Labor and delivery suite and newborn nursery; and

(7) Psychiatric unit.

c. A training program shall ensure opportunities for the student to accomplish the appropriate skill competencies in the field environment. The training program shall use an appropriate emergency medical care service program to provide field experience as required in approved education standards pursuant to subrule 131.5(1).

d. A training program shall have liability insurance and shall offer liability insurance to students while they are enrolled in the training program.

131.5(4) *Staff.*

a. A training program medical director shall be a physician licensed under Iowa Code chapter 148.

b. A training program director who is an appropriate health care professional shall be appointed. This individual shall be a full-time educator or a practitioner in emergency or critical care.

c. Course coordinators, outreach course coordinators, and primary instructors used by the training program shall be currently endorsed as EMS instructors.

d. The instructional staff shall be comprised of physicians, nurses, pharmacists, emergency medical care personnel, or other health care professionals who have appropriate education and experience in emergency and critical care.

e. Preceptors shall be assigned in each of the clinical units in which emergency medical care students are obtaining clinical experience and field experience. The preceptors shall supervise student activities to ensure the quality and relevance of the experience. Student activity records shall be kept and reviewed by the immediate supervisor(s) and by the program director and course coordinator.

f. If a training program's medical director resigns, the training program director shall report this to the department and provide a curriculum vitae for the medical director's replacement. A new course shall not be started until a qualified medical director has been appointed.

g. A training program shall maintain records pertaining to each instructor used which include, as a minimum, the instructor's qualifications.

h. A training program is responsible for ensuring that each instructor is experienced in the area being taught and adheres to the education standards.

i. The training program shall ensure that each practical examination evaluator and mock patient is familiar with the NREMT practical examination requirements and procedures. Practical examination evaluators shall attend a workshop sponsored by the department and have the evaluator endorsement.

131.5(5) *Advisory committee.* There shall be an advisory committee which includes training program representatives and representatives from other groups such as affiliated medical facilities, local medical establishments, and ambulance, rescue and first response service programs.

131.5(6) *Student records.* A training program shall maintain an individual record for each student. Training program policy and department requirements will determine contents. These requirements include, but are not limited to:

a. Application;

b. Current certifications and endorsements;

c. Student record or transcript of hours and performance (including examinations) in classroom, clinical, and field experience settings.

131.5(7) *Selection of students.* There may be a selection committee to select students. The selection committee shall use, as a minimum, the prerequisites outlined in rule 641—131.2(147A).

131.5(8) *Students.*

a. A student may perform any procedures and skills for which the student has received training if the student is under the direct supervision of a physician or physician designee or under the remote supervision of a physician or physician designee with direct field supervision by an appropriately certified emergency medical care provider.

b. A student shall not be substituted for the regular personnel of any affiliated medical facility or service program but may be employed while enrolled in the training program.

c. A student is not eligible to continue functioning as a student of the training program in the clinical or field setting if the student is not in good standing with the training program, once the student has met the training program requirements, or once the student has been approved for certification testing.

131.5(9) *Financing and administration.*

a. There shall be sufficient funding available to the training program to ensure that each class started can be completed.

b. Tuition charged to students shall be accurately stated.

c. Advertising for training programs shall be appropriate.

d. A training program shall provide to each student, no later than the first session of the course, a guide that outlines, as a minimum:

(1) Course objectives.

(2) Required hours for completion.

(3) Minimum acceptable scores on interim testing.

(4) Attendance requirements.

(5) Grievance procedure.

(6) Disciplinary actions that may be invoked, the grounds for such actions, and the process provided.

(7) Requirements for certification.

131.5(10) *Training program application, inspection and approval.*

a. A training program graduating students at the paramedic level after December 31, 2012, must be accredited by, or must have submitted a self-study application to, the Committee on Accreditation for the Emergency Medical Services Professions.

b. A training program seeking initial or renewal approval shall use the EMS Training Program Application provided by the department. The application shall include, as a minimum:

(1) Names of appropriate officials of the training program;

(2) Evidence of availability of clinical resources;

(3) Evidence of availability of physical facilities;

(4) Evidence of qualified faculty;

(5) Qualifications and major responsibilities of each faculty member;

(6) Policies used for selection, promotion, and graduation of trainees;

(7) Practices followed in safeguarding the health and well-being of trainees and of patients receiving emergency medical care within the scope of the training program; and

(8) Level(s) of EMS certification to be offered.

c. A new training program shall submit a needs assessment which justifies the need for the training program.

d. Applications shall be reviewed by the department in accordance with the 2005 Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions, published by the Commission on Accreditation of Allied Health Education Programs. Failure to comply with the standards may lead to disciplinary action as described in rule 641—131.8(147A).

e. The department shall perform an on-site inspection of the training program's facilities and clinical resources. The purpose of the inspection is to examine educational objectives, patient care practices, facilities and administrative practices and to prepare a written report for review and action by the department.

f. The department shall inspect each training program at least once every five years. The department without prior notification may make additional inspections at times, places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

g. No person shall interfere with the inspection activities of the department or its agents. Interference with or failure to allow an inspection may be cause for disciplinary action regarding training program approval.

h. Representatives of the training program may be required by the department to meet with the department at the time the application and inspection report are discussed.

i. A written report of department action and the department inspection report shall be sent to the training program.

j. Training program approval shall not exceed five years.

k. A training program shall notify the department, in writing, of any change in ownership or control within 30 days.

l. Temporary variances. If during a period of authorization there is some occurrence that temporarily causes a training program to be in noncompliance with these rules, the department may grant a temporary variance. Temporary variances to these rules (not to exceed six months in length per any approved request) may be granted by the department to a currently authorized training program. Requests for temporary variances shall apply only to the training program requesting the variance and shall apply only to those requirements and standards for which the department is responsible. To request a variance, the training program shall:

(1) Notify the department verbally (as soon as possible) of the need to request a temporary variance. The program shall submit to the department, within ten days after having given verbal notification to the department, a written explanation for the temporary variance request. The address is Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075.

(2) Cite the rule from which the variance is requested.

(3) State why compliance with the rule cannot be maintained.

(4) Explain the alternative arrangements that have been or will be made regarding the variance request.

(5) Estimate the period of time for which the variance will be needed.

m. Training program applications and on-site inspection reports are public information.

131.5(11) *Out-of-state training program application and approval.*

a. An out-of-state training program shall apply to the department for approval.

b. An out-of-state training program seeking department approval shall use the out-of-state training program application provided by the department. The application shall include, as a minimum:

(1) Verification of approval to conduct initial EMS training by the authorizing agency within the out-of-state training program's home state;

(2) Evidence of oversight provided by a physician medical director;

(3) Evidence of qualified faculty;

(4) Evidence of curriculum utilized;

(5) Evidence of written contracts between the out-of-state training program and clinical and field sites being utilized within Iowa; and

(6) Description of practices followed in safeguarding the health and well-being of trainees and of patients receiving emergency medical care within the scope of the training program.

c. An out-of-state training program shall provide the department with a roster of students who will be participating in the clinical or field experience within the state of Iowa and, for each program, the sites where the students will be participating.

d. An out-of-state training program shall not be authorized to provide initial EMS training within the state of Iowa.

e. An out-of-state training program shall be limited to utilization of clinical or field sites or both within Iowa.

f. Representatives of the out-of-state training program may be required by the department to meet with the department at the time the application is discussed.

g. An out-of-state training program approval shall not exceed five years.

h. An out-of-state training program shall notify the department, in writing, of any change in ownership, control, or approval status by the out-of-state training program's authorizing state agency within 30 days.

131.5(12) *Out-of-state students.*

a. An out-of-state student shall be registered in good standing in an approved out-of-state training program.

b. An out-of-state student may perform any procedures and skills for which the student is training provided that the procedure or skill is within the Iowa scope of practice policy of a comparable Iowa emergency medical care provider. The student must be under the direct supervision of a physician or physician designee or under the remote supervision of a physician or physician designee with direct supervision by an appropriately certified emergency medical care provider.

c. An out-of-state student shall not be substituted for personnel of any affiliated medical facility or service program but may be employed while enrolled in the training program.

d. An out-of-state student participating in the clinical or field setting within the state of Iowa shall provide documentation of liability insurance.

e. An out-of-state student is not eligible to continue functioning as a student of the approved out-of-state training program in the clinical or field setting if the student is not in good standing with the approved out-of-state training program, once the student has met the training program's requirements, or once the student has been approved for certification testing.

f. An out-of-state student shall not be eligible for Iowa EMS certification without meeting the requirements for certification through reciprocity in subrule 131.4(9).

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.6(147A) Continuing education providers—approval, record keeping and inspection.

131.6(1) Continuing education courses for emergency medical care personnel may be approved by the department, an EMS training program or a national EMS continuing education accreditation entity.

131.6(2) A training program may conduct continuing education courses (utilizing appropriate instructors) pursuant to subrule 131.4(6).

a. Each training program shall assign a sponsor number to each appropriate continuing education course using an assignment system approved by the department.

b. Course approval shall be completed prior to the course's being offered.

c. Each training program shall maintain a participant record that includes, as a minimum:

(1) Name.

(2) Address.

(3) Certification number.

(4) Course sponsor number.

(5) Course instructor.

(6) Date of course.

(7) CEHs awarded.

d. Each training program shall submit to the department on a quarterly basis a completed Approved EMS Continuing Education Form.

131.6(3) Record keeping and record inspection.

a. To ensure compliance or to verify the validity of any training program application, the department may request additional information or inspect the records of any continuing education provider who is currently approved or who is seeking approval.

b. No person shall interfere with the inspection activities of the department or its agents. Interference with or failure to allow an inspection may be cause for disciplinary action regarding training program approval.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.7(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of emergency medical care personnel certificates or renewal.

131.7(1) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

131.7(2) Method of discipline. The department has the authority to impose the following disciplinary sanctions against an emergency medical care provider:

a. Issue a citation and warning.

b. Impose a civil penalty not to exceed $1000.

c. Require reexamination.

d. Require additional education or training.

e. Impose a period of probation under specific conditions.

f. Prohibit permanently, until further order of the department, or for a specific period, a provider's ability to engage in specific procedures, methods, acts or activities incident to the practice of the profession.

g. Suspend a certificate until further order of the department or for a specific period.

h. Deny an application for certification.

i. Revoke a certification.

j. Impose such other sanctions as allowed by law and as may be appropriate.

131.7(3) The department may deny an application for issuance or renewal of an emergency medical care provider certificate, including endorsement, or may impose any of the disciplinary sanctions provided in subrule 131.7(2) when it finds that the applicant or certificate holder has committed any of the following acts or offenses:

a. Negligence in performing emergency medical care.

b. Failure to follow the directions of supervising physicians or their designees.

c. Rendering treatment not authorized under Iowa Code chapter 147A.

d. Fraud in procuring certification or renewal including, but not limited to:

(1) An intentional perversion of the truth in making application for a certification to practice in this state;

(2) False representations of a material fact, whether by word or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application for a certification in this state; or

(3) Attempting to file or filing with the department or training program any false or forged diploma or certificate or affidavit or identification or qualification in making an application for a certification in this state.

e. Professional incompetency. Professional incompetency includes, but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of practice.

(2) A substantial deviation from the standards of learning or skill ordinarily possessed and applied by other emergency medical care providers in the state of Iowa acting in the same or similar circumstances.

(3) A failure to exercise the degree of care which is ordinarily exercised by the average emergency medical care provider acting in the same or similar circumstances.

(4) Failure to conform to the minimal standard of acceptable and prevailing practice of certified emergency medical care providers in this state.

f. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of the profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof

of actual injury need not be established. Acts which may constitute unethical conduct include, but are not limited to:

(1) Verbally or physically abusing a patient or coworker.

(2) Improper sexual contact with or making suggestive, lewd, lascivious or improper remarks or advances to a patient or coworker.

(3) Betrayal of a professional confidence.

(4) Engaging in a professional conflict of interest.

(5) Falsification of medical records.

g. Engaging in any conduct that subverts or attempts to subvert a department investigation.

h. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

i. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

j. Failure to report another emergency medical care provider to the department for any violations listed in these rules, pursuant to Iowa Code chapter 147A.

k. Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

l. Representing oneself as an emergency medical care provider when one's certification has been suspended or revoked or when one's certification is lapsed or has been placed on inactive status.

m. Permitting the use of a certification by a noncertified person for any purpose.

n. Mental or physical inability reasonably related to and adversely affecting the emergency medical care provider's ability to practice in a safe and competent manner.

o. Being adjudged mentally incompetent by a court of competent jurisdiction.

p. Sexual harassment of a patient, student, or supervisee. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

q. Habitual intoxication or addiction to drugs.

(1) The inability of an emergency medical care provider to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

(2) The excessive use of drugs which may impair an emergency medical care provider's ability to practice with reasonable skill or safety.

(3) Obtaining, possessing, attempting to obtain or possess, or administering controlled substances without lawful authority.

r. Fraud in representation as to skill, ability or certification.

s. Willful or repeated violations of Iowa Code chapter 147A or these rules.

t. Violating a statute of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which relates to the provision of emergency medical care, including but not limited to a crime involving dishonesty, fraud, theft, embezzlement, controlled substances, substance abuse, assault, sexual abuse, sexual misconduct, or homicide. A copy of the record of conviction or plea of guilty is conclusive evidence of the violation.

u. Having certification to practice emergency medical care suspended or revoked or having other disciplinary action taken by a licensing or certifying authority of this state or another state, territory or country. A copy of the record or order of suspension, revocation or disciplinary action is conclusive or prima facie evidence.

v. Falsifying certification renewal reports or failure to comply with the renewal audit request.

w. Acceptance of any fee by fraud or misrepresentation.

x. Repeated failure to comply with standard precautions for preventing transmission of infectious diseases as issued by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

y. Violating privacy and confidentiality. An emergency medical care provider shall not disclose or be compelled to disclose patient information unless required or authorized by law.

z. Discrimination. An emergency medical care provider shall not practice, condone, or facilitate discrimination against a patient, student, or supervisee on the basis of race, ethnicity, national origin,

color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability, diagnosis, or social or economic status.

aa. Practicing emergency medical services or using a designation of certification or otherwise holding oneself out as practicing emergency medical services at a certain level of certification when the emergency medical care provider is not certified at such level.

ab. Failure to respond within 30 days of receipt, unless otherwise specified, of communication from the department which was sent by registered or certified mail.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.8(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of training program approval or renewal.

131.8(1) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

131.8(2) Method of discipline. The department has the authority to impose the following disciplinary sanctions against a training program:

a. Issue a citation and warning.

b. Impose a period of probation under specific conditions.

c. Prohibit permanently, until further order of the department, or for a specific period, a program's ability to engage in specific procedures, methods, acts or activities incident to the practice of the profession.

d. Suspend an authorization until further order of the department or for a specific period.

e. Deny an application for authorization.

f. Revoke an authorization.

g. Impose such other sanctions as allowed by law and as may be appropriate.

131.8(3) The department may impose any of the disciplinary sanctions provided in subrule 131.8(2) when it finds that the training program or applicant has failed to meet the applicable provisions of these rules or has committed any of the following acts or offenses:

a. Fraud in procuring approval or renewal.

b. Falsification of training or continuing education records.

c. Suspension or revocation of approval to provide emergency medical care training or other disciplinary action taken pursuant to Iowa Code chapter 147A. A certified copy of the record or order of suspension, revocation or disciplinary action is conclusive or prima facie evidence.

d. Engaging in any conduct that subverts or attempts to subvert a department investigation.

e. Failure to respond within 30 days of receipt of communication from the department which was sent by registered or certified mail.

f. Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

g. Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

h. Submission of a false report of continuing education or failure to submit the quarterly report of continuing education.

i. Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

j. Representing itself as an approved training program or continuing education provider when approval has been suspended or revoked or when approval has lapsed or has been placed on inactive status.

k. Using an unqualified individual as an instructor or evaluator.

l. Allowing verbal or physical abuse of a student or staff.

m. A training program provider or continuing education provider shall not sexually harass a patient, student, or supervisee. Sexual harassment includes sexual advances, sexual solicitation, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

n. Betrayal of a professional confidence.

o. Engaging in a professional conflict of interest.

p. Discrimination. A training program or continuing education provider shall not practice, condone, or facilitate discrimination against a patient, student, or supervisee on the basis of race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability, diagnosis, or social or economic status.

q. Failure to comply with the 2005 Standards and Guidelines for the Accreditation of Educational Programs in the Emergency Medical Services Professions, published by the Commission on Accreditation of Allied Health Education Programs.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.9(147A) Reinstatement of certification.

131.9(1) Any person whose certification to practice has been revoked or suspended may apply to the department for reinstatement in accordance with the terms and conditions of the order of revocation or suspension, unless the order of revocation provides that the certification is permanently revoked.

131.9(2) If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur or if the certification was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the order or the date of the voluntary surrender.

131.9(3) All proceedings for reinstatement shall be initiated by the respondent, who shall file with the department an application for reinstatement of the certification. Such application shall be docketed in the original case in which the certification was revoked, suspended, or relinquished. All proceedings upon the application for reinstatement shall be subject to the same rules of procedure as other cases before the department.

131.9(4) An application for reinstatement shall allege facts which, if established, will be sufficient to enable the department to determine that the basis for the revocation or suspension of the respondent's certification no longer exists and that it will be in the public interest for the certification to be reinstated. The burden of proof to establish such facts shall be on the respondent.

131.9(5) An order denying or granting reinstatement shall be based upon a decision which incorporates findings of facts and conclusions of law. The order shall be published as provided for in this chapter.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.10(147A) Certification denial.

131.10(1) An applicant who has been denied certification by the department may appeal the denial and request a hearing on the issues related to the licensure denial by serving a notice of appeal and request for hearing upon the department not more than 20 days following the date of mailing of the notification of certification denial to the applicant. The request for hearing shall specifically delineate the facts to be contested at hearing.

131.10(2) All hearings held pursuant to this rule shall be held pursuant to the process outlined in this chapter.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.11(147A) Emergency adjudicative proceedings. To the extent necessary to prevent or avoid immediate danger to the public health, safety or welfare and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend a certificate in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

131.11(1) Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

a. Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

b. Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

c. Whether the individual required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

e. Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

131.11(2) Issuance of order.

a. An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

b. The written emergency adjudicative order shall be immediately delivered to the individual who is required to comply with the order. Delivery shall be made by one or more of the following procedures:

(1) Personal delivery.

(2) Certified mail, return receipt requested, to the last address on file with the department.

(3) Fax. Fax may be used as the sole method of delivery if the individual required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

c. To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

d. Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the individual who is required to comply with the order.

e. After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

f. Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the individual that is required to comply with the order is the party requesting the continuance.

[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

641—131.12(147A) Complaints, investigations and appeals.

131.12(1) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

131.12(2) All complaints regarding emergency medical care personnel, training programs or continuing education providers, or those purporting to be or operating as the same, shall be reported to the department in writing. The address is Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075.

131.12(3) An emergency medical care provider who has knowledge of an emergency medical care provider or service program that has violated Iowa Code chapter 147A, 641—Chapter 132 or these rules shall report such information to the department.

131.12(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

131.12(5) A determination of mental incompetence by a court of competent jurisdiction automatically suspends a certificate for the duration of the certificate unless the department orders otherwise.

131.12(6) Notice of denial, issuance of a citation and warning, probation, suspension or revocation shall be affected in accordance with the requirements of Iowa Code section 17A.12. Notice to the alleged violator of denial, probation, suspension or revocation shall be served by certified mail, return receipt requested, or by personal service.

131.12(7) Any request for a hearing concerning the denial, citation and warning, probation, suspension or revocation shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice to take action. The address is Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075. If the request is made within the 20-day time period, the notice to take action shall be deemed to be suspended pending the hearing. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. If no request for a hearing is received within the 20-day time period, the department's notice of denial, citation and warning, probation, suspension or revocation shall become the department's final agency action.

131.12(8) Upon receipt of a request for hearing, the department shall forward the request within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

131.12(9) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

131.12(10) When the administrative law judge makes a proposed decision and order, it shall be served by certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 131.12(11).

131.12(11) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

131.12(12) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections and rulings on them.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

131.12(13) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or by personal service.

131.12(14) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

131.12(15) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075.

131.12(16) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

131.12(17) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, the news media or employer.
[**ARC 9443B**, IAB 4/6/11, effective 8/1/11]

These rules are intended to implement Iowa Code chapter 147A.

[Filed 1/20/00, Notice 12/1/99—published 2/9/00, effective 3/15/00]
[Filed emergency 9/14/00—published 10/4/00, effective 9/14/00]
[Filed 1/10/02, Notice 11/28/01—published 2/6/02, effective 3/13/02]
[Filed 1/13/05, Notice 11/24/04—published 2/2/05, effective 3/9/05]
[Filed emergency 7/13/05 after Notice 6/8/05—published 8/3/05, effective 7/13/05]
[Filed 7/12/06, Notice 5/24/06—published 8/2/06, effective 9/6/06]
[Filed emergency 11/8/06—published 12/6/06, effective 1/1/07]
[Filed 1/10/07, Notice 12/6/06—published 1/31/07, effective 3/7/07]
[Filed 7/13/07, Notice 5/23/07—published 8/1/07, effective 9/5/07]
[Filed 5/14/08, Notice 3/26/08—published 6/4/08, effective 7/9/08]
[Filed 11/12/08, Notice 9/24/08—published 12/3/08, effective 1/7/09]
[Filed ARC 8230B (Notice ARC 7969B, IAB 7/15/09), IAB 10/7/09, effective 11/11/09]
[Filed ARC 8660B (Notice ARC 8497B, IAB 1/27/10), IAB 4/7/10, effective 5/12/10]
[Filed ARC 9443B (Notice ARC 9342B, IAB 1/26/11), IAB 4/6/11, effective 8/1/11]
[Filed ARC 0062C (Notice ARC 0002C, IAB 2/8/12), IAB 4/4/12, effective 5/9/12]
[Filed ARC 0480C (Notice ARC 0377C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13]
[Filed ARC 1404C (Notice ARC 1292C, IAB 1/22/14), IAB 4/2/14, effective 5/7/14]

CHAPTER 132
EMERGENCY MEDICAL SERVICES—SERVICE PROGRAM AUTHORIZATION

[Joint Rules pursuant to 147A.4]
[Prior to 7/29/87, Health Department[470] Ch 132]

641—132.1(147A) Definitions. For the purpose of these rules, the following definitions shall apply:

"Advanced emergency medical technician" or *"AEMT"* means an individual who has successfully completed a course of study based on the United States Department of Transportation's Advanced Emergency Medical Technician Instructional Guidelines (January 2009), has passed the National Registry of Emergency Medical Technicians (NREMT) practical and cognitive examinations for the AEMT, and is currently certified by the department as an AEMT.

"Ambulance" means any privately or publicly owned ground vehicle specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated.

"Ambulance service" means any privately or publicly owned service program which utilizes ambulances in order to provide patient transportation and emergency medical services.

"Automated defibrillator" means any external semiautomatic device that determines whether defibrillation is required.

"Automated external defibrillator" or *"AED"* means an external semiautomated device that determines whether defibrillation is required.

"CEH" means "continuing education hour" which is based upon a minimum of 50 minutes of training per hour.

"Continuous quality improvement (CQI)" means a program that is an ongoing process to monitor standards at all EMS operational levels including the structure, process, and outcomes of the patient care event.

"CPR" means training and successful course completion in cardiopulmonary resuscitation, AED and obstructed airway procedures for all age groups according to recognized national standards.

"Critical care paramedic" or *"CCP"* means a currently certified paramedic specialist or paramedic who has successfully completed a critical care course of instruction approved by the department and has received endorsement from the department as a critical care paramedic.

"Critical care transport" or *"CCT"* means specialty care patient transportation, when medically necessary for a critically ill or injured patient needing critical care paramedic skills, provided by an authorized ambulance service that is approved by the department to provide critical care transportation and staffed by one or more critical care paramedics or other health care professional in an appropriate specialty area.

"Current course completion" means written recognition given for training and successful course completion of CPR with an expiration date or a recommended renewal date that exceeds the current date.

"Deficiency" means noncompliance with Iowa Code chapter 147A or these rules.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Direct supervision" means services provided by an EMS provider in a hospital setting or other health care entity in which health care is ordinarily performed when in the personal presence of a physician or under the direction of a physician who is immediately available or under the direction of a physician assistant or registered nurse who is immediately available and is acting consistent with adopted policies and protocols of a hospital or other health care entity.

"Emergency medical care" means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by protocol.
5. Any medical procedure authorized by 641—subrule 131.3(3).

"Emergency medical care provider" means an individual who has been trained to provide emergency and nonemergency medical care at the EMR, EMT, AEMT, paramedic or other certification levels recognized by the department before 2011 and who has been issued a certificate by the department.

"Emergency medical responder" or *"EMR"* means an individual who has successfully completed a course of study based on the United States Department of Transportation's Emergency Medical Responder Instructional Guidelines (January 2009), has passed the NREMT practical and cognitive examinations for the EMR, and is currently certified by the department as an EMR.

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

"Emergency medical technician" or *"EMT"* means an individual who has successfully completed a course of study based on the United States Department of Transportation's Emergency Medical Technician Instructional Guidelines (January 2009), has passed the NREMT practical and cognitive examinations for the EMT, and is currently certified by the department as an EMT.

"Emergency medical technician-basic (EMT-B)" means an individual who has successfully completed the current United States Department of Transportation's Emergency Medical Technician-Basic curriculum and department enhancements, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-B.

"Emergency medical technician-intermediate (EMT-I)" means an individual who has successfully completed an EMT-intermediate curriculum approved by the department, passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-I.

"Emergency medical technician-paramedic" or *"EMT-P"* means an individual who has successfully completed the United States Department of Transportation's EMT-Intermediate (1999) or the 1985 or earlier DOT EMT-P curriculum, has passed the department's approved written and practical examinations, and is currently certified by the department as an EMT-P.

"Emergency medical transportation" means the transportation, by ambulance, of sick, injured or otherwise incapacitated persons who require emergency medical care.

"EMS advisory council" means a council appointed by the director to advise the director and develop policy recommendations concerning regulation, administration, and coordination of emergency medical services in the state.

"EMS contingency plan" means an agreement or dispatching policy between two or more ambulance service programs that addresses how and under what circumstances patient transportation will be provided in a given service area when coverage is not possible due to unforeseen circumstances.

"EMS system" is any specific arrangement of emergency medical personnel, equipment, and supplies designed to function in a coordinated fashion.

"Endorsement" means an approval granted by the department authorizing an individual to serve as an EMS-I, EMS-E or CCP.

"First responder (FR)" means an individual who has successfully completed the current United States Department of Transportation's First Responder curriculum and department enhancements, passed the department's approved written and practical examinations, and is currently certified by the department as an FR.

"First response vehicle" means any privately or publicly owned vehicle which is used solely for the transportation of emergency medical care personnel and equipment to and from the scene of a medical or nonmedical emergency.

"Hospital" means any hospital licensed under the provisions of Iowa Code chapter 135B.

"Inclusion criteria" means criteria determined by the department and adopted by reference to determine which patients are to be included in the Iowa EMS service program registry or the trauma registry.

"Intermediate" means an emergency medical technician-intermediate.

"Iowa EMS Patient Registry Data Dictionary" means reportable data elements for all ambulance service responses and definitions determined by the department and adopted by reference.

"Medical direction" means direction, advice, or orders provided by a medical director, supervising physician, or physician designee (in accordance with written parameters and protocols) to emergency medical care personnel.

"Medical director" means any physician licensed under Iowa Code chapter 148, 150, or 150A who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Mutual aid" means an agreement, preferably in writing, between two or more services that addresses how and under what circumstances each service will respond to a request for assistance in situations that exhaust available resources.

"Nonemergency transportation" means transportation that may be provided for those persons determined to need transportation only.

"Nontransport service" means any privately or publicly owned rescue or first response service program which does not provide patient transportation (except when no ambulance is available or in a disaster situation) and utilizes only rescue or first response vehicles to provide emergency medical care at the scene of an emergency.

"Off-line medical direction" means the monitoring of EMS providers through retrospective field assessments and treatment documentation review, critiques of selected cases with the EMS personnel, and statistical review of the system.

"On-line medical direction" means immediate medical direction provided directly to service program EMS providers, in accordance with written parameters and protocols, by the medical director, supervising physician or physician designee either on-scene or by any telecommunications system.

"Paramedic" means an individual who has successfully completed a course of study based on the United States Department of Transportation's Paramedic Instructional Guidelines (January 2009), has passed the NREMT practical and cognitive examinations for the paramedic, and is currently certified by the department as a paramedic.

"Paramedic specialist (PS)" means an individual who has successfully completed the current United States Department of Transportation's EMT-Paramedic curriculum or equivalent, passed the department's approved written and practical examinations, and is currently certified by the department as a paramedic specialist.

"Patient" means any individual who is sick, injured, or otherwise incapacitated.

"Patient care report (PCR)" means a computerized or written report that documents the assessment and management of the patient by the emergency care provider in the out-of-hospital setting.

"Physician" means any individual licensed under Iowa Code chapter 148, 150, or 150A.

"Physician assistant (PA)" means an individual licensed pursuant to Iowa Code chapter 148C.

"Physician designee" means any registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistant examiners. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the care provided by emergency medical care providers.

"Preceptor" means an individual who has been assigned by the training program, clinical facility or service program to supervise students while the students are completing their clinical or field experience. A preceptor must be an emergency medical care provider certified at the level being supervised or higher, or must be licensed as a registered nurse, physician's assistant or physician.

"Protocols" means written directions and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols must be approved by the service program's medical director and address the care of both adult and pediatric patients.

"Registered nurse (RN)" means an individual licensed pursuant to Iowa Code chapter 152.

"Reportable patient data" means data elements and definitions determined by the department and adopted by reference to be reported to the Iowa EMS service program registry or the trauma registry or a trauma care facility on patients meeting the inclusion criteria.

"Rescue vehicle" means any privately or publicly owned vehicle which is specifically designed, modified, constructed, equipped, staffed and used regularly for rescue or extrication purposes at the scene of a medical or nonmedical emergency.

"Service director" means an individual who is responsible for the operation and administration of a service program.

"Service program" or *"service"* means any medical care ambulance service or nontransport service that has received authorization by the department.

"Service program area" means the geographic area of responsibility served by any given ambulance or nontransport service program.

"Student" means any individual enrolled in a training program and participating in the didactic, clinical, or field experience portions.

"Supervising physician" means any physician licensed under Iowa Code chapter 148, 150, or 150A. The supervising physician is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

"Tiered response" means a rendezvous of service programs to allow the transfer of patient care.

"Training program" means an NCA-approved Iowa college, the Iowa law enforcement academy or an Iowa hospital approved by the department to conduct emergency medical care training.

"Transport agreement" means a written agreement between two or more service programs that specifies the duties and responsibilities of the agreeing parties to ensure appropriate transportation of patients in a given service area.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10; **ARC 9357B**, IAB 2/9/11, effective 3/16/11; **ARC 0063C**, IAB 4/4/12, effective 5/9/12]

641—132.2(147A) Authority of emergency medical care provider.

132.2(1) Rescinded IAB 2/7/01, effective 3/14/01.

132.2(2) An emergency medical care provider who holds an active certification issued by the department may:

a. Render via on-line medical direction emergency and nonemergency medical care in those areas for which the emergency medical care provider is certified, as part of an authorized service program:

(1) At the scene of an emergency;

(2) During transportation to a hospital;

(3) While in the hospital emergency department;

(4) Until patient care is directly assumed by a physician or by authorized hospital personnel; and

(5) During transfer from one medical care facility to another or to a private home.

b. Function in any hospital or any other entity in which health care is ordinarily provided only when under the direct supervision of a physician when:

(1) Enrolled as a student in and approved by a training program;

(2) Fulfilling continuing education requirements;

(3) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician as a member of an authorized service program, or in an individual capacity, by rendering lifesaving services in the facility in which employed or assigned pursuant to the emergency medical care provider's certification and under direct supervision of a physician, physician assistant, or registered nurse. An emergency medical care provider shall not routinely function without the direct supervision of a physician, physician assistant, or registered nurse. However, when the physician, physician assistant, or registered nurse cannot directly assume emergency care of the patient, the emergency medical care personnel may perform, without direct supervision, emergency medical care procedures for which certified, if the life of the patient is in immediate danger and such care is required to preserve the patient's life;

(4) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician, as a member of an authorized service program, or in an individual capacity, to perform nonlifesaving procedures for which certified and designated in a written job description. Such procedures may be performed after the patient is observed by and when the emergency medical care provider is under the supervision of the physician, physician assistant, or

registered nurse, including when the registered nurse is not acting in the capacity of a physician designee, and where the procedure may be immediately abandoned without risk to the patient.

132.2(3) When emergency medical care personnel are functioning in a capacity identified in subrule 132.2(2), paragraph *"a,"* they may perform emergency and nonemergency medical care without contacting a supervising physician or physician designee if written protocols have been approved by the service program medical director which clearly identify when the protocols may be used in lieu of voice contact.

132.2(4) Scope of practice.

a. Emergency medical care providers shall provide only those services and procedures as are authorized within the scope of practice for which they are certified.

b. Scope of Practice for Iowa EMS Providers (April 2013) is hereby incorporated and adopted by reference for emergency medical care providers. For any differences that may occur between the Scope of Practice adopted by reference and these administrative rules, the administrative rules shall prevail.

c. The department may grant a variance for changes to the Scope of Practice that have not yet been adopted by these rules. A variance to these rules may be granted by the department pursuant to 132.14(1).

d. Scope of Practice for Iowa EMS Providers is available through the Iowa Department of Public Health, Bureau of EMS, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

132.2(5) The department may approve other emergency medical care skills on a limited pilot project basis. Requests for a pilot project application shall be made to the department.

132.2(6) An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days.

[**ARC 8230B**, IAB 10/7/09, effective 11/11/09; **ARC 0063C**, IAB 4/4/12, effective 5/9/12; **ARC 0480C**, IAB 12/12/12, effective 1/16/13; **ARC 1404C**, IAB 4/2/14, effective 5/7/14]

641—132.3(147A) Emergency medical care providers—requirements for enrollment in training programs. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.4(147A) Emergency medical care providers—certification, renewal standards and procedures, and fees. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.5(147A) Training programs—standards, application, inspection and approval. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.6(147A) Continuing education providers—approval, record keeping and inspection. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.7(147A) Service program—authorization and renewal procedures, inspections and transfer or assignment of certificates of authorization.

132.7(1) *General requirements for authorization and renewal of authorization.*

a. An ambulance or nontransport service in this state that desires to provide emergency medical care, in the out-of-hospital setting, shall apply to the department for authorization to establish a program utilizing certified emergency medical care providers for delivery of care at the scene of an emergency or nonemergency, during transportation to a hospital, during transfer from one medical care facility to another or to a private home, or while in the hospital emergency department and until care is directly assumed by a physician or by authorized hospital personnel. Application for authorization shall be made on forms provided by the department. Applicants shall complete and submit the forms to the department at least 30 days prior to the anticipated date of authorization.

b. To renew service program authorization, the service program shall continue to meet the requirements of Iowa Code chapter 147A and these rules. The renewal application shall be completed and submitted to the department at least 30 days before the current authorization expires.

c. Applications for authorization and renewal of authorization may be obtained upon request to: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

d. The department shall approve an application when the department is satisfied that the program proposed by the application will be operated in compliance with Iowa Code chapter 147A and these administrative rules.

e. Service program authorization is valid for a period of three years from its effective date unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked.

f. Service programs shall be fully operational upon the effective date and at the level specified on the certificate of authorization and shall meet all applicable requirements of Iowa Code chapter 147A and these rules. Deficiencies that are identified shall be corrected within a time frame determined by the department.

g. The certificate of authorization shall be issued to the service program based in the city named in the application. Any ambulance service or nontransport service that operates from more than one city shall apply for and, if approved, shall receive an inclusive authorization for each city of operation that is listed in the application.

h. Any service program owner in possession of a certificate of authorization as a result of transfer or assignment shall continue to meet all applicable requirements of Iowa Code chapter 147A and these rules. In addition, the new owner shall apply to the department for a new certificate of authorization within 30 days following the effective date of the transfer or assignment.

i. Service programs that acquire and maintain current status with a nationally recognized EMS service program accreditation entity that meets or exceeds Iowa requirements may be exempted from the service application/inspection process. A copy of the state service application and accreditation inspection must be filed with the department for approval.

132.7(2) *Out-of-state service programs.*

a. Service programs located in other states which wish to provide emergency medical care in Iowa must meet all requirements of Iowa Code chapter 147A and these rules and must be authorized by the department except when:

(1) Transporting patients from locations within Iowa to destinations outside of Iowa;

(2) Transporting patients from locations outside of Iowa to destinations within Iowa;

(3) Transporting patients to or from locations outside of Iowa that requires travel through Iowa;

(4) Responding to a request for mutual aid in this state; or

(5) Making an occasional EMS response to locations within Iowa and then transporting the patients to destinations within Iowa.

b. An out-of-state service program that meets any of the exception criteria established in 132.7(2) shall be authorized to provide emergency medical care by the state in which the program resides and shall provide the department with verification of current state authorization upon request.

132.7(3) *Air ambulances.* Rescinded IAB 4/7/10, effective 5/12/10.

132.7(4) *Service program inspections.*

a. The department shall inspect each service program at least once every three years. The department without prior notification may make additional inspections at times, places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

b. The department may request additional information from or may inspect the records of any service program which is currently authorized or which is seeking authorization to ensure continued compliance or to verify the validity of any information presented on the application for service program authorization.

c. The department may inspect the patient care records of a service program to verify compliance with Iowa Code chapter 147A and these rules.

d. No person shall interfere with the inspection activities of the department or its agents pursuant to Iowa Code section 135.36.

e. Interference with or failure to allow an inspection by the department or its agents may be cause for disciplinary action in reference to service program authorization.

132.7(5) *Temporary service program authorization.*

a. A temporary service program authorization may be issued to services that wish to operate during special events that may need emergency medical care coverage. Temporary authorization is valid for a period of 30 days unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked. Temporary authorization shall apply to those requirements and standards for which the department is responsible. Applicants shall complete and submit the necessary forms to the department at least 30 days prior to the anticipated date of need.

b. The service shall meet applicable requirement of these rules, but may apply for a variance using the criteria outlined in rule 641—132.14(147A).

c. The service shall submit a justification which demonstrates the need for the temporary service program authorization.

d. The service shall submit a report, to the department, within 30 days after the expiration of the temporary authorization which includes as a minimum:

(1) Number of patients treated;

(2) Types of treatment rendered;

(3) Any operational or medical problems.

132.7(6) *Conditional service program authorization.* Rescinded IAB 2/6/02, effective 3/13/02.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10; **ARC 9357B**, IAB 2/9/11, effective 3/16/11]

641—132.8(147A) Service program levels of care and staffing standards.

132.8(1) A service program seeking ambulance authorization shall:

a. Apply for authorization at one of the following levels:

(1) EMT-B/EMT.

(2) EMT-I.

(3) AEMT.

(4) EMT-P.

(5) PS/Paramedic.

b. Maintain an adequate number of ambulances and personnel to provide 24-hour-per-day, 7-day-per-week coverage. Ambulances shall comply with paragraph 132.8(1)*"d."* The number of ambulances and personnel to be maintained shall be determined by the department, and shall be based upon, but not limited to, the following:

(1) Number of calls;

(2) Service area and population; and

(3) Availability of other services in the area.

c. Provide as a minimum, on each ambulance call, the following staff:

(1) One currently certified EMT-B or EMT.

(2) One currently licensed driver. The service shall document each driver's training in CPR (AED training not required), in emergency driving techniques and in the use of the service's communications equipment. Training in emergency driving techniques shall include:

1. A review of Iowa laws regarding emergency vehicle operations.

2. A review of the service program's driving policy for first response vehicles, ambulances, rescue vehicles or personal vehicles of an emergency medical care provider responding as a member of the service. The policy shall include, at a minimum:

- Frequency and content of driver's training requirements.
- Criteria for response with lights or sirens or both.
- Speed limits when responding with lights or sirens or both.
- Procedure of approaching intersections with lights or sirens or both.
- Notification process in the event of a motor vehicle collision involving a first response vehicle, ambulance, rescue vehicle or personal vehicle of an emergency medical care provider responding as a member of the service.

3. Behind-the-wheel driving of the service's first response vehicles, ambulances and rescue vehicles.

d. Submit an EMS contingency plan that will be put into operation when coverage pursuant to the 24/7 rule in paragraph 132.8(1)*"b"* is not possible due to unforeseen circumstances.

e. Report frequency of use of the contingency plan to the department upon request.

f. Seek approval from the department to provide nontransport coverage in addition to or in lieu of ambulance authorization.

g. Advertise or otherwise imply or hold itself out to the public as an authorized ambulance service only to the level of care maintained 24 hours per day, seven days a week.

h. Apply to the department to receive approval to provide critical care transportation based upon appropriately trained staff and approved equipment.

i. Unless otherwise established by protocol approved by the medical director, the emergency medical care provider with the highest level of certification (on the transporting service) shall attend the patient.

132.8(2) A service program seeking nontransport authorization shall:

a. Apply for authorization at one of the following levels:

(1) First responder/EMR.

(2) EMT-B/EMT.

(3) EMT-I.

(4) AEMT.

(5) EMT-P.

(6) PS/Paramedic.

b. For staffing purposes provide, as a minimum, a transport agreement.

c. Advertise or otherwise hold itself out to the public as an authorized nontransport service program only to the level of care maintained 24 hours per day, seven days a week.

d. Not be prohibited from transporting patients in an emergency situation when lack of transporting resources would cause an unnecessary delay in patient care.

132.8(3) Service program operational requirements. Ambulance and nontransport service programs shall:

a. Complete and maintain a patient care report concerning the care provided to each patient. Ambulance services shall provide, at a minimum, a PCR verbal report upon delivery of a patient to a receiving facility and shall provide a complete PCR within 24 hours to the receiving facility.

b. Utilize department protocols as the standard of care. The service program medical director may make changes to the department protocols provided the changes are within the EMS provider's scope of practice and within acceptable medical practice. A copy of the changes shall be filed with the department.

c. Ensure that personnel duties are consistent with the level of certification and the service program's level of authorization.

d. Maintain current personnel rosters and personnel files. The files shall include the names and addresses of all personnel and documentation that verifies EMS provider credentials including, but not limited to:

(1) Current provider level certification.

(2) Current course completions/certifications/endorsements as may be required by the medical director.

(3) PA and RN exception forms for appropriate personnel and verification that PA and RN personnel have completed the appropriate EMS level continuing education.

e. If requested by the department, notify the department in writing of any changes in personnel rosters.

f. Have a medical director and 24-hour-per-day, 7-day-per-week on-line medical direction available.

g. Ensure that the appropriate service program personnel respond as required in this rule and that they respond in a reasonable amount of time.

h. Notify the department in writing within seven days of any change in service director or ownership or control or of any reduction or discontinuance of operations.

i. Select a new or temporary medical director if for any reason the current medical director cannot or no longer wishes to serve in that capacity. Selection shall be made before the current medical director relinquishes the duties and responsibilities of that position.

j. Within seven days of any change of medical director, notify the department in writing of the selection of the new or temporary medical director who must have indicated in writing a willingness to serve in that capacity.

k. Not prevent a registered nurse or physician assistant from supplementing the staffing of an authorized service program provided equivalent training is documented pursuant to Iowa Code sections 147A.12 and 147A.13.

l. Not be authorized to utilize a manual defibrillator (except paramedic, paramedic specialist).

m. Implement a continuous quality improvement program that provides a policy to include as a minimum:

(1) Medical audits.

(2) Skills competency.

(3) Follow-up (loop closure/resolution).

n. Require physician assistants and registered nurses providing care pursuant to Iowa Code sections 147A.12 and 147A.13 to meet CEH requirements approved by the medical director.

o. Document an equipment maintenance program to ensure proper working condition and appropriate quantities.

p. Ensure a response to requests for assistance when dispatched by a public safety answering point within the primary service area identified in the service program's authorization application.

q. Submit reportable patient data identified in subrule 132.8(7) via electronic transfer. Data shall be submitted in a format approved by the department.

r. Submit reportable patient data identified in subrule 132.8(7) to the department for each calendar quarter. Reportable patient data shall be submitted no later than 90 days after the end of the quarter.

132.8(4) Equipment and vehicle standards. The following standards shall apply:

a. Ambulances placed into service after July 1, 2002, shall meet, as a minimum, the National Truck and Equipment Association's Ambulance Manufacture Division (AMD) performance specifications.

b. All EMS service programs shall carry equipment and supplies in quantities as determined by the medical director and appropriate to the service program's level of care and available certified EMS personnel and as established in the service program's approved protocols.

c. Pharmaceutical drugs and over-the-counter drugs may be carried and administered upon completion of training and pursuant to the service program's established protocols approved by the medical director.

d. All drugs shall be maintained in accordance with the rules of the state board of pharmacy examiners.

e. Accountability for drug exchange, distribution, storage, ownership, and security shall be subject to applicable state and federal requirements. The method of accountability shall be described in the written pharmacy agreement. A copy of the written pharmacy agreement shall be submitted to the department.

f. Each ambulance service program shall maintain a telecommunications system between the emergency medical care provider and the source of the service program's medical direction and other appropriate entities. Nontransport service programs shall maintain a telecommunications system between the emergency medical care provider and the responding ambulance service and other appropriate entities.

g. All telecommunications shall be conducted in an appropriate manner and on a frequency approved by the Federal Communications Commission and the department.

132.8(5) Preventative maintenance. Each ambulance service program shall document a preventative maintenance program to make certain that:

a. Vehicles are fully equipped and maintained in a safe operating condition. In addition:

(1) All ground ambulances shall be housed in a garage or other facility that prevents engine, equipment and supply freeze-up and windshield icing. An unobstructed exit to the street shall also be maintained;

(2) The garage or other facility shall be adequately heated or each response vehicle shall have permanently installed auxiliary heating units to sufficiently heat the engine and patient compartment; and

(3) The garage or other facility shall be maintained in a clean, safe condition free of debris or other hazards.

b. The exterior and interior of the vehicles are kept clean. The interior and equipment shall be cleaned after each use as necessary. When a patient with a communicable disease has been transported or treated, the interior and any equipment or nondisposable supplies coming in contact with the patient shall be thoroughly disinfected.

c. All equipment stored in a patient compartment is secured so that, in the event of a sudden stop or movement of the vehicle, the patient and service program personnel are not injured by moving equipment.

d. All airway, electrical and mechanical equipment is kept clean and in proper operating condition.

e. Compartments provided within the vehicles and the medical and other supplies stored therein are kept in a clean and sanitary condition.

f. All linens, airway and oxygen equipment or any other supplies or equipment coming in direct patient contact is of a single-use disposable type or cleaned, laundered or disinfected prior to reuse.

g. Freshly laundered blankets and linen or disposable linens are used on cots and pillows and are changed after each use.

h. Proper storage is provided for clean linen.

i. Soiled supplies shall be appropriately disposed of according to current biohazard practices.

132.8(6) Service program—incident and accident reports.

a. Incidents of fire or other destructive or damaging occurrences or theft of a service program ambulance, equipment, or drugs shall be reported to the department within 48 hours following the occurrence of the incident.

b. A copy of the motor vehicle accident report required under Iowa Code subsection 321.266(2), relating to the reporting of an accident resulting in personal injury, death or property damage, shall be submitted to the department within seven days following an accident involving a service program vehicle.

c. A service program must report the termination of an emergency medical care provider due to negligence, professional incompetency, unethical conduct or substance use to the department within ten days following the termination.

132.8(7) Adoption by reference. The Iowa EMS Patient Registry Data Dictionary identified in 641—paragraph 136.2(1)*"c"* is adopted and incorporated by reference for inclusion criteria and reportable patient data. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.

a. The Iowa EMS Patient Registry Data Dictionary identified in 641—paragraph 136.2(1)*"c"* is available through the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the EMS bureau Web site (www.idph.state.ia.us/ems).

b. The department shall prepare compilations for release or dissemination on all reportable patient data entered into the EMS service program registry during the reporting period. The compilations shall include, but not be limited to, trends and patient care outcomes for local, regional, and statewide evaluations. The compilations shall be made available to all service programs submitting reportable patient data to the registry.

c. Access and release of reportable patient data and information.

(1) The data collected by and furnished to the department pursuant to this subrule are confidential records of the condition, diagnosis, care, or treatment of patients or former patients, including outpatients, pursuant to Iowa Code section 22.7. The compilations prepared for release or dissemination from the data collected are not confidential under Iowa Code section 22.7, subsection 2. However, information

which individually identifies patients shall not be disclosed, and state and federal law regarding patient confidentiality shall apply.

(2) The department may approve requests for reportable patient data for special studies and analysis provided the request has been reviewed and approved by the deputy director of the department with respect to the scientific merit and confidentiality safeguards, and the department has given administrative approval for the proposal. The confidentiality of patients and the EMS service program shall be protected.

(3) The department may require entities requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable patient data.

d. To the extent possible, activities under this subrule shall be coordinated with other health data collection methods.

e. Quality assurance.

(1) For the purpose of ensuring the completeness and quality of reportable patient data, the department or authorized representative may examine all or part of the patient care report as necessary to verify or clarify all reportable patient data submitted by a service program.

(2) Review of a patient care report by the department shall be scheduled in advance with the service program and completed in a timely manner.

f. The director, pursuant to Iowa Code section 147A.4, may grant a variance from the requirements of these rules for any service program, provided that the variance is related to undue hardships in complying with this chapter.

132.8(8) The patient care report is a confidential document and shall be exempt from disclosure pursuant to Iowa Code subsection 22.7(2) and shall not be accessible to the general public. Information contained in these reports, however, may be utilized by any of the indicated distribution recipients and may appear in any document or public health record in a manner which prevents the identification of any patient or person named in these reports.

132.8(9) Implementation. The director may grant exceptions and variances from the requirements of this chapter for any ambulance or nontransport service. Exceptions or variations shall be reasonably related to undue hardships which existing services experience in complying with this chapter. Services requesting exceptions and variances shall be subject to other applicable rules adopted pursuant to Iowa Code chapter 147A.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10; **ARC 9357B**, IAB 2/9/11, effective 3/16/11; **ARC 9444B**, IAB 4/6/11, effective 5/11/11; **ARC 0063C**, IAB 4/4/12, effective 5/9/12]

641—132.9(147A) Service program—off-line medical direction.

132.9(1) The medical director shall be responsible for providing appropriate medical direction and overall supervision of the medical aspects of the service program and shall ensure that those duties and responsibilities are not relinquished before a new or temporary replacement is functioning in that capacity.

132.9(2) The medical director's duties include, but need not be limited to:

a. Developing, approving and updating protocols to be used by service program personnel that meet or exceed the minimum standard protocols developed by the department.

b. Developing and maintaining liaisons between the service, other physicians, physician designees, hospitals, and the medical community served by the service program.

c. Monitoring and evaluating the activities of the service program and individual personnel performance, including establishment of measurable outcomes that reflect the goals and standards of the EMS system.

d. Assessing the continuing education needs of the service and individual service program personnel and assisting them in the planning of appropriate continuing education programs.

e. Being available for individual evaluation and consultation to service program personnel.

f. Performing or appointing a designee to complete the medical audits required in subrule 132.9(4).

g. Developing and approving an applicable continuous quality improvement policy demonstrating type and frequency of review, including an action plan and follow-up.

h. Informing the medical community of the emergency medical care being provided according to approved protocols in the service program area.

i. Helping to resolve service operational problems.

j. Approving or removing an individual from service program participation.

132.9(3) Supervising physicians, physician designees, or other appointees as defined in the continuous quality improvement policy referenced in 132.9(2)*"g"* may assist the medical director by:

a. Providing medical direction.

b. Reviewing the emergency medical care provided.

c. Reviewing and updating protocols.

d. Providing and assessing continuing education needs for service program personnel.

e. Helping to resolve operational problems.

132.9(4) The medical director or other qualified designees shall randomly audit (at least quarterly) documentation of calls where emergency medical care was provided. The medical director shall randomly review audits performed by the qualified appointee. The audit shall be in writing and shall include, but need not be limited to:

a. Reviewing the patient care provided by service program personnel and remedying any deficiencies or potential deficiencies that may be identified regarding medical knowledge or skill performance.

b. Response time and time spent at the scene.

c. Overall EMS system response to ensure that the patient's needs were matched to available resources including, but not limited to, mutual aid and tiered response.

d. Completeness of documentation.

132.9(5) Rescinded IAB 2/6/02, effective 3/13/02.

132.9(6) On-line medical direction when provided through a hospital.

a. The medical director shall designate in writing at least one hospital which has established a written on-line medical direction agreement with the department. It shall be the medical director's responsibility to notify the department in writing of changes regarding this designation.

b. Hospitals signing an on-line medical direction agreement shall:

(1) Ensure that the supervising physicians or physician designees will be available to provide on-line medical direction via telecommunications on a 24-hour-per-day basis.

(2) Identify the service programs for which on-line medical direction will be provided.

(3) Establish written protocols for use by supervising physicians and physician designees who provide on-line medical direction.

(4) Administer a quality assurance program to review orders given. The program shall include a mechanism for the hospital and service program medical directors to discuss and resolve any identified problems.

c. A hospital which has a written medical direction agreement with the department may provide medical direction for any or all service program authorization levels and may also agree to provide backup on-line medical direction for any other service program when that service program is unable to contact its primary source of on-line medical direction.

d. Only supervising physicians or physician designees shall provide on-line medical direction. A physician assistant, registered nurse or emergency medical care provider (of equal or higher level) may relay orders to emergency medical care personnel, without modification, from a supervising physician. A physician designee may not deviate from approved protocols.

e. The hospital shall provide, upon request to the department, a list of supervising physicians and physician designees providing on-line medical direction.

f. Rescinded IAB 2/6/02, effective 3/13/02.

g. The department may verify a hospital's communications system to ensure compliance with the on-line medical direction agreement.

h. A supervising physician or physician designee who gives orders (directly or via communications equipment from some other point) to an emergency medical care provider is not subject

to criminal liability by reason of having issued the orders and is not liable for civil damages for acts or omissions relating to the issuance of the orders unless the acts or omissions constitute recklessness.

i. Nothing in these rules requires or obligates a hospital, supervising physician or physician designee to approve requests for orders received from emergency medical care personnel.

NOTE: Hospitals in other states may participate provided the applicable requirements of this subrule are met.

[**ARC 0063C**, IAB 4/4/12, effective 5/9/12]

641—132.10(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal.

132.10(1) All complaints regarding the operation of authorized emergency medical care service programs, or those purporting to be or operating as the same, shall be reported to the department. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

132.10(2) Complaints and the investigative process will be treated as confidential in accordance with Iowa Code section 22.7.

132.10(3) Service program authorization may be denied, issued a civil penalty not to exceed $1000, issued a citation and warning, placed on probation, suspended, revoked, or otherwise disciplined by the department in accordance with Iowa Code subsection 147A.5(3) for any of the following reasons:

a. Knowingly allowing the falsifying of a patient care report (PCR).

b. Failure to submit required reports and documents.

c. Delegating professional responsibility to a person when the service program knows that the person is not qualified by training, education, experience or certification to perform the required duties.

d. Practicing, condoning, or facilitating discrimination against a patient, student or employee based on race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability diagnosis, or social or economic status.

e. Knowingly allowing sexual harassment of a patient, student or employee. Sexual harassment includes sexual advances, sexual solicitations, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

f. Failure or repeated failure of the applicant or alleged violator to meet the requirements or standards established pursuant to Iowa Code chapter 147A or the rules adopted pursuant to that chapter.

g. Obtaining or attempting to obtain or renew or retain service program authorization by fraudulent means or misrepresentation or by submitting false information.

h. Engaging in conduct detrimental to the well-being or safety of the patients receiving or who may be receiving emergency medical care.

i. Failure to correct a deficiency within the time frame required by the department.

132.10(4) The department shall notify the applicant of the granting or denial of authorization or renewal, or shall notify the alleged violator of action to issue a citation and warning, place on probation or suspend or revoke authorization or renewal pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a denial, citation and warning, probation, suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

132.10(5) Any requests for appeal concerning the denial, citation and warning, probation, suspension or revocation of service program authorization or renewal shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. After the hearing, or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the denial, citation and warning, probation, suspension or revocation. If no request

for appeal is received within the 20-day time period, the department's notice of denial, probation, suspension or revocation shall become the department's final agency action.

132.10(6) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

132.10(7) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

132.10(8) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 132.10(9).

132.10(9) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

132.10(10) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections, and rulings thereon.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

132.10(11) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

132.10(12) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

132.10(13) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Bureau of Emergency Medical Services, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

132.10(14) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

132.10(15) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, the news media or employer.

132.10(16) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

132.10(17) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend a certificate in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety or welfare have been identified and determined to be continuing;

(3) Whether the program required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the service program that is required to comply with the order by utilizing one or more of the following procedures:

1. Personal delivery.

2. Certified mail, return receipt requested, to the last address on file with the department.

3. Fax. Fax may be used as the sole method of delivery if the service program required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the service program that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the service program that is required to comply with the order is the party requesting the continuance.

[**ARC 8661B**, IAB 4/7/10, effective 5/12/10]

641—132.11(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of emergency medical care personnel certificates or renewal. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.12(147A) Complaints and investigations—denial, citation and warning, probation, suspension, or revocation of training program or continuing education provider approval or renewal. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.13(147A) Complaints, investigations and appeals. Rescinded IAB 2/9/00, effective 3/15/00.

641—132.14(147A) Temporary variances.

132.14(1) If during a period of authorization there is some occurrence that temporarily causes a service program to be in noncompliance with these rules, the department may grant a temporary variance. Temporary variances to these rules (not to exceed six months in length per any approved request) may be

granted by the department to a currently authorized service program. Requests for temporary variances shall apply only to the service program requesting the variance and shall apply only to those requirements and standards for which the department is responsible.

132.14(2) To request a variance, the service program shall:

a. Notify the department verbally (as soon as possible) of the need to request a temporary variance. Submit to the department, within ten days after having given verbal notification to the department, a written explanation for the temporary variance request. The address and telephone number are Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075; (515)725-0326.

b. Cite the rule from which the variance is requested.

c. State why compliance with the rule cannot be maintained.

d. Explain the alternative arrangements that have been or will be made regarding the variance request.

e. Estimate the period of time for which the variance will be needed.

f. Rescinded IAB 2/2/05, effective 3/9/05.

132.14(3) Upon notification of a request for variance, the department shall take into consideration, but shall not be limited to:

a. Examining the rule from which the temporary variance is requested to determine if the request is appropriate and reasonable.

b. Evaluating the alternative arrangements that have been or will be made regarding the variance request.

c. Examining the effect of the requested variance upon the level of care provided to the general populace served.

d. Requesting additional information if necessary.

132.14(4) Preliminary approval or denial shall be provided verbally within 24 hours. Final approval or denial shall be issued in writing within ten days after having received the written explanation for the temporary variance request and shall include the reason for approval or denial. If approval is granted, the effective date and the duration of the temporary variance shall be clearly stated.

132.14(5) Rescinded, effective July 10, 1987.

132.14(6) Any request for appeal concerning the denial of a request for temporary variance shall be in accordance with the procedures outlined in rule 641—132.10(147A).

132.14(7) Rescinded IAB 2/3/93, effective 3/10/93.

641—132.15(147A) Transport options for fully authorized EMT-P, PS, and paramedic service programs.

132.15(1) Upon responding to an emergency call, ambulance or nontransport EMT-P, PS, and paramedic level services may make a determination at the scene as to whether emergency medical transportation or nonemergency transportation is needed. The determination shall be made by an EMT-P, paramedic or paramedic specialist and shall be based upon the nonemergency transportation protocol approved by the service program's medical director. When applying this protocol, the following criteria, as a minimum, shall be used to determine the appropriate transport option:

a. Primary assessment,

b. Focused history and physical examination,

c. Chief complaint,

d. Name, address and age, and

e. Nature of the call for assistance.

Emergency medical transportation shall be provided whenever any of the above criteria indicate that treatment should be initiated.

132.15(2) If treatment is not indicated, the service program may make arrangements for nonemergency transportation. If arrangements are made, the service program shall remain at the scene

until nonemergency transportation arrives. During the wait for nonemergency transportation, however, the ambulance or nontransport service may respond to an emergency.
[**ARC 0063C**, IAB 4/4/12, effective 5/9/12]

641—132.16(147A) Public access defibrillation. Rescinded IAB 2/2/05, effective 3/9/05.

These rules are intended to implement Iowa Code chapter 147A.

[Filed 5/11/79, Notice 4/4/79—published 5/30/79, effective 7/5/79]
[Filed emergency 3/27/81—published 4/15/81, effective 3/27/81]
[Filed without Notice 5/21/81—published 6/10/81, effective 7/15/81]
[Filed emergency 7/15/81—published 8/5/81, effective 7/15/81]
[Filed emergency 2/4/82—published 3/3/82, effective 3/1/82]
[Filed 10/27/82, Notice 9/1/82—published 11/24/82, effective 12/29/82]
[Filed emergency 12/16/82—published 1/5/83, effective 12/30/82]
[Filed emergency 9/20/83—published 10/12/83, effective 9/21/83]
[Filed 9/15/83, Notice 7/6/83—published 10/12/83, effective 11/16/83]
[Filed emergency 12/26/84—published 1/16/85, effective 12/31/84]
[Filed emergency after Notice 5/8/85, Notice 3/27/85—published 6/5/85, effective 5/17/85]
[Filed emergency 9/11/85—published 10/9/85, effective 9/11/85]
[Filed emergency 12/24/85—published 1/15/86, effective 12/31/85]
[Filed 5/30/86, Notice 3/26/86—published 6/18/86, effective 7/23/86]
[Filed emergency 7/1/86—published 7/16/86, effective 7/1/86][1]
[Filed 8/28/86, Notice 4/9/86—published 9/24/86, effective 10/29/86]
[Filed emergency 9/19/86—published 10/8/86, effective 9/19/86]
[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]
[Filed 7/10/87, Notice 2/11/87—published 7/29/87, effective 9/2/87]
[Filed emergency 1/30/89—published 2/22/89, effective 1/31/89]
[Filed emergency 5/10/89—published 5/31/89, effective 5/12/89]
[Filed 9/14/89, Notice 6/28/89—published 10/4/89, effective 11/8/89]
[Filed 6/22/90, Notice 4/18/90—published 7/11/90, effective 8/15/90]
[Filed 3/13/92, Notice 12/11/91—published 4/1/92, effective 5/6/92]
[Filed 1/15/93, Notice 9/30/92—published 2/3/93, effective 3/10/93]
[Filed 1/14/94, Notice 10/13/93—published 2/2/94, effective 3/9/94]
[Filed 9/20/95, Notice 8/2/95—published 10/11/95, effective 11/15/95]
[Filed 7/10/96, Notice 6/5/96—published 7/31/96, effective 9/4/96]
[Filed 9/16/96, Notice 7/31/96—published 10/9/96, effective 11/13/96]
[Filed emergency 1/23/98—published 2/11/98, effective 1/23/98]
[Filed 2/26/98, Notice 9/10/97—published 3/25/98, effective 4/29/98]
[Filed 3/18/98, Notice 1/14/98—published 4/8/98, effective 5/13/98]
[Filed 5/15/98, Notice 3/11/98—published 6/3/98, effective 7/8/98]
[Filed 11/10/98, Notice 9/23/98—published 12/2/98, effective 1/6/99]
[Filed 1/20/00, Notice 12/1/99—published 2/9/00, effective 3/15/00]
[Filed emergency 9/14/00—published 10/4/00, effective 9/14/00]
[Filed 1/18/01, Notice 11/29/00—published 2/7/01, effective 3/14/01]
[Filed 1/10/02, Notice 11/28/01—published 2/6/02, effective 3/13/02]
[Filed 1/13/05, Notice 11/24/04—published 2/2/05, effective 3/9/05][2]
[Filed emergency 7/13/05 after Notice 6/8/05—published 8/3/05, effective 7/13/05]
[Filed 7/12/06, Notice 5/24/06—published 8/2/06, effective 9/6/06]
[Filed 11/12/08, Notice 9/24/08—published 12/3/08, effective 1/7/09]
[Filed ARC 8230B (Notice ARC 7969B, IAB 7/15/09), IAB 10/7/09, effective 11/11/09]
[Filed ARC 8661B (Notice ARC 8498B, IAB 1/27/10), IAB 4/7/10, effective 5/12/10]
[Filed ARC 9357B (Notice ARC 9240B, IAB 11/17/10), IAB 2/9/11, effective 3/16/11]
[Filed ARC 9444B (Notice ARC 9343B, IAB 1/26/11), IAB 4/6/11, effective 5/11/11]

[Filed ARC 0063C (Notice ARC 0001C, IAB 2/8/12), IAB 4/4/12, effective 5/9/12]
[Filed ARC 0480C (Notice ARC 0377C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13]
[Filed ARC 1404C (Notice ARC 1292C, IAB 1/22/14), IAB 4/2/14, effective 5/7/14]

[1] See IAB, Inspections and Appeals Department.

[2] Rescission of paragraph 132.14(2)*"f"* inadvertently omitted from 2/2/05 Supplement.

CHAPTER 205
Reserved

CHAPTER 206
IOWA HEALTH INFORMATION NETWORK

641—206.1(135) Scope and applicability. This chapter describes how the department will address issues regarding the Iowa health information network, including: the development of policies and procedures for auditing participants' usage of the Iowa health information network and enforcing compliance with applicable standards, requirements, rules and procedures; the process by which individuals can decline to have their health information shared through the Iowa health information network; and the process by which the department will notify individuals if there has been unauthorized access to or disclosure of their protected health information through the Iowa health information network.
[**ARC 1405C**, IAB 4/2/14, effective 5/7/14]

641—206.2(135) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Advisory council" means the electronic health information advisory council established in Iowa Code section 135.156(2)*"a."*

"Board" means the state board of health established in Iowa Code chapter 136.

"Breach" means breach as such term is defined in the HIPAA Privacy Rule.

"Department" means the Iowa department of public health.

"Executive committee" means the executive committee of the electronic health information advisory council established in Iowa Code section 135.156(2)*"b."*

"HIPAA" means the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, as amended by the HITECH Act, and the regulations promulgated thereunder, including the Privacy Rule, the Security Rule and the Omnibus Final Rule.

"Individual" means a patient or client of a participant.

"Iowa health information network" means the health information exchange operated by the department pursuant to Iowa Code section 135.155.

"Opt out" means to decline to have one's health information exchanged through the Iowa health information network.

"Participant" means an authorized organization or individual that has voluntarily agreed to enter into a participation agreement to access or use the Iowa health information network.

"Participation agreement" means the agreement that is entered into between the department and a participant and prescribes the terms and conditions for access and use of the Iowa health information network.

"Privacy policies and security policies" means the department's rules, regulations, policies and procedures for access to and use of the Iowa health information network, as approved and amended by the executive committee and advisory council and the board, that are posted electronically on the Iowa health information network Web site or otherwise furnished to participants.

"Protected health information" means protected health information as defined in HIPAA that is created, transmitted or received by an authorized participant.

"Provider" means a person or organization that is a health care provider under HIPAA and is licensed or otherwise permitted to provide health care items and services under applicable state law.

"Security incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information available through the Iowa health information network or interference with Iowa health information network operations, including attempted and successful privacy breaches.
[**ARC 1405C**, IAB 4/2/14, effective 5/7/14]

641—206.3(135) Policy development and governance. The department is required to develop and implement the privacy policies and security policies to protect protected health information exchanged through the Iowa health information network. The policies must be reviewed by the executive committee

and advisory council and approved by the board prior to implementation. Any changes to the policies must go through the same review and approval process.
[**ARC 1405C**, IAB 4/2/14, effective 5/7/14]

641—206.4(135) Monitoring and audit. The department shall monitor and audit participant usage of the Iowa health information network in a manner consistent with the privacy policies and security policies.

206.4(1) The department shall enforce the privacy policies and security policies, which shall include audit and monitoring requirements for participants.

206.4(2) Participant monitoring and audit activity requirements shall be included in the participation agreement. Participants unwilling or unable to abide by the requirements and participants that violate the policies or terms of the participation agreement may face sanctions up to and including suspension or termination of the participation agreement.
[**ARC 1405C**, IAB 4/2/14, effective 5/7/14]

641—206.5(135) Consumer participation in the Iowa health information network. Pursuant to Iowa Code section 135.156E(2), consumers have the opportunity to opt out of participation in the Iowa health information network.

206.5(1) The department shall explain the process and provide forms for patients to complete in order to opt out of participation in the Iowa health information network. The information shall be made available in places including, but not limited to, provider offices and on the Iowa health information network Web site.

206.5(2) Patients who decline to have their health information shared through the Iowa health information network may later choose to have their information shared by providing verification of identity.
[**ARC 1405C**, IAB 4/2/14, effective 5/7/14]

641—206.6(135) Security incidents, breaches.

206.6(1) The department and all participants shall promptly investigate, respond to and report privacy breaches related to the Iowa health information network in compliance with applicable federal and state law.

206.6(2) The department shall include in the privacy policies and security policies more detailed requirements regarding security incidents and shall develop a security incident response plan identifying the responsible parties and action steps to be taken in the event of a security incident.
[**ARC 1405C**, IAB 4/2/14, effective 5/7/14]

641—206.7(135) Health information audit. The department shall make available upon request and on the Iowa health information network Web site a form for individuals to request an audit report showing who or what system has accessed their health information through the Iowa health information network.

206.7(1) Individuals may request an audit report by contacting the department by:

Mail: Office of Health IT
Iowa Department of Public Health
Lucas State Office Building
321 E. 12th Street
Des Moines, Iowa 50319

Fax: (515)281-4958

E-mail: ehealth@idph.state.ia.us

The department may require proof of legal authority to view health information records.

206.7(2) The department shall process the health information audit request and provide a response to the individual within 30 days of receipt of the request.
[**ARC 1405C**, IAB 4/2/14, effective 5/7/14]

These rules are intended to implement Iowa Code sections 135.156E(2) and 135.156E(9).

[Filed ARC 1405C (Notice ARC 1315C, IAB 2/5/14), IAB 4/2/14, effective 5/7/14]

SPEECH PATHOLOGISTS AND AUDIOLOGISTS

CHAPTER 300 LICENSURE OF SPEECH PATHOLOGISTS AND AUDIOLOGISTS
CHAPTER 301 RESERVED
CHAPTER 302 RESERVED
CHAPTER 303 CONTINUING EDUCATION FOR SPEECH PATHOLOGISTS AND AUDIOLOGISTS
CHAPTER 304 DISCIPLINE FOR SPEECH PATHOLOGISTS AND AUDIOLOGISTS

CHAPTER 300
LICENSURE OF SPEECH PATHOLOGISTS AND AUDIOLOGISTS

645—300.1(147) Definitions. For purposes of these rules, the following definitions shall apply:

"Active license" means a license that is current and has not expired.

"ASHA" means the American Speech-Language Hearing Association.

"Assistant" means a person who works under the supervision of an Iowa-licensed speech pathologist or audiologist, does not meet the requirements to be licensed as a speech pathologist or audiologist, and meets the minimum requirements set forth in these rules.

"Audiologist" means a person who engages in the application of principles, methods and procedures for measurement, testing, evaluation, prediction, consultation, counseling, instruction, habilitation, rehabilitation, or remediation related to disorders of hearing and associated communication disorders for the purpose of nonmedically evaluating, identifying, preventing, ameliorating, modifying, or remediating such disorders and conditions in individuals or groups of individuals, including the determination and use of appropriate amplification.

"Board" means the board of speech pathology and audiology.

"Full-time" means a minimum of 30 hours per week.

"Grace period" means the 30-day period following expiration of a license when the license is still considered to be active. In order to renew a license during the grace period, a licensee is required to pay a late fee.

"Inactive license" means a license that has expired because it was not renewed by the end of the grace period. The category of "inactive license" may included licenses formerly known as lapsed, inactive, delinquent, closed, or retired.

"Licensee" means any person licensed to practice as a speech pathologist or audiologist in the state of Iowa.

"License expiration date" means December 31 of odd-numbered years.

"Licensure by endorsement" means the issuance of an Iowa license to practice speech pathology or audiology to an applicant who is or has been licensed in another state.

"On site" means:

1. To be continuously on site and present in the department or facility where services are being provided;
2. To be immediately available to assist the person being supervised in the services being performed; and
3. To provide continued direction of appropriate aspects of each treatment session in which a component of treatment is delegated.

"Reactivate" or *"reactivation"* means the process as outlined in rule 645—300.17(17A,147,272C) by which an inactive license is restored to active status.

"Reciprocal license" means the issuance of an Iowa license to practice speech pathology or audiology to an applicant who is currently licensed in another state which has a mutual agreement with the Iowa board of speech pathology and audiology to license persons that have the same or similar qualifications to those required in Iowa.

"Reinstatement" means the process as outlined in 645—11.31(272C) by which a licensee who has had a license suspended or revoked or who has voluntarily surrendered a license may apply to have the license reinstated, with or without conditions. Once the license is reinstated, the licensee may apply for active status.

"Speech pathologist" means a person who engages in the application of principles, methods, and procedures for the measurement, testing, evaluation, prediction, consultation, counseling, instruction, habilitation, rehabilitation, or remediation related to the development and disorders of speech, fluency, voice, or language for the purpose of nonmedically evaluating, preventing, ameliorating, modifying, or remediating such disorders and conditions in individuals or groups of individuals.

645—300.2(147) Speech pathology and audiology services subject to regulation. The provision of speech pathology or audiology services in Iowa through telephonic, electronic, or other means, regardless of the location of the speech/language pathologist or audiologist, shall constitute the practice of speech pathology or audiology and shall require Iowa licensure.

645—300.3(147) Requirements for licensure. The following criteria shall apply to licensure:

300.3(1) The applicant shall complete a board-approved application packet. Application forms may be obtained from the board's Web site (http://www.idph.state.ia.us/licensure) or directly from the board office. All applications shall be sent to Board of Speech Pathology and Audiology, Professional Licensure Division, Fifth Floor, Lucas State Office Building, Des Moines, Iowa 50319-0075.

300.3(2) The applicant shall complete the application form according to the instructions contained in the application. If the application is not completed according to the instructions, the application will not be reviewed by the board.

300.3(3) Each application shall be accompanied by the appropriate fees payable to the Board of Speech Pathology and Audiology. The fees are nonrefundable.

300.3(4) The application shall include:

a. An official copy of a current American Speech-Language Hearing Association (ASHA) certificate of clinical competence; or

b. Submission of the following:

(1) Official copies of academic transcripts sent directly from the school to the board showing proof of possession of a master's degree in speech pathology or a master's or doctoral degree in audiology or the equivalent of one of these degrees and official verification of completion of not less than 400 hours of supervised clinical training;

(2) Verification of nine months of full-time clinical experience, or equivalent, completed after the master's degree, under the supervision of a licensed speech pathologist or audiologist or as a part of the doctoral degree; and

(3) Results of the Praxis Examination.

300.3(5) Licensees who were issued their licenses within six months prior to the renewal shall not be required to renew their licenses until the renewal date two years later.

300.3(6) Incomplete applications that have been on file in the board office for more than two years shall be:

a. Considered invalid and shall be destroyed; or

b. Maintained upon written request of the applicant. The applicant is responsible for requesting that the file be maintained.

[**ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—300.4(147) Educational qualifications.

300.4(1) The applicant shall possess the following:

a. A master's degree from an accredited school, college or university with a major in speech pathology; or

b. A master's or doctoral degree from an accredited school, college or university with a major in audiology.

300.4(2) Foreign-trained speech pathologists and audiologists shall:

a. Provide an equivalency evaluation of their educational credentials by one of the following: International Educational Research Foundations, Inc., Credentials Evaluation Service, P.O. Box 3665, Culver City, CA 90231-3665, telephone (310)258-9451, Web site www.ierf.org or E-mail at info@ierf.org; International Credentialing Associates, Inc., 7245 Bryan Dairy Road, Bryan Dairy Business Park II, Largo, FL 33777, telephone (727)549-8555. The professional curriculum must be equivalent to that stated in these rules. A candidate shall bear the expense of the curriculum evaluation.

b. Provide a notarized copy of the certificate or diploma awarded to the applicant from a speech pathology or audiology program in the country in which the applicant was educated.

c. Receive a final determination from the board regarding the application for licensure.

645—300.5(147) Examination requirements. The examination required by the board shall be the Praxis Examination in speech pathology or audiology. This examination is administered by the Educational Testing Service.

300.5(1) The applicant has full responsibility for making arrangements to take the Praxis Examination in speech pathology or audiology and for bearing all expenses associated with taking the examination. The applicant also has the responsibility for having the examination scores sent directly to the board from the Educational Testing Service.

300.5(2) The board shall determine the qualifying scores for both the speech pathology and audiology examinations.

[**ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—300.6(147) Temporary clinical license. A temporary clinical license for the purpose of obtaining clinical experience as a prerequisite for licensure is valid for one year and may be renewed at the discretion of the board.

300.6(1) A speech pathology applicant must submit the following to the board:

a. Evidence of supervision by a speech pathologist with an active, current Iowa license in good standing;

b. An official application form provided by the board and completed by the applicant;

c. An official copy of the transcript, sent directly from the school to the board, showing proof of possession of a master's degree in speech pathology;

d. Official verification of completion of not less than 400 hours of supervised clinical training in an accredited college or university;

e. The temporary clinical license fee; and

f. Results of the Praxis Examination.

300.6(2) An audiology applicant or an applicant completing a doctoral externship must submit the following to the board:

a. Evidence of supervision by an audiologist with an active, current Iowa license in good standing. The applicant completing an audiology doctoral externship must show evidence of on-site supervision;

b. An official application form provided by the board and completed by the applicant;

c. An official copy of the transcript, sent directly from the school to the board, showing proof of possession of a master's degree in audiology;

d. Official verification of completion of not less than 400 hours of supervised clinical training in an accredited college or university;

e. The temporary clinical license fee; and

f. Results of the Praxis Examination.

300.6(3) The plan for supervised clinical experience must be approved by the board before the applicant starts practice and shall:

a. Include at least nine months of full-time clinical experience, or equivalent;

b. Include supervision by an Iowa-licensed speech pathologist or audiologist, as appropriate. If the applicant is being supervised by more than one individual, each supervisor must submit a supervised clinical experience plan for approval. If there is a change in the supervised clinical experience plan at any

time during the supervised clinical experience, the licensee must contact the board for approval within 30 days of the change;

c. Be kept by the supervisor for two years from the last date of the clinical experience; and

d. Include a completed supervised clinical experience report form that shall be submitted to the board of speech pathology and audiology upon the applicant's successful completion of the nine months of full-time clinical experience. If the applicant was supervised by more than one individual, each supervisor must submit a supervised clinical experience report. The applicant may then apply for licensure.

[**ARC 8872B**, IAB 6/30/10, effective 8/4/10; **ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—300.7(147) Temporary permit.

300.7(1) A nonresident may apply to the board for a temporary permit to practice speech pathology or audiology:

a. For a period not to exceed three months;

b. By submitting a letter to support the need for such a permit;

c. By submitting documents to show that the applicant has substantially the same qualifications as required for licensure in Iowa;

d. By submitting the documentation prior to the date the applicant intends to begin practice; and

e. By submitting the temporary permit fee.

300.7(2) The applicant shall receive a final determination from the board regarding the application for a temporary permit.

645—300.8(147) Use of assistants. A licensee shall, in the delivery of professional services, utilize assistants only to the extent provided in these rules.

300.8(1) *Duties.*

a. *Speech pathology assistant I.* A speech pathology assistant I works with an individual for whom significant improvement is expected within a reasonable amount of time.

b. *Speech pathology assistant II.* A speech pathology assistant II works with an individual for whom maintenance of present level of communication is the goal; or for whom, based on the history and diagnosis, only slow improvement is expected.

c. *Audiology assistant I.* An audiology assistant I is more broadly trained and may be given a variety of duties depending upon the individual's training.

d. *Audiology assistant II.* An audiology assistant II is trained specifically for a single task for screening.

300.8(2) *Minimum requirements.*

a. A speech pathology assistant I or II or audiology assistant I must satisfy the following minimum requirements:

(1) Reach the age of majority;

(2) Complete a high school education, or its equivalent; and

(3) Complete one of the following:

1. A three-semester-hour (or four-quarter-hour) course in introductory speech and language pathology for speech pathology assistants or in audiology for audiology assistants from an accredited educational institution and 15 hours of instruction in the specific tasks which the assistant will be performing; or

2. A minimum training period comprised of 75 clock hours on instruction and practicum experience.

b. An audiology assistant II must satisfy the following requirements:

(1) Reach the age of majority.

(2) Complete a high school education, or its equivalent.

(3) Complete a minimum of 15 clock hours of instruction and practicum experience in the specific task which the assistant will be performing.

300.8(3) *Utilization.* Utilization of a speech pathology or audiology assistant requires that a plan be developed by the licensee desiring to utilize that assistant, consisting of the following information:

a. Documentation that the assistant meets minimum requirements;

b. A written plan of the activities and supervision that must be kept by the licensee supervising the assistant. This supervision must include direct on-site observation for a minimum of 20 percent of the assistant's direct patient care for level I speech pathology and level I audiology assistants and 10 percent for level II speech pathology assistants. Level II audiology assistants must be supervised 10 percent of the time. At least half of that time must be direct on-site observation with the other portion provided as time interpreting results;

c. A listing of the facilities where the assistant will be utilized; and

d. A statement, signed by the licensee and the assistant, that the rules pertaining to assistants have been read by both.

300.8(4) *Maximum number of assistants.* A licensee may not utilize more than three assistants unless a plan of supervision is filed and approved by the board.

300.8(5) *Supervisor responsibilities.* A licensee who utilizes an assistant shall have the following responsibilities:

a. To be legally responsible for the actions of the assistant in that assistant's performance of assigned duties with a client;

b. To make all professional decisions relating to the management of a client;

c. To ensure that the assistant is assigned only those duties and responsibilities for which the assistant has been specifically trained and is qualified to perform;

d. To ensure compliance of the assistant(s) under supervision with the provisions of these rules by providing periodic direct observation and supervision of the activities of the assistant; and

e. To submit to the board of speech pathology and audiology upon request a copy of the plan of activities and supervision for each assistant and documentation of the dates each assistant was utilized by the licensee.

645—300.9(147) Licensure by endorsement. An applicant who has been a licensed speech pathologist or audiologist under the laws of another jurisdiction shall file an application for licensure by endorsement with the board office. The board may receive by endorsement any applicant from the District of Columbia or another state, territory, province or foreign country who:

1. Submits to the board a completed application;
2. Pays the licensure fee;
3. Shows evidence of a current ASHA certificate or at least nine months of full-time clinical experience or its equivalent;
4. Shows evidence that the Praxis Examination scores have been sent directly from the examination service to the board;
5. Provides official copies of the academic transcripts; and
6. Provides verification of license(s) from every jurisdiction in which the applicant has been licensed, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification direct from the jurisdiction's board office if the verification provides:

- Licensee's name;
- Date of initial licensure;
- Current licensure status; and
- Any disciplinary action taken against the license.

[**ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—300.10(147) Licensure by reciprocal agreement. Rescinded IAB 6/30/10, effective 8/4/10.

645—300.11(147) License renewal.

300.11(1) The biennial license renewal period for a license to practice speech pathology or audiology shall begin on January 1 of an even-numbered year and end on December 31 of the next odd-numbered

year. The licensee is responsible for renewing the license prior to its expiration. Failure of the licensee to receive notice from the board does not relieve the licensee of the responsibility for renewing the license.

300.11(2) An individual who was issued an initial license within six months of the license renewal date will not be required to renew the license until the subsequent renewal date two years later.

300.11(3) A licensee seeking renewal shall:

a. Meet the continuing education requirements of rule 645—303.2(147) and the mandatory reporting requirements of subrule 300.11(4). A licensee whose license was reactivated during the current renewal compliance period may use continuing education credit earned during the compliance period for the first renewal following reactivation; and

b. Submit the completed renewal application and renewal fee before the license expiration date.

c. An individual who was issued a license within six months of the license renewal date will not be required to renew the license until the subsequent renewal two years later.

300.11(4) Mandatory reporter training requirements.

a. A licensee who, in the scope of professional practice or in the licensee's employment responsibilities, examines, attends, counsels or treats children in Iowa shall indicate on the renewal application completion of two hours of training in child abuse identification and reporting in the previous five years or condition(s) for waiver of this requirements as identified in paragraph *"e."*

b. A licensee who, in the course of employment, examines, attends, counsels or treats adults in Iowa shall indicate on the renewal application completion of two hours of training in dependent adult abuse identification and reporting in the previous five years or condition(s) for waiver of this requirement as identified in paragraph *"e."*

c. A licensee who, in the scope of professional practice or in the course of employment, examines, attends, counsels or treats both adults and children in Iowa shall indicate on the renewal application completion of training in abuse identification and reporting for dependent adults and children in the previous five years or condition(s) for waiver of this requirement as identified in paragraph *"e."*

Training may be completed through separate courses as identified in paragraphs *"a"* and *"b"* or in one combined two-hour course that includes curricula for identifying and reporting child abuse and dependent adult abuse. The course shall be a curriculum approved by the Iowa department of public health abuse education review panel.

d. The licensee shall maintain written documentation for five years after mandatory training as identified in paragraphs *"a"* to *"c,"* including program date(s), content, duration, and proof of participation.

e. The requirement for mandatory training for identifying and reporting child and dependent adult abuse shall be suspended if the board determines that suspension is in the public interest or that a person at the time of license renewal:

(1) Is engaged in active duty in the military service of this state or the United States.

(2) Holds a current waiver by the board based on evidence of significant hardship in complying with training requirements, including an exemption of continuing education requirements or extension of time in which to fulfill requirements due to a physical or mental disability or illness as identified in 645—Chapter 303.

f. The board may select licensees for audit of compliance with the requirements in paragraphs *"a"* to *"e."*

300.11(5) Upon receiving the information required by this rule and the required fee, board staff shall administratively issue a two-year license and shall send the licensee a wallet card by regular mail. In the event the board receives adverse information on the renewal application, the board shall issue the renewal license but may refer the adverse information for further consideration or disciplinary investigation.

300.11(6) A person licensed to practice as a speech pathologist or audiologist shall keep the person's license certificate and wallet card displayed in a conspicuous public place at the primary site of practice.

300.11(7) Late renewal. The license shall become late when the license has not been renewed by the expiration date on the wallet card. The licensee shall be assessed a late fee as specified in 645—subrule 305.1(3). To renew a late license, the licensee shall complete the renewal requirements and submit the late fee within the grace period.

300.11(8) Inactive license. A licensee who fails to renew the license by the end of the grace period has an inactive license. A licensee whose license is inactive continues to hold the privilege of licensure in Iowa, but may not practice as a speech pathologist or audiologist in Iowa until the license is reactivated. A licensee who practices as a speech pathologist or audiologist in the state of Iowa with an inactive license may be subject to disciplinary action by the board, injunctive action pursuant to Iowa Code section 147.83, criminal sanctions pursuant to Iowa Code section 147.86, and other available legal remedies.
[**ARC 9947B**, IAB 12/28/11, effective 2/1/12]

645—300.12(17A,147,272C) Board meetings.

300.12(1) Board meetings shall be governed in accordance with Iowa Code chapter 21, and board proceedings shall be conducted to ensure that all members have equal rights, privileges and obligations.

300.12(2) A majority of the members of the board shall constitute a quorum.

300.12(3) The board shall discuss all motions prior to a vote to allow for full and free discussion of every motion.

300.12(4) Official action, including filing of formal charges or imposition of discipline, requires a majority vote of members present.
[**ARC 9947B**, IAB 12/28/11, effective 2/1/12]

645—300.13(272C) Lapsed licenses. Rescinded IAB 9/14/05, effective 10/19/05.

645—300.14(147) Duplicate certificate or wallet card. Rescinded IAB 6/30/10, effective 8/4/10.

645—300.15(147) Reissued certificate or wallet card. Rescinded IAB 6/30/10, effective 8/4/10.

645—300.16(17A,147,272C) License denial. Rescinded IAB 6/30/10, effective 8/4/10.

645—300.17(17A,147,272C) License reactivation. To apply for reactivation of an inactive license, a licensee shall:

300.17(1) Submit a reactivation application on a form provided by the board.

300.17(2) Pay the reactivation fee that is due as specified in 645—Chapter 305.

300.17(3) Provide verification of current competence to practice speech pathology and audiology by satisfying one of the following criteria:

a. If the license has been on inactive status for five years or less, an applicant must provide the following:

(1) Verification of the license(s) from every jurisdiction in which the applicant is or has been licensed and is or has been practicing during the time period the Iowa license was inactive, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification from a jurisdiction's board office if the verification includes:

1. Licensee's name;
2. Date of initial licensure;
3. Current licensure status; and
4. Any disciplinary action taken against the license; and

(2) Verification of completion of 30 hours of continuing education within two years of application for reactivation.

b. If the license has been on inactive status for more than five years, an applicant must provide the following:

(1) Verification of the license(s) from every jurisdiction in which the applicant is or has been licensed and is or has been practicing during the time period the Iowa license was inactive, sent directly from the jurisdiction(s) to the board office. Web-based verification may be substituted for verification from a jurisdiction's board office if the verification includes:

1. Licensee's name;
2. Date of initial licensure;
3. Current licensure status; and

4. Any disciplinary action taken against the license; and

(2) Verification of completion of 60 hours of continuing education within two years of application for reactivation; or

(3) Verification of passing the Praxis Examination in speech pathology or audiology within the last two years prior to application for reactivation.

[**ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—300.18(17A,147,272C) License reinstatement. A licensee whose license has been revoked, suspended, or voluntarily surrendered must apply for and receive reinstatement of the license in accordance with 645—11.31(272C) and must apply for and be granted reactivation of the license in accordance with 300.17(17A,147,272C) prior to practicing speech pathology and audiology in this state.

These rules are intended to implement Iowa Code chapters 17A, 147 and 272C.

[Filed 2/2/77, Notice 12/29/76—published 2/23/77, effective 3/30/77]
[Filed emergency 8/14/81—published 9/2/81, effective 8/14/81]
[Filed 8/28/81, Notice 3/4/81—published 9/16/81, effective 10/21/81]
[Filed 10/22/82, Notice 8/18/82—published 11/10/82, effective 12/17/82]
[Filed 1/14/83, Notice 11/24/82—published 2/2/83, effective 3/11/83]
[Filed 6/15/83, Notice 4/13/83—published 7/6/83, effective 8/11/83]
[Filed emergency 11/1/83 after Notice 9/14/83—published 11/23/83, effective 11/1/83]
[Filed 1/21/85, Notice 11/21/84—published 2/13/85, effective 3/20/85]
[Filed 6/18/86, Notice 4/9/86—published 7/16/86, effective 8/20/86]
[Filed 7/29/88, Notice 3/23/88—published 8/24/88, effective 9/28/88]
[Filed 7/29/88, Notice 5/4/88—published 8/24/88, effective 9/28/88]
[Filed 6/9/89, Notice 2/8/89—published 6/28/89, effective 8/2/89]
[Filed 4/12/91, Notice 1/9/91—published 5/1/91, effective 6/5/91]
[Filed 8/1/91, Notice 5/1/91—published 8/21/91, effective 9/25/91]
[Filed 11/22/91, Notice 8/21/91—published 12/11/91, effective 1/15/92]
[Filed 1/29/93, Notice 9/30/92—published 2/17/93, effective 4/1/93]
[Filed 2/23/94, Notice 12/8/93—published 3/16/94, effective 4/22/94]
[Filed 5/28/99, Notice 3/10/99—published 6/16/99, effective 7/21/99]
[Filed 2/15/00, Notice 12/15/99—published 3/8/00, effective 4/12/00]
[Filed 11/9/00, Notice 9/20/00—published 11/29/00, effective 1/3/01]
[Filed 8/30/01, Notice 5/30/01—published 9/19/01, effective 10/24/01]
[Filed 5/9/02, Notice 4/3/02—published 5/29/02, effective 7/3/02]
[Filed 8/14/03, Notice 5/28/03—published 9/3/03, effective 10/8/03]
[Filed 2/27/04, Notice 12/10/03—published 3/17/04, effective 4/21/04]
[Filed 8/22/05, Notice 6/8/05—published 9/14/05, effective 10/19/05][◊]
[Filed 12/22/08, Notice 10/22/08—published 1/14/09, effective 2/18/09]
[Filed ARC 8872B (Notice ARC 8639B, IAB 4/7/10), IAB 6/30/10, effective 8/4/10]
[Filed ARC 9947B (Notice ARC 9767B, IAB 10/5/11), IAB 12/28/11, effective 2/1/12]
[Filed ARC 1397C (Notice ARC 1314C, IAB 2/5/14), IAB 4/2/14, effective 5/7/14]

◊ Two or more ARCs

CHAPTER 303
CONTINUING EDUCATION FOR SPEECH PATHOLOGISTS AND AUDIOLOGISTS

645—303.1(147) Definitions. For the purpose of these rules, the following definitions shall apply:

"AAA" means the American Association of Audiology.

"Active license" means a license that is current and has not expired.

"Approved program/activity" means a continuing education program/activity meeting the standards set forth in these rules.

"ASHA" means the American Speech-Language Hearing Association.

"Audit" means the selection of licensees for verification of satisfactory completion of continuing education requirements during a specified time period.

"Board" means the board of speech pathology and audiology.

"Continuing education" means a planned individual learning experience or activity that is directly related to the sciences or contemporary clinical practice of audiology, speech-language pathology and speech-language-hearing science and whose content and focus are beyond the basic preparation required for entry into the professions. These activities result in improving, adding to, or positively changing the knowledge and skills of the licensee to improve the safety and welfare of the public.

"Hour of continuing education" means at least 50 minutes spent by a licensee in actual attendance at and completion of an approved continuing education activity.

"Inactive license" means a license that has expired because it was not renewed by the end of the grace period. The category of "inactive license" may include licenses formerly known as lapsed, inactive, delinquent, closed, or retired.

"License" means license to practice.

"Licensee" means any person licensed to practice speech pathology or audiology or both in the state of Iowa.

[**ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—303.2(147) Continuing education requirements.

303.2(1) The biennial continuing education compliance period shall extend for a two-year period between January 1 of each even-numbered year and December 31 of each odd-numbered year. Each biennium, each person who is licensed to practice as a speech pathology or audiology licensee in this state shall be required to complete a minimum of 30 hours of continuing education approved by the board. A person holding licensure in both speech pathology and audiology must meet the requirements for each profession.

303.2(2) Requirements of new licensees. Those persons licensed for the first time shall not be required to complete continuing education as a prerequisite for the first renewal of their licenses. Continuing education hours acquired anytime from the initial licensing until the second license renewal may be used. The new licensee will be required to complete a minimum of 30 hours of continuing education per biennium for each subsequent license renewal.

303.2(3) Hours of continuing education credit may be obtained by participation in a continuing education program or activity. Such programs and activities may take place individually or in group settings including in-person conferences, journal readings, teleconferences, videoconferences and online programs or activities as long as such programs and activities meet the criteria specified in the definition of continuing education in rule 645—303.1(147).

303.2(4) No hours of continuing education shall be carried over into the next biennium except as stated for second renewal. A licensee whose license was reactivated during the current renewal compliance period may use continuing education earned during the compliance period for the first renewal following reactivation.

303.2(5) It is the responsibility of each licensee to finance the cost of continuing education.

[**ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—303.3(147,272C) Standards.

303.3(1) *General criteria.* A continuing education program or activity that meets all of the following criteria is appropriate for continuing education credit if the continuing education program or activity:

a. Meets the definition of continuing education as defined in rule 645—303.1(147);

b. Is conducted by individuals who have specialized education, training and experience by reason of which said individuals should be considered qualified concerning the subject matter of the program. At the time of audit, the board may request the qualifications of presenters;

c. Fulfills state program goals, objectives, or both; and

d. Provides proof of attendance to licensees in attendance including:

(1) Date(s), location, course title, presenter(s);

(2) Number of program contact hours; and

(3) Certificate of completion or evidence of successful completion of the course provided by the course sponsor.

303.3(2) *Specific criteria.*

a. Subject matters that integrally relate to the practice of speech pathology or audiology or both that will be considered for approval are:

(1) Basic communication processes. Information (beyond the basic licensure requirements) applicable to the normal development and use of speech, language, and hearing, i.e., anatomic and physiologic bases for the normal development and use of speech, language, and hearing; physical bases and processes of the production and perception of speech, language, and hearing; linguistic and psycholinguistic variables related to normal development and use of speech, language, and hearing; and technological, biomedical, engineering, and instrumentation information which would enable expansion of knowledge in the basic communication processes.

(2) Professional areas. Information pertaining to disorders of speech, language, and hearing, i.e., various types of disorders of communication, their manifestations, classification and causes; evaluation skills, including procedures, techniques, and instrumentation for assessment; and management procedures and principles in habilitation and rehabilitation of communication disorders. The board shall accept dysphagia courses provided by qualified instructors.

(3) Related areas. Study pertaining to the understanding of human behavior, both normal and abnormal, as well as services available from related professions which apply to the contemporary practice of speech-language pathology/audiology, e.g., theories of learning and behavior; services available from related professions that also deal with persons who have disorders of communication; information from these professions about the sensory, physical, emotional, social or intellectual states of child or adult; professional ethics; clinical supervision; counseling; and interviewing.

Unacceptable subject matter includes personal development, human relations, collective bargaining, and tours. While desirable, these subjects are not applicable to licensees' skill, knowledge and competence as expressed in Iowa Code section 272C.2, paragraph *"g."* Such courses will receive no credit toward the minimum 30 hours required for license renewal.

b. A licensee may elect to take the Praxis Examination in speech pathology or audiology in lieu of earning continuing education credits. The licensee shall have the results of the examination sent to the board by the agency administering the examination.

c. A licensee may present professional programs which meet the criteria in this rule. Two hours of credit will be allowed for each hour of newly developed presentation material. A course schedule or brochure must be maintained for audit.

d. A combined total of six hours per biennium may be used for the following activities:

(1) Government regulations;

(2) CPR, child abuse and dependent adult abuse; and

(3) A maximum of two hours may be used for business-related topics.

e. An applicant shall provide official transcripts indicating successful completion of academic courses which apply to the field of speech pathology and audiology in order to receive the following continuing education credits:

1 academic semester hour = 15 continuing education hours of credit

1 academic trimester hour = 12 continuing education hours of credit

1 academic quarter hour = 10 continuing education hours of credit

f. A maximum of 16 hours of continuing education credit may be earned per biennium by participation in continuing education programs and activities which meet the criteria in this rule and which are completed through journal readings, teleconference or videoconference participation, and online program participation. In addition, such programs and activities must include a posttest that the participant must pass in order to receive continuing education credit.

[**ARC 1397C**, IAB 4/2/14, effective 5/7/14]

645—303.4(147,272C) Audit of continuing education report. Rescinded IAB 6/30/10, effective 8/4/10.

645—303.5(147,272C) Automatic exemption. Rescinded IAB 6/30/10, effective 8/4/10.

645—303.6(147,272C) Continuing education exemption for disability or illness. Rescinded IAB 6/30/10, effective 8/4/10.

645—303.7(147,272C) Grounds for disciplinary action. Rescinded IAB 6/30/10, effective 8/4/10.

645—303.8(147,272C) Continuing education exemption for inactive practitioners. Rescinded IAB 9/14/05, effective 10/19/05.

645—303.9(147,272C) Continuing education waiver for disability or illness. Rescinded IAB 9/14/05, effective 10/19/05.

645—303.10(147,272C) Reinstatement of inactive practitioners. Rescinded IAB 9/14/05, effective 10/19/05.

645—303.11(272C) Hearings. Rescinded IAB 9/14/05, effective 10/19/05.

These rules are intended to implement Iowa Code section 272C.2 and chapter 147.

[Filed 11/9/00, Notice 9/20/00—published 11/29/00, effective 1/3/01]
[Filed 8/30/01, Notice 5/30/01—published 9/19/01, effective 10/24/01]
[Filed 5/9/02, Notice 4/3/02—published 5/29/02, effective 7/3/02]
[Filed 8/14/03, Notice 5/28/03—published 9/3/03, effective 10/8/03]
[Filed 8/22/05, Notice 6/8/05—published 9/14/05, effective 10/19/05][◊]
[Filed 12/22/08, Notice 10/22/08—published 1/14/09, effective 2/18/09]
[Filed ARC 8872B (Notice ARC 8639B, IAB 4/7/10), IAB 6/30/10, effective 8/4/10]
[Filed ARC 1397C (Notice ARC 1314C, IAB 2/5/14), IAB 4/2/14, effective 5/7/14]

◊ Two or more ARCs

CHAPTER 4
PHARMACIST-INTERNS

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 3]

657—4.1(155A) Definitions.

"Board" means the Iowa board of pharmacy.

"Pharmacist-intern" or *"intern"* means a person enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board, who is registered with the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. "Pharmacist-intern" includes a graduate of an approved college of pharmacy, or a foreign graduate who has established educational equivalency pursuant to the requirements of rule 657—4.7(155A), who is registered with the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist in Iowa. "Pharmacist-intern" may include an individual participating in a residency or fellowship program in Iowa, whether or not the individual is licensed as a pharmacist in another state.

"Pharmacist preceptor" or *"preceptor"* means a pharmacist licensed to practice pharmacy whose license is current and in good standing. Preceptors shall meet the conditions and requirements of rule 657—4.9(155A). No pharmacist shall serve as a preceptor while the pharmacist's license to practice pharmacy is the subject of disciplinary sanction by a pharmacist licensing authority.

[**ARC 9784B**, IAB 10/5/11, effective 11/9/11; **ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.2(155A) Goal and objectives of internship.

4.2(1) *Goal.* The goal of internship is for the pharmacist-intern, over a period of time, to attain and build upon the knowledge, skills, responsibilities, and ability to safely, efficiently, and effectively practice pharmacy under the laws and rules of the state of Iowa.

4.2(2) *Objectives.* The objectives of internship are as follows:

a. Managing drug therapy to optimize patient outcomes. The pharmacist-intern shall evaluate the patient and patient information to determine the presence of a disease or medical condition, to determine the need for treatment or referral, and to identify patient-specific factors that affect health, pharmacotherapy, or disease management; ensure the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems; and monitor the patient and patient information and manage the drug regimen to promote health and ensure safe and effective pharmacotherapy.

b. Ensuring the safe and accurate preparation and dispensing of medications. The pharmacist-intern shall perform calculations required to compound, dispense, and administer medication; select and dispense medications; and prepare and compound extemporaneous preparations and sterile products.

c. Providing drug information and promoting public health. The pharmacist-intern shall access, evaluate, and apply information to promote optimal health care; educate patients and health care professionals regarding prescription medications, nonprescription medications, and medical devices; and educate patients and the public regarding wellness, disease states, and medical conditions.

d. Adhering to professional and ethical standards. The pharmacist-intern shall comply with professional, legal, moral, and ethical standards relating to the practice of pharmacy and the operation of the pharmacy.

e. Understanding the management of pharmacy operations. The pharmacist-intern shall develop a general understanding of the business procedures of a pharmacy and develop knowledge concerning the employment and supervision of pharmacy employees.

657—4.3(155A) 1500-hour requirements. Internship credit may be obtained only after internship registration with the board and commencement of the first professional year in a college of pharmacy. Internship shall consist of a minimum of 1500 hours, all of which may be a college-based clinical program approved or accepted by the board. Programs shall be structured to provide experience in community, institutional, and clinical pharmacy practices. A pharmacist-intern may acquire additional

hours under the supervision of one or more preceptors in a traditional licensed general or hospital pharmacy, at a rate of no more than 48 hours per week, where the goal and objectives of internship in rule 657—4.2(155A) apply. Credit toward any additional hours will be allowed, at a rate not to exceed 10 hours per week, for an internship served concurrent with academic training and outside a college-based clinical program. "Concurrent time" means internship experience acquired while the person is a full-time student carrying, in a given school term, at least 75 percent of the average number of credit hours per term needed to graduate and receive an entry-level degree in pharmacy. Recognized academic holiday periods, such as spring break and winter break, shall not be considered "concurrent time." The competencies in subrule 4.2(2) and the concurrent time limitations of this rule shall not apply to college-based clinical programs.
[**ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.4(155A) Iowa colleges of pharmacy clinical internship programs. The board shall periodically review the clinical component of internship programs of the colleges of pharmacy located in Iowa. The board reserves the right to set conditions relating to the approval of such programs.

657—4.5(155A) Out-of-state internship programs. Candidates enrolled in out-of-state colleges of pharmacy who complete the internship requirements of that state shall be deemed to have satisfied Iowa's internship requirements. Candidates shall submit documentation from the out-of-state internship program certifying completion of that state's requirements. Candidates enrolled in colleges of pharmacy located in states with no formal internship training program shall submit documentation from that state's board of pharmacy or college of pharmacy certifying that the candidate has completed all prelicensure training requirements.

657—4.6(155A) Registration, reporting, and authorized functions. Every person shall register with the board before beginning the person's internship experience, whether or not for the purpose of fulfilling the requirements of rule 657—4.3(155A). Registration is required of all students enrolled in Iowa colleges of pharmacy upon commencement of the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall annually certify to the board the names of students who are enrolled in the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall, within two weeks of any change, certify to the board the names of students who have withdrawn from the college of pharmacy.

4.6(1) *Application for registration—required information.* Application for registration as a pharmacist-intern shall be on forms provided by the board, and all requested information shall be provided on or with such application. The application shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number; and name and location of college of pharmacy and anticipated month and year of graduation. The college of pharmacy shall certify the applicant's eligibility to practice as a pharmacist-intern.

4.6(2) *Supervision and authorized functions.* A licensed pharmacist shall be on duty in the pharmacy and shall be responsible for the actions of a pharmacist-intern during all periods of internship training. At the discretion of the supervising pharmacist, the following judgmental functions, usually restricted to a pharmacist, may be delegated to pharmacist-interns registered by the board:

a. Verification of the accuracy, validity, and appropriateness of the filled prescription or medication order;

b. Review and assessment of patient records for purposes identified in rule 657—8.21(155A);

c. Patient counseling.

4.6(3) *Term of registration.* Registration shall remain in effect as long as the board is satisfied that the intern is pursuing a degree in pharmacy in good faith and with reasonable diligence. A pharmacist-intern may request that the intern's registration be extended beyond the automatic termination of the registration pursuant to the procedures and requirements of 657—Chapter 34. Except as provided by the definition of pharmacist-intern in rule 657—4.1(155A), registration shall automatically terminate upon the earliest of any of the following:

a. Licensure to practice pharmacy in any state;

b. Lapse in the pursuit of a degree in pharmacy; or

c. One year following graduation from the college of pharmacy.

4.6(4) *Identification, reports, and notifications.* Credit for internship time will not be granted unless registration and other required records or affidavits are completed.

a. The pharmacist-intern shall be so designated in all relationships with the public and health professionals. While on duty in the pharmacy, the intern shall wear visible to the public a name badge including the designation "pharmacist-intern" or "pharmacy student."

b. Registered interns shall notify the board office within ten days of a change of name or address.

c. Notarized affidavits of experience in non-college-sponsored programs shall be filed with the board office after the successful completion of the internship. These affidavits shall certify only the number of hours and dates of training obtained outside a college-based clinical program as provided in rule 657—4.3(155A). An individual registered as a pharmacist-intern while participating in an Iowa residency or fellowship program shall not be required to file affidavits of experience.

4.6(5) *No credit prior to registration.* Credit will not be given for internship experience obtained prior to the individual's registration as a pharmacist-intern. Credit for Iowa college-based clinical programs will not be granted unless registration is issued before the student begins the program.

4.6(6) *Nontraditional internship.* Internship training at any site which is not licensed as a general or hospital pharmacy is considered nontraditional internship.

a. *Application.* Prior to beginning a period of nontraditional internship, the intern shall submit a written application, on forms provided by the board, for approval of the objectives of the nontraditional internship. The application shall identify objectives consistent with the unique learning experiences of the intern and consistent with the goal and objectives of internship in rule 657—4.2(155A).

b. *Preceptor.* A preceptor supervising a pharmacist-intern in a nontraditional internship shall be a currently licensed pharmacist in the state where the internship is served, and the requirements of rule 657—4.9(155A) shall apply to all preceptors.

c. *Certification, not credit.* Hours obtained in nontraditional internship shall not be credited toward the total 1500 hours required pursuant to rule 657—4.3(155A) prior to licensure to practice pharmacy in Iowa. The board may, however, certify hours obtained in one or more approved nontraditional internships in recognition of the pharmacist-intern's training outside the scope of traditional pharmacy practice. Certification shall not be granted for experience obtained in a nontraditional internship unless the board, prior to the intern's beginning the period of internship, approved the objectives of the internship.

[**ARC 9784B**, IAB 10/5/11, effective 11/9/11; **ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.7(155A) Foreign pharmacy graduates. Foreign pharmacy graduates who are candidates for licensure in Iowa will be required to obtain a minimum of 1500 hours of internship in a licensed pharmacy or other board-approved location.

4.7(1) *Registration.* Candidates shall register with the board as provided in rule 657—4.6(155A). Internship credit will not be granted until the candidate has been issued an intern registration. Applications for registration shall be accompanied by certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) as provided in 657—subrule 2.10(1).

4.7(2) *Certification of hours.* Following completion of any period of internship, internship hours shall be certified to the board by submission of notarized affidavits of experience as provided in paragraph 4.6(4)*"c."*

4.7(3) *Credit for foreign pharmacy practice.* The board may grant credit to a foreign pharmacy graduate, based on the candidate's experience in the practice of pharmacy, for all or any portion of the required 1500 hours of internship training. The candidate shall provide detailed information regarding the candidate's experience in the practice of pharmacy. The board shall determine, on a case-by-case basis, whether and to what extent the candidate's experience meets the goals and objectives established in rule 657—4.2(155A).

[**ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.8(155A) Fees. The fee for registration as a pharmacist-intern is $30, plus applicable surcharge pursuant to 657—30.8(155A), which shall be payable with the application.

657—4.9(155A) Preceptor requirements.

4.9(1) *Licensed pharmacist.* A preceptor shall be a licensed pharmacist in good standing in the state where the internship is to be served pursuant to the definition of pharmacist preceptor in rule 657—4.1(155A).

4.9(2) *Affidavits.* A preceptor shall be responsible for completing the affidavit certifying the number of hours and the dates of each internship training period under the supervision of the preceptor for any period of internship completed outside a college-based clinical program.

4.9(3) *Number of interns.* A preceptor may supervise no more than two pharmacist-interns concurrently.

4.9(4) *Responsibility.* A preceptor shall be responsible for all functions performed by a pharmacist-intern.

[**ARC 1406C**, IAB 4/2/14, effective 5/7/14]

657—4.10(155A) Denial of pharmacist-intern registration. The board may deny an application for registration as a pharmacist-intern for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A or 205, or any rule of the board.

657—4.11(155A) Discipline of pharmacist-interns.

4.11(1) *Grounds for discipline.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205, or any rule of the board.

4.11(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacist-intern registration.

b. Suspension of a pharmacist-intern registration until further order of the board or for a specified period.

c. Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts.

d. Such other sanctions allowed by law as may be appropriate.

These rules are intended to implement Iowa Code section 155A.6.

[Filed 7/19/67; amended 2/13/73]
[Filed 11/24/76, Notice 10/20/76—published 12/15/76, effective 1/19/77]
[Filed 11/9/77, Notice 10/5/77—published 11/30/77, effective 1/4/78]
[Filed 10/20/78, Notice 8/9/78—published 11/15/78, effective 1/9/79]
[Filed 8/28/79, Notice 5/30/79—published 9/19/79, effective 10/24/79]
[Filed 9/10/82, Notice 6/9/82—published 9/29/82, effective 11/8/82]
[Filed 12/22/87, Notice 11/4/87—published 1/13/88, effective 2/17/88]
[Filed emergency 1/21/88—published 2/10/88, effective 1/22/88]
[Filed 11/17/88, Notice 8/24/88—published 12/14/88, effective 1/18/89]
[Filed emergency 5/16/89—published 6/14/89, effective 5/17/89]
[Filed 8/31/90, Notice 6/13/90—published 9/19/90, effective 10/24/90]
[Filed 4/26/91, Notice 2/20/91—published 5/15/91, effective 6/19/91]
[Filed 12/10/96, Notice 8/28/96—published 1/1/97, effective 2/5/97]
[Filed 2/27/97, Notice 1/1/97—published 3/26/97, effective 4/30/97]
[Filed 4/22/99, Notice 3/10/99—published 5/19/99, effective 6/23/99]
[Filed 9/8/99, Notice 6/2/99—published 10/6/99, effective 11/10/99]
[Filed 2/18/00, Notice 12/15/99—published 3/22/00, effective 4/26/00]
[Filed 2/7/01, Notice 10/18/00—published 3/7/01, effective 4/11/01]

[Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02]
[Filed 12/22/04, Notice 11/10/04—published 1/19/05, effective 2/23/05]
[Filed 3/22/06, Notice 1/18/06—published 4/12/06, effective 5/17/06]
[Filed ARC 9784B (Notice ARC 9555B, IAB 6/15/11), IAB 10/5/11, effective 11/9/11]
[Filed ARC 1406C (Notice ARC 1237C, IAB 12/11/13), IAB 4/2/14, effective 5/7/14]

CHAPTER 10
CONTROLLED SUBSTANCES
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 8]

657—10.1(124) Who shall register. Any person or business located in Iowa that manufactures, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, or that proposes to engage in such activities with controlled substances in the state, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.6(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business.

Manufacturers, distributors, reverse distributors, importers and exporters, individual practitioners (M.D., D.O., D.D.S., D.V.M., D.P.M., O.D., P.A., resident physician, advanced registered nurse practitioner), pharmacies, hospitals and animal shelters, care facilities, researchers and dog trainers, analytical laboratories, and teaching institutions shall register on forms provided by the board office. To be eligible to register, individual practitioners must hold a current, active license in good standing, issued by the appropriate Iowa professional licensing board, to practice their profession in Iowa.

657—10.2(124) Application forms. Application forms may be obtained from the Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Forms are also available on the board's Web site, www.state.ia.us/ibpe. Registration renewal forms will be mailed to each registrant approximately 60 days before the expiration date of the registration. A registrant who has not received a renewal form 45 days before the expiration date of the registration is responsible for contacting the board to request an application.

10.2(1) *Signature requirements.* Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

a. If the applicant is an individual practitioner, the practitioner shall sign the application and supporting documents.

b. If the applicant is a business, the application and supporting documents shall be signed by the person ultimately responsible for the security and maintenance of controlled substances at the registered location.

10.2(2) *Submission of multiple applications.* Any person or business required to obtain more than one registration may submit all applications in one package. Each application shall be complete and shall not refer to any accompanying application or any attachment to an accompanying application for required information.

657—10.3(124) Registration and renewal. For each registration or timely renewal of a registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities, or conduct chemical analysis with controlled substances listed in Schedules I through V of Iowa Code chapter 124, registrants shall pay a biennial fee of $90.

10.3(1) *Time and method of payment.* Registration and renewal fees shall be paid at the time the application for registration or renewal is submitted. Payment should be made in the form of a personal, certified, or cashier's check or a money order made payable to the Iowa Board of Pharmacy. Payments made in the form of foreign currency or third-party endorsed checks will not be accepted.

10.3(2) *Late renewal.* Any registered person or business may apply, on forms provided by the board office, for registration renewal not more than 60 days prior to the expiration of the registration. Failure to renew a registration prior to the first day of the month following expiration shall require payment of the renewal fee and a penalty fee of $90. Payment shall be made as specified in subrule 10.3(1).
[**ARC 0504C**, IAB 12/12/12, effective 1/16/13]

657—10.4(124) Exemptions—registration fee. The registration fee is waived for federal, state, and local law enforcement agencies and for the following federal and state institutions: hospitals, health care

or teaching institutions, and analytical laboratories authorized to possess, manufacture, distribute, and dispense controlled substances in the course of official duties.

10.4(1) *Law enforcement officials.* In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall maintain a registration to conduct chemical analysis. Such laboratories shall be exempt from payment of a fee for registration.

10.4(2) *Registration and duties not exempt.* Exemption from payment of a registration or registration renewal fee as provided in this rule does not relieve the agency or institution of registration or of any other requirements or duties prescribed by law.

657—10.5(124) Separate registration for independent activities; coincident activities. The following activities are deemed to be independent of each other and shall require separate registration. Any person or business engaged in more than one of these activities shall be required to separately register for each independent activity, provided, however, that registration in an independent activity shall authorize the registrant to engage in activities identified coincident with that independent activity.

10.5(1) *Manufacturing controlled substances.* A person or business registered to manufacture controlled substances in Schedules I through V may distribute any substances for which registration to manufacture was issued. A person or business registered to manufacture controlled substances in Schedules II through V may conduct chemical analysis and preclinical research, including quality control analysis, with any substances listed in those schedules for which the person or business is registered to manufacture.

10.5(2) *Distributing controlled substances.* This independent activity includes the delivery, other than by administering or dispensing, of controlled substances listed in Schedules I through V. No coincident activities are authorized.

10.5(3) *Dispensing or instructing with controlled substances.* This independent activity includes, but is not limited to, prescribing by individual practitioners, dispensing by pharmacies and hospitals, and conducting instructional activities with controlled substances listed in Schedules II through V. A person or business registered for this independent activity may conduct research and instructional activities with those substances for which the person or business is registered to the extent authorized under state law.

10.5(4) *Conducting research with controlled substances listed in Schedule I.* A researcher may manufacture or import the substances for which registration was issued provided that such manufacture or import is permitted under the federal Drug Enforcement Administration (DEA) registration. A researcher may distribute the substances for which registration was issued to persons or businesses registered or authorized to conduct research with that class of substances or registered or authorized to conduct chemical analysis with controlled substances.

10.5(5) *Conducting research with controlled substances listed in Schedules II through V.* A researcher may conduct chemical analysis with controlled substances in those schedules for which registration was issued, may manufacture such substances if and to the extent such manufacture is permitted under the federal DEA registration, and may import such substances for research purposes. A researcher may distribute controlled substances in those schedules for which registration was issued to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempt from registration pursuant to Iowa Code subsection 124.302(3), and may conduct instructional activities with controlled substances.

10.5(6) *Conducting chemical analysis with controlled substances.* A person or business registered to conduct chemical analysis with controlled substances listed in Schedules I through V may manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempt from registration pursuant to Iowa Code subsection 124.302(3); may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

10.5(7) *Importing or exporting controlled substances.* A person or business registered to import controlled substances listed in Schedules I through V may distribute any substances for which such registration was issued.

657—10.6(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, or dispensed unless the person or business is exempt from registration pursuant to Iowa Code subsection 124.302(3) or this rule.

10.6(1) *Warehouse.* A warehouse where controlled substances are stored by or on behalf of a registered person or business shall be exempt from registration except as follows:

a. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to registered locations other than the registered location from which the substances were delivered to the warehouse.

b. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to persons exempt from registration pursuant to Iowa Code subsection 124.302(3).

10.6(2) *Sales office.* An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised shall be exempt from registration. Such office shall not contain controlled substances, except substances used for display purposes or for lawful distribution as samples, and shall not serve as a distribution point for filling sales orders.

10.6(3) *Prescriber's office.* An office used by a prescriber who is registered at another location and where controlled substances are prescribed but where no supplies of controlled substances are maintained shall be exempt from registration. However, a prescriber who practices at more than one office location where controlled substances are administered or otherwise dispensed as a regular part of the prescriber's practice shall register at each location wherein the prescriber maintains supplies of controlled substances.

10.6(4) *Prescriber in hospital.* A prescriber who is registered at another location and who treats patients and may order the administration of controlled substances in a hospital other than the prescriber's registered practice location shall not be required to obtain a separate registration for the hospital.

10.6(5) *Affiliated interns, residents, or foreign physicians.* An individual practitioner who is an intern, resident, or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom the registrant is employed provided that:

a. The hospital or other institution by which the individual practitioner is employed has determined that the practitioner is permitted to dispense or prescribe drugs by the appropriate licensing board;

b. Such individual practitioner is acting only in the scope of employment in the hospital or institution;

c. The hospital or other institution authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital registration and designates a specific internal code number, letters, or combination thereof which shall be appended to the institution's DEA registration number, preceded by a hyphen (e.g., AP1234567-10 or AP1234567-12); and

d. The hospital or institution maintains a current list of internal code numbers identifying the corresponding individual practitioner, available for the purpose of verifying the authority of the prescribing individual practitioner.

657—10.7 to **10.9** Reserved.

657—10.10(124,147,155A) Inspection. The board may inspect, or cause to be inspected, the establishment of an applicant or registrant. The board shall review the application for registration and other information regarding an applicant or registrant in order to determine whether the applicant or registrant has met the applicable standards of Iowa Code chapter 124 and these rules.

657—10.11(124) Modification or termination of registration. A registered individual or business may apply to modify a current registration as provided by this rule.

10.11(1) *Change of substances authorized.* Any registrant may apply to modify the substances authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, telephone number, registration number, and the substances or schedules to be added to or removed from the registration and shall be signed by the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

10.11(2) *Change of address of registered location.*

a. Individual practitioner, researcher, analytical laboratory, or teaching institution. An entity registered under these classifications may apply to change the address of the registered location by submitting a written request to the board. The request shall include the registrant's name, current address, new address, telephone number, effective date of the address change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

b. Pharmacy, hospital, care facility, manufacturer, distributor, importer, or exporter. An entity registered under these classifications shall apply to change the address of the registered location by submitting a completed application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 657—10.3(124) shall accompany each completed application.

10.11(3) *Change of registrant's name.*

a. Individual practitioner, researcher, analytical laboratory, or teaching institution. An entity registered under these classifications may apply to change the registrant's name by submitting a written request to the board. The request shall include the registrant's current name, the new name, address, telephone number, effective date of the name change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification. Change of name, as used in this paragraph, refers to a change of the legal name of the registrant and does not authorize the transfer of a registration issued to an individual practitioner or researcher to another individual practitioner or researcher.

b. Pharmacy, hospital, care facility, manufacturer, distributor, importer, or exporter. An entity registered under these classifications shall apply to change the registrant name by submitting a completed application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 657—10.3(124) shall accompany each completed application.

10.11(4) *Change of ownership of registered business entity.* A change of immediate ownership of a pharmacy, hospital, care facility, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the completion of an application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 10.3(124) shall accompany each completed application.

10.11(5) *Change of responsible individual.* Any registrant, except an individual practitioner, a researcher, a hospital, or a pharmacy, may apply to change the responsible individual authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, telephone number, the name and title of the current responsible individual and of the new responsible individual, the effective date of the change, and the registration number, and shall be signed by the new responsible individual. No fee shall be required for the modification.

a. Individual practitioners and researchers. Responsibility under a registration issued to an individual practitioner or researcher shall remain with the named individual practitioner or researcher. The responsible individual under such registration may not be changed.

b. Pharmacies and hospitals. The responsible pharmacist may execute a power of attorney for DEA order forms to change responsibility under the registration issued to the pharmacy or hospital. The power of attorney shall include the name, address, DEA registration number, and Iowa uniform controlled substances Act (CSA) registration number of the registrant. The power of attorney shall

identify the current and new responsible individuals and shall authorize the new responsible individual to execute applications and official DEA order forms to requisition Schedule II controlled substances. The power of attorney shall be signed by both individuals, shall be witnessed by two adults, and shall be maintained by the registrant and available for inspection or copying by representatives of the board or other state or federal authorities.

10.11(6) *Termination of registration.* A registration issued to an individual shall terminate upon the death of the individual. A registration issued to an individual or business shall terminate when the registered individual or business ceases legal existence, discontinues business, or discontinues professional practice.

657—10.12(124) Denial, modification, suspension, or revocation of registration.

10.12(1) *Grounds for suspension or revocation.* The board may suspend or revoke any registration upon a finding that the registrant:

a. Has furnished false or fraudulent material information in any application filed under this chapter;

b. Has had the registrant's federal registration to manufacture, distribute, or dispense controlled substances suspended or revoked;

c. Has been convicted of a public offense under any state or federal law relating to any controlled substance. For the purpose of this rule only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant's appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even though entry of the judgment or sentence has been withheld and the individual has been placed on probation;

d. Has committed such acts as would render the registrant's registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section; or

e. Has been subject to discipline by the registrant's respective professional licensing board and the discipline revokes, suspends, or modifies the registrant's authority regarding controlled substances (including, but not limited to, limiting or prohibiting the registrant from prescribing or handling controlled substances). A certified copy of the record of licensee discipline or a copy of the licensee's surrender of the professional license shall be conclusive evidence.

10.12(2) *Limited suspension or revocation.* If the board finds grounds to suspend or revoke a registration, the board may limit revocation or suspension of the registration to the particular controlled substance with respect to which the grounds for revocation or suspension exist. If the revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by revocation or suspension; no fee shall be required for the new certificate of registration. The registrant shall deliver the old certificate of registration to the board.

10.12(3) *Denial of registration or registration renewal.* If upon examination of an application for registration or registration renewal, including any other information the board has or receives regarding the applicant, the board determines that the issuance of the registration would be inconsistent with the public interest, the board shall serve upon the applicant an order to show cause why the registration should not be denied.

10.12(4) *Considerations in denial of registration.* In determining the public interest, the board shall consider all of the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

b. Compliance with applicable state and local law.

c. Any convictions of the applicant under any federal and state laws relating to any controlled substance.

d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion.

e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.

f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.

g. Any other factors relevant to and consistent with the public health and safety.

10.12(5) *Order to show cause.* Before denying, modifying, suspending, or revoking a registration, the board shall serve upon the applicant or registrant an order to show cause why the registration should not be denied, modified, revoked, or suspended. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before an administrative law judge or the board at a time and place not less than 30 days after the date of service of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted. If the order to show cause involves the possible denial of registration renewal, the order shall be served not later than 30 days before the expiration of the registration. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing unless the board issues an order of immediate suspension pursuant to subrule 10.12(9).

10.12(6) *Hearing requested.* If an applicant or registrant who has received an order to show cause desires a hearing on the matter, the applicant or registrant shall file a request for a hearing within 30 days after the date of service of the order to show cause. If a hearing is requested, the board shall hold a hearing pursuant to 657—Chapter 35 at the time and place stated in the order and without regard to any criminal prosecution or other proceeding. Unless otherwise ordered by the board, an administrative law judge employed by the department of inspections and appeals shall be assigned to preside over the case and to render a proposed decision for the board's consideration.

10.12(7) *Waiver of hearing.* If an applicant or registrant entitled to a hearing on an order to show cause fails to file a request for hearing, or if the applicant or registrant requests a hearing but fails to appear at the hearing, the applicant or registrant shall be deemed to have waived the opportunity for a hearing unless the applicant or registrant shows good cause for such failure.

10.12(8) *Final board order when hearing waived.* If an applicant or registrant entitled to a hearing waives or is deemed to have waived the opportunity for a hearing, the executive director of the board may cancel the hearing and issue, on behalf of the board, the board's final order on the order to show cause.

10.12(9) *Order of immediate suspension.* The board may suspend any registration simultaneously with the service upon the registrant of an order to show cause why such registration should not be revoked or suspended if it finds there is an imminent danger to the public health or safety that warrants such action. If the board suspends a registration simultaneously with the service of the order to show cause upon the registrant, it shall serve an order of immediate suspension containing a statement of its findings regarding the danger to public health or safety upon the registrant with the order to show cause. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, under the provisions of the Iowa administrative procedure Act, unless sooner withdrawn by the board or dissolved by the order of the district court or an appellate court.

10.12(10) *Disposition of controlled substances.* If the board suspends or revokes a registration, the registrant shall promptly return the certificate of registration to the board. Also, upon service of the order of the board suspending or revoking the registration, the registrant shall deliver all affected controlled substances in the registrant's possession to the board or authorized agent of the board. Upon receiving the affected controlled substances from the registrant, the board or its authorized agent shall place all such substances under seal and retain the sealed controlled substances pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order's becoming final, all such controlled substances may be forfeited to the state.

10.12(11) *Notifications.* The board shall promptly notify the DEA and the Iowa department of public safety of all orders suspending or revoking registration and all forfeitures of controlled substances.

657—10.13 and **10.14** Reserved.

657—10.15(124,155A) Security requirements. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a person has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion.

10.15(1) *Physical security.* Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet. However, pharmacies and hospitals may disperse these substances throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances.

10.15(2) *Factors in evaluating physical security systems.* In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors it deems relevant to the need for strict compliance with the requirements of this rule:

a. The type of activity conducted;

b. The type, form, and quantity of controlled substances handled;

c. The location of the premises and the relationship such location bears to security needs;

d. The type of building construction comprising the facility and the general characteristics of the building or buildings;

e. The type of vault, safe, and secure enclosures available;

f. The type of closures on vaults, safes, and secure enclosures;

g. The adequacy of key control systems or combination lock control systems;

h. The adequacy of electric detection and alarm systems, if any;

i. The adequacy of supervision over employees having access to controlled substances, to storage areas, or to manufacturing areas;

j. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

k. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

l. The availability of local police protection or of the registrant's or applicant's security personnel; and

m. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.

10.15(3) *Manufacturing and compounding storage areas.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored pursuant to federal laws and regulations.

657—10.16(124) Report of theft or loss. A registrant shall report in writing, on forms provided by the board, any theft or significant loss of any controlled substance when the loss is attributable to other than inadvertent error. The report shall be submitted to the board office within two weeks of the discovery of the theft or loss. Thefts shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action is taken against them. A copy of the report shall be maintained in the files of the registrant, and the board will provide a copy of the report to the DEA. In addition to this required report, DEA requires the registrant to deliver notice, immediately

upon discovery of a theft or significant loss of controlled substances, to the nearest DEA field office via telephone, facsimile, or a brief written message explaining the circumstances.

657—10.17(124) Accountability of stock supply. An individual who administers a controlled substance from a non-patient-specific, stock supply in an institutional setting shall personally document on a separate readily retrievable record system each dose administered, wasted, or returned to the pharmacy. Such documentation shall not be delegated to another individual. Wastage documentation shall include the signature or unique electronic signature or identification of a witnessing licensed health care practitioner.

Distribution records for non-patient-specific, floor-stocked controlled substances shall bear the following information:

1. Patient's name;
2. Prescriber who ordered drug;
3. Name of drug, dosage form, and strength;
4. Time and date of administration to patient and quantity administered;
5. Signature or unique electronic signature of individual administering controlled substance;
6. Returns to the pharmacy;
7. Waste, which is required to be witnessed and cosigned by another licensed health care practitioner.

[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—10.18(124) Disposal. Any persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of such drugs pursuant to the procedures and requirements of this rule. Disposal records shall be maintained in the files of the registrant.

10.18(1) *Registrant stock supply.* Pharmacy personnel, registrants, and registrant staff shall remove from current inventory and dispose of controlled substances by one of the following procedures.

a. The responsible individual shall utilize the services of a DEA-registered and Iowa-licensed disposal firm.

b. The board may authorize and instruct the registrant to dispose of the controlled substances in one of the following manners:

(1) By delivery to an agent of the board or to the board office;

(2) By destruction of the drugs in the presence of a board officer, agent, inspector, or other authorized individual; or

(3) By such other means as the board may determine to ensure that drugs do not become available to unauthorized persons.

10.18(2) *Waste.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient from a registrant's stock or emergency supply or resulting from drug compounding operations may be destroyed or otherwise disposed of by the registrant or a pharmacist in witness of one other licensed health care provider or a registered pharmacy technician 18 years of age or older pursuant to this subrule. A written record of the wastage shall be made and maintained by the registrant for a minimum of two years following the destruction or other disposal. The record shall include the signatures of the individual destroying or otherwise disposing of the waste controlled substance and of the witnessing licensed health care provider or registered pharmacy technician and shall identify the following:

a. The controlled substance wasted;

b. The date of destruction or other disposition;

c. The quantity or estimated quantity of the wasted controlled substance;

d. The source of the controlled substance, including identification of the patient to whom the substance was administered or the drug compounding process utilizing the controlled substance; and

e. The reason for the waste.

10.18(3) *Previously dispensed controlled substances.* Controlled substances dispensed to or for a patient and subsequently requiring destruction due to discontinuance of the drug, death of the patient, or other reasons necessitating destruction may be destroyed or otherwise disposed of by a pharmacist in witness of one other responsible adult pursuant to this subrule. All licenses and registrations issued to the pharmacy, the pharmacist, and any individual witnessing the destruction or other disposition shall not be subject to sanctions relating to controlled substances at the time of the destruction or disposition. The individuals involved in the destruction or other disposition shall not have been subject to any criminal, civil, or administrative action relating to violations of controlled substances laws, rules, or regulations within the past five years. The pharmacist in charge shall be responsible for designating pharmacists authorized to participate in the destruction or other disposition pursuant to this subrule. The authorized pharmacist shall prepare and maintain in the pharmacy a readily retrievable record of the destruction or other disposition, which shall be clearly marked to indicate the destruction or other disposition of noninventory or patient drugs. The record shall include, at a minimum, the following:

a. The source of the controlled substance (patient identifier or administering practitioner, if applicable, prescription number or other unique identification number, and date of return);

b. The name, strength, and dosage form of the substance;

c. The quantity returned and destroyed or otherwise disposed of;

d. The date the substance is destroyed or otherwise disposed of;

e. The signatures or other unique identification of the pharmacist and the witness;

f. The name and address of the dispensing pharmacy or practitioner if the controlled substance was not dispensed by the pharmacy completing the destruction.

[**ARC 0749C**, IAB 5/29/13, effective 7/3/13]

657—10.19 and **10.20** Reserved.

657—10.21(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and signed on, the day issued. Controlled substances prescriptions shall be valid for six months following date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled.

10.21(1) *Form of prescription.* All prescriptions shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and DEA registration number of the prescriber. All prescriptions issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber's written or electronic signature. When an oral order is not permitted, or when a prescriber is unable to prepare and transmit an electronic prescription in compliance with DEA requirements for electronic prescriptions, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. If the prescriber utilizes an electronic prescription application that meets DEA requirements for electronic prescriptions, the prescriber may electronically prepare and transmit a prescription for a controlled substance to a pharmacy that utilizes a pharmacy prescription application that meets DEA requirements for electronic prescriptions. A prescriber's agent may prepare a prescription for the review, authorization, and manual or electronic signature of the prescriber but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription. An electronic prescription for a controlled substance shall not be transmitted to a pharmacy except by the prescriber in compliance with DEA regulations. A prescriber shall securely maintain the unique authentication credentials issued to the prescriber for utilization of the electronic prescription application and authentication of the prescriber's electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other prescriber, agent, or individual. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

10.21(2) *Verification by pharmacist.* The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in each case when a written or oral prescription

for a Schedule II controlled substance is presented for filling and neither the prescribing individual practitioner issuing the prescription nor the patient or patient's agent is known to the pharmacist. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in any case when the pharmacist questions the validity of, including the legitimate medical purpose for, the prescription. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist's name or unique identifier.

10.21(3) *Intern, resident, foreign physician.* An intern, resident, or foreign physician exempt from registration pursuant to subrule 10.6(5) shall include on all prescriptions issued the hospital's registration number and the special internal code number assigned by the hospital in lieu of the prescriber's registration number required by this rule. Each prescription shall include the stamped or legibly printed name of the intern, resident, or foreign physician as well as the prescriber's signature.

10.21(4) *Valid prescriber/patient relationship.* Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or to oversee the patient's use of the controlled substance, a prescription shall lose its validity. A prescriber/patient relationship shall be deemed broken when the prescriber dies, retires, or moves out of the local service area or when the prescriber's authority to prescribe is suspended, revoked, or otherwise modified to exclude authority for the schedule in which the prescribed substance is listed. The pharmacist, upon becoming aware of the situation, shall cancel the prescription and any remaining refills. However, the pharmacist shall exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new prescription can be issued.

10.21(5) *Schedule II prescriptions.* With appropriate verification, a pharmacist may add information provided by the patient or patient's agent, such as the patient's address, to a Schedule II controlled substance prescription. A pharmacist shall never change the patient's name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber. After consultation with the prescriber or the prescriber's agent and documentation of such consultation, a pharmacist may change or add the following information on a Schedule II controlled substance prescription:

a. The drug strength;

b. The dosage form;

c. The drug quantity;

d. The directions for use;

e. The date the prescription was issued; and

f. The prescriber's address or DEA registration number.

[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—10.22(124) Schedule II emergency prescriptions.

10.22(1) *Emergency situation defined.* For the purposes of authorizing an oral or facsimile transmission of a prescription for a Schedule II controlled substance listed in Iowa Code section 124.206, the term "emergency situation" means those situations in which the prescribing practitioner determines that all of the following apply:

a. Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

b. No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance.

c. It is not reasonably possible for the prescribing practitioner to provide a manually signed written prescription to be presented to the pharmacy before the pharmacy dispenses the controlled substance or the prescribing practitioner is unable to provide a DEA-compliant electronic prescription to the pharmacy before the pharmacy dispenses the controlled substance.

10.22(2) *Requirements of emergency prescription.* In the case of an emergency situation as defined in subrule 10.22(1), a pharmacist may dispense a controlled substance listed in Schedule II pursuant to a facsimile transmission or upon receiving oral authorization of a prescribing individual practitioner provided that:

a. The quantity prescribed and dispensed is limited to the smallest available quantity to meet the needs of the patient during the emergency period. Dispensing beyond the emergency period requires a written prescription manually signed by the prescribing individual practitioner or a DEA-compliant electronic prescription.

b. If the pharmacist does not know the prescribing individual practitioner, the pharmacist shall make a reasonable effort to determine that the authorization came from an authorized prescriber. The pharmacist shall record the manner by which the authorization was verified and include the pharmacist's name or unique identification.

c. The pharmacist shall prepare a temporary written record of the emergency prescription. The temporary written record shall consist of a hard copy of the facsimile transmission or a written record of the oral transmission authorizing the emergency dispensing. A written record is not required to consist of a handwritten record and may be a printed facsimile or a print of a computer-generated record of the prescription if the printed record includes all of the required elements for the prescription. If the emergency prescription is transmitted by the practitioner's agent, the record shall include the first and last names and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via facsimile transmission, the means of transmission shall not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the written prescription, and the hard-copy record of the facsimile transmission shall not be obscured or rendered illegible due to such security features.

e. Within seven days after authorizing an emergency prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of 657—10.21(124,126,155A), the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the emergency order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. The written prescription shall be attached to and maintained with the temporary written record prepared pursuant to paragraph *"c."*

f. The pharmacist shall notify the board and the DEA if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to so notify the board and the DEA, or failure of the prescribing individual to deliver the required written prescription as herein required, shall void the authority conferred by this subrule.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 9410B**, IAB 3/9/11, effective 4/13/11; **ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—10.23(124) Schedule II prescriptions—partial filling. The partial filling of a prescription for a controlled substance listed in Schedule II is permitted as provided in this rule.

10.23(1) *Insufficient supply on hand.* If the pharmacist is unable to supply the full quantity called for in a prescription and makes a notation of the quantity supplied on the prescription record, a partial fill of the prescription is permitted. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescriber. No further quantity may be supplied beyond 72 hours without a new prescription.

10.23(2) *Long-term care or terminally ill patient.* A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units as provided by this subrule.

a. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

b. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient." For each partial filling, the dispensing pharmacist shall record on the back of the

prescription, or on another appropriate uniformly maintained and readily retrievable record, the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

c. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

d. Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to rule 657—21.4(124,155A).

657—10.24(124) Schedule II medication order. Schedule II controlled substances may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.18(124,155A), as applicable.

657—10.25(124) Schedule II—issuing multiple prescriptions. An individual prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance pursuant to the provisions and limitations of this rule.

10.25(1) *Refills prohibited.* The issuance of refills for a Schedule II controlled substance is prohibited. The use of multiple prescriptions for the dispensing of Schedule II controlled substances, pursuant to this rule, ensures that the prescriptions are treated as separate dispensing authorizations and not as refills of an original prescription.

10.25(2) *Legitimate medical purpose.* Each separate prescription issued pursuant to this rule shall be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice.

10.25(3) *Dates and instructions.* Each prescription issued pursuant to this rule shall be dated as of and manually signed by the prescriber on the day the prescription is issued. Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.

10.25(4) *Authorized fill date unalterable.* Regardless of the provisions of subrule 10.21(5), when a prescription contains instructions from the prescriber indicating that the prescription shall not be filled before a certain date, a pharmacist shall not fill the prescription before that date. The pharmacist shall not contact the prescriber for verbal authorization to fill the prescription before the fill date originally indicated by the prescriber pursuant to this rule.

10.25(5) *Number of prescriptions and authorized quantity.* An individual prescriber may issue for a patient as many separate prescriptions, to be filled sequentially pursuant to this rule, as the prescriber deems necessary to provide the patient with adequate medical care. The cumulative effect of the filling of each of these separate prescriptions shall result in the receipt by the patient of a quantity of the Schedule II controlled substance not exceeding a 90-day supply.

10.25(6) *Prescriber's discretion.* Nothing in this rule shall be construed as requiring or encouraging an individual prescriber to issue multiple prescriptions pursuant to this rule or to see the prescriber's patients only once every 90 days when prescribing Schedule II controlled substances. An individual prescriber shall determine, based on sound medical judgment and in accordance with established medical standards, how often to see patients and whether it is appropriate to issue multiple prescriptions pursuant to this rule.

[**ARC 8172B**, IAB 9/23/09, effective 10/28/09]

657—10.26 Reserved.

657—10.27(124,155A) Facsimile transmission of a controlled substance prescription. With the exception of an authorization for emergency dispensing as provided in rule 657—10.22(124), a prescription for a controlled substance may be transmitted via facsimile from a prescriber to a pharmacy as provided in rule 657—21.9(124,155A).

10.27(1) *Schedule II prescription.* A prescription for a Schedule II controlled substance may be transmitted via facsimile to the pharmacy only as provided in rules 657—21.12(124,155A) to 657—21.16(124,155A).

10.27(2) *Schedule III, IV, or V prescription.* A prescription for a Schedule III, IV, or V controlled substance may be transmitted via facsimile to the pharmacy only as provided in rule 657—21.9(124,155A).

[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

657—10.28(124,155A) Schedule III, IV, or V refills. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which it was issued nor be refilled more than five times.

10.28(1) *Record.* Each filling and refilling of a prescription shall be entered on the prescription or on another uniformly maintained and readily retrievable record.

a. The following information shall be retrievable by the prescription number: the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, the unique identification of the dispensing pharmacist for each refill, and the total number of refills authorized for that prescription.

b. If the pharmacist merely initials or affixes the pharmacist's unique identifier and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

10.28(2) *Oral refill authorization.* The prescribing practitioner may authorize additional refills of Schedule III, IV, or V controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

a. The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issuance of the original prescription.

b. The pharmacist who obtains the oral authorization records from the prescriber who issued the original prescription records on or with the original prescription the date, the quantity of each refill, the number of additional refills authorized, and the pharmacist's unique identification.

c. The quantity of each additional refill is equal to or less than the quantity authorized for the initial filling of the original prescription.

d. The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

10.28(3) *Automated data processing record system.* An automated data processing record system may be used for the storage and retrieval of Schedule III, IV, and V controlled substance prescription fill and refill information subject to the conditions and requirements of rules 657—21.4(124,155A) and 657—21.5(124,155A).

657—10.29(124,155A) Schedule III, IV, or V partial fills. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that each partial fill is recorded in the same manner as a refill. The total quantity dispensed in all partial fills shall not exceed the total quantity prescribed. No dispensing shall occur later than six months after the date on which the prescription was issued.

657—10.30(124,155A) Schedule III, IV, and V medication order. A Schedule III, IV, or V controlled substance may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.

657—10.31(124,155A) Dispensing Schedule V controlled substances without a prescription. A controlled substance listed in Schedule V, which substance is not a prescription drug as determined under the federal Food, Drug and Cosmetic Act, and excepting products containing ephedrine, pseudoephedrine, or phenylpropanolamine, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.31(1) *Who may dispense.* Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit,

after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.31(2) *Frequency and quantity.* Dispensing at retail to the same purchaser in any 48-hour period shall be limited to no more than one of the following quantities of a Schedule V controlled substance:

a. 240 cc (8 ounces) of any controlled substance containing opium.

b. 120 cc (4 ounces) of any other controlled substance.

c. 48 dosage units of any controlled substance containing opium.

d. 24 dosage units of any other controlled substance.

10.31(3) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.31(4) *Identification.* The pharmacist shall require every purchaser under this rule not known by the pharmacist to present a government-issued photo identification, including proof of age when appropriate.

10.31(5) *Record.* A bound record book (i.e., with pages sewn or glued to the spine) for dispensing of Schedule V controlled substances pursuant to this rule shall be maintained by the pharmacist. The book shall contain the name and address of each purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the substance to the purchaser.

10.31(6) *Prescription not required under other laws.* No other federal or state law or regulation requires a prescription prior to distributing or dispensing a Schedule V controlled substance.

657—10.32(124,155A) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription. A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.32(1) *Who may dispense.* Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit, after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.32(2) *Packaging of nonliquid forms.* A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.32(3) *Frequency and quantity.* Dispensing at retail to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of ephedrine, pseudoephedrine, or phenylpropanolamine; dispensing at retail to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.32(4) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.32(5) *Identification.* The pharmacist shall require every purchaser under this rule to present a current government-issued photo identification, including proof of age when appropriate. The pharmacist shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.32(6) *Record.* Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor's office of drug control policy pursuant to 657—Chapter 100. If the real-time electronic repository is unavailable for use, the purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).

a. *Alternate record contents.* The alternate record shall contain the following:

(1) The name, address, and signature of the purchaser.

(2) The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

(3) The date and time of the purchase.

(4) The name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the product.

b. Alternate record format. The record shall be maintained using one of the following options:

(1) A hard-copy record.

(2) A record in the pharmacy's electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.

(3) A record in an electronic data collection system that captures each of the data elements required by this subrule and that is capable of producing a hard-copy printout of a record.

c. PTS records retrieval. Pursuant to 657—subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

10.32(7) *Notice required.* The pharmacy shall ensure that the following notice is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products and that the notice is displayed with or on the electronic signature device or is displayed in the dispensing area and visible to the public:

"WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both."

[**ARC 8892B**, IAB 6/30/10, effective 9/1/10]

657—10.33(124,155A) Schedule II perpetual inventory in pharmacy. Each pharmacy located in Iowa that dispenses Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained by the pharmacy and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

10.33(1) *Record format.* The perpetual inventory record may be maintained in a manual or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed.

10.33(2) *Information included.* The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by national drug code (NDC) number. The record shall be updated to identify each prescription filled and each shipment received. The record shall also include incident reports and reconciliation records pursuant to subrules 10.33(3) and 10.33(4).

10.33(3) *Changes to a record.* If a perpetual inventory record is able to be changed, the individual making a change to the record shall complete an incident report documenting the change. The incident report shall identify the specific information that was changed including the information before and after the change, shall identify the individual making the change, and shall include the date and the reason the record was changed. If the electronic record system documents within the perpetual inventory record all of the information that must be included in an incident report, a separate report is not required.

10.33(4) *Reconciliation.* The pharmacist in charge shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the pharmacist in charge shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 657—10.16(124) and to the DEA pursuant to federal DEA regulations. Periodic reconciliation records shall be maintained and

available for review and copying by the board or agents of the board for a period of two years from the date of the record. The reconciliation process may be completed using either of the following procedures or a combination thereof:

a. The dispensing pharmacist verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. If controlled substances are maintained on the patient care unit, the nurse or other responsible licensed health care provider verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. All discrepancies shall be reported to the pharmacist in charge. If any Schedule II controlled substances in the pharmacy's current inventory have been dispensed and verified in this manner within the year, and there are no discrepancies noted, no additional reconciliation action is required. A drug that has had no activity within the year shall be reconciled pursuant to paragraph *"b"* of this subrule.

b. A physical count of each Schedule II controlled substance stocked by the pharmacy shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. The physical count and reconciliation may be completed over a period of time not to exceed one year in a manner that ensures that the perpetual inventory and the physical inventory of Schedule II controlled substances are annually reconciled. The individual performing the reconciliation shall record the date, the time, the individual's initials or unique identification, and any discrepancies between the physical inventory and the perpetual inventory. Any discrepancies between the physical inventory and the perpetual inventory shall be reported to the pharmacist in charge.

657—10.34(124,155A) Records. Every inventory or other record required to be kept under this chapter or under Iowa Code chapter 124 shall be kept by the registrant and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in these rules. Controlled substances records shall be maintained in a readily retrievable manner that establishes the receipt and distribution of all controlled substances. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department.

10.34(1) *Schedule I and II records.* Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.

10.34(2) *Schedule III, IV, and V records.* Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the required information is readily retrievable from the ordinary business records of the registrant.

10.34(3) *Date of record.* The date on which a controlled substance is actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution.

10.34(4) *Receipt and disbursement records.* Each record of receipt or disbursement of controlled substances, unless otherwise provided in these rules or pursuant to federal law, shall include the following:

a. The name of the substance;

b. The strength and dosage form of the substance;

c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from whom the substances were acquired;

d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to whom the substances were distributed; and

e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to whom the substances were distributed for disposal, if appropriate.

10.34(5) *Dispensing records.* Each record of dispensing of controlled substances to a patient or research subject shall include the following information:

a. The name and address of the person to whom dispensed;

b. The date of dispensing;

c. The name of the substance;

d. The quantity of the substance dispensed; and

e. The name or unique identification of the individual who dispensed or administered the substance.

10.34(6) *Ordering or distributing Schedule I or II controlled substances - DEA Form 222.* Except as otherwise provided by subrule 10.34(7) and under federal law, a DEA Form 222 is required for each distribution of a Schedule I or II controlled substance. An order form may be executed only on behalf of the registrant named on the order form and only if the registrant's DEA and Iowa registrations for the substances being purchased have not expired or been revoked or suspended by the issuing agency.

a. Order forms shall be obtained, executed, and filled pursuant to DEA requirements. Each form shall be complete, legible, and properly prepared, executed, and endorsed and shall contain no alteration, erasure, or change of any kind.

b. The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier.

c. The purchaser shall maintain Copy 3 of the order form in the files of the registrant. Upon receipt of the substances from the supplier, the purchaser shall record on Copy 3 of the order form the quantity of each substance received, and the date of receipt, and shall initial each line identifying a substance received.

d. The supplier shall record on Copy 1 and Copy 2 of the order form the quantity of each substance distributed to the purchaser and the date on which the shipment is made. The supplier shall maintain Copy 1 of the order form in the files of the supplier and shall forward Copy 2 of the order form to the DEA district office.

e. Order forms shall be maintained separately from all other records of the registrant.

f. Each unaccepted, defective, or otherwise "void" order form and any attached statement or other documents relating to any order form shall be maintained in the files of the registrant.

g. If the registration of any purchaser of Schedule I or II controlled substances is terminated for any reason, or if the name or address of the registrant as shown on the registration is changed, the registrant shall return all unused order forms to the DEA district office.

10.34(7) *Ordering or distributing Schedule I or II controlled substances - electronic ordering system.* A registrant authorized to order or distribute Schedule I or II controlled substances via the DEA Controlled Substances Ordering System (CSOS) shall comply with the requirements of the DEA relating to that system, including the maintenance and security of digital certificates, signatures, and passwords and all record-keeping and reporting requirements.

a. For an electronic order to be valid, the purchaser shall sign the electronic order with a digital signature issued to the purchaser or the purchaser's agent by the DEA.

b. An electronic order may include controlled substances that are not in Schedules I and II and may also include noncontrolled substances.

c. A purchaser shall submit an order to a specific wholesale distributor appropriately licensed to distribute in Iowa.

d. Prior to filling an order, a supplier shall verify the integrity of the signature and the order, verify that the digital certificate has not expired, check the validity of the certificate, and verify the registrant's authority to order the controlled substances.

e. The supplier shall retain an electronic record of every order, including a record of the number of commercial or bulk containers furnished for each item and the date on which the supplier shipped the containers to the purchaser. The shipping record shall be linked to the electronic record of the order. Unless otherwise provided under federal law, a supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

f. If an order cannot be filled for any reason, the supplier shall notify the purchaser and provide a statement as to the reason the order cannot be filled. When a purchaser receives such a statement from a

supplier, the purchaser shall electronically link the statement of nonacceptance to the original electronic order. Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

g. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and shall identify the individual reconciling the order. A purchaser shall, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser shall also retain all copies of each unfilled or defective order and each linked statement.

h. A supplier shall retain each original order filled and all linked records for two years. A supplier shall, for each electronic order filled, forward to the DEA within two business days either a copy of the electronic order or an electronic report of the order in a format specified by the DEA.

i. Records of CSOS electronic orders and all linked records shall be maintained by a supplier and a purchaser for two years following the date of shipment or receipt, respectively. Records may be maintained electronically or in hard-copy format. Records that are maintained electronically shall be readily retrievable from all other records, shall be easily readable or easily rendered into a readable format, shall be readily retrievable at the registered location, and shall be made available to the board, to the board's agents, or to the DEA upon request. Records maintained in hard-copy format shall be maintained in the same manner as DEA Form 222.

[**ARC 8539B**, IAB 2/24/10, effective 4/1/10]

657—10.35(124,155A) Physical count and record of inventory. Responsibility for ensuring that a required inventory is timely completed shall rest with the registrant or, in the case of a registered business, shall rest with the owner of the business. A registrant or owner of a registered business may delegate the actual taking of any inventory. The person or persons responsible for taking the inventory shall sign the completed inventory record.

10.35(1) *Record and procedure.* Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.33(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken.

b. Each inventory shall be maintained in a handwritten, typewritten, or electronically printed form at the registered location. An inventory of Schedule II controlled substances shall be maintained separately from an inventory of all other controlled substances.

c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. These shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical services programs or care facility emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant.

d. A separate inventory shall be made for each registered location and for each independent activity registered except as otherwise provided under federal law.

e. The inventory shall be taken either prior to opening or following the close of business on the inventory date, and the inventory record shall identify either opening or close of business.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

(1) The name of the substance;

(2) The strength and dosage form of the substance; and

(3) The quantity of the substance.

g. For all substances listed in Schedule I or II, and for all solid oral and injectable hydrocodone-containing products, the quantity shall be an exact count or measure of the substance.

h. For all substances listed in Schedule III, IV, or V, except for hydrocodone-containing products identified in paragraph *"g"* herein, the quantity may be an estimated count or measure of the substance unless the container has been opened and originally held more than 100 dosage units. If the opened

commercial container originally held more than 100 dosage units, an exact count of the contents shall be made. Liquid oral hydrocodone-containing products packaged in incremented containers shall be measured to the nearest increment; products packaged in nonincremented containers may be estimated to the nearest one-fourth container.

10.35(2) *Initial inventory.* A new registrant shall take an inventory of all stocks of controlled substances on hand on the date the new registrant first engages in the manufacture, distribution, or dispensing of controlled substances. If the registrant commences business or the registered activity with no controlled substances on hand, the initial inventory shall record that fact.

10.35(3) *Annual inventory.* After the initial inventory is taken, a registrant shall take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within one year of the previous inventory date.

10.35(4) *Change of ownership.* Both the current owner and the prospective owner shall be responsible for ensuring that an inventory of all controlled substances is timely completed whenever there is a change of ownership of any pharmacy or drug wholesaler licensed pursuant to Iowa Code section 155A.13 or 155A.17, respectively.

10.35(5) *Change of pharmacist in charge (PIC).* An inventory of all controlled substances shall be completed whenever there is a change of PIC. The inventory shall be taken following the close of business the last day of the terminating PIC's employment and prior to opening for business the first day of the new PIC's employment. A single inventory shall be sufficient if there is no lapse between employment of the terminating PIC and the new PIC.

10.35(6) *Change of registered location.* A registrant shall take an inventory of all controlled substances whenever there is a change of registered location. The inventory shall be taken following the close of business the last day at the location being vacated. This inventory shall serve as the ending inventory for the location being vacated as well as a record of beginning inventory for the new location.

10.35(7) *Discontinuing registered activity.* A registrant shall take an inventory of controlled substances at the close of business the last day the registrant is engaged in registered activities. If the registrant is selling or transferring the remaining controlled substances to another registrant, this inventory shall serve as the ending inventory for the registrant discontinuing business as well as a record of additional or starting inventory for the registrant to whom the substances are transferred.

10.35(8) *Newly controlled substances.* On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances, any registrant who possesses the newly controlled substance shall take an inventory of all stocks of the substance on hand. That initial inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the newly controlled substance shall be included in each inventory made by the registrant.

657—10.36(124) Samples and other complimentary packages—records. Complimentary packages and samples of controlled substances may be distributed to practitioners pursuant to federal and state law only if the person distributing the items leaves with the practitioner a specific written list of the items delivered.

10.36(1) *Distribution record.* The record form for the distribution of complimentary packages of controlled substances shall contain the following information:

a. The name, address, and DEA registration number of the supplier;

b. The name, address, and DEA registration number of the practitioner;

c. The name, strength, and quantity of the specific controlled substances delivered; and

d. The date of delivery.

10.36(2) *Reports to the board.* Any person who distributes controlled substances pursuant to this rule shall report all such distributions to the board. Reports shall:

a. Include the information identified in subrule 10.36(1). Reports may consist of copies of those distribution records or may be computer-generated listings identifying those distributions.

b. Be submitted as soon as practicable after distribution to the practitioner but no less often than once each calendar quarter.

10.36(3) *Practitioner records.* A practitioner who regularly administers or dispenses controlled substances shall keep records of the receipt and disbursement of such drugs, including complimentary packages and samples. Records shall be filed in a readily retrievable manner in accordance with federal requirements and shall be made available for inspection and copying by agents of the board or other authorized individuals for at least two years from the date of the record.

657—10.37(124,126) Revision of controlled substances schedules.

10.37(1) *Application for exception.* Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in any of the schedules in Iowa Code chapter 124 excepted from the application of all or any part of that chapter may apply to the board for such exception.

a. An application for an exception under this rule shall provide evidence that an exception has been granted under the federal Controlled Substances Act.

b. The board shall permit any interested person to file written comments on or objections to the proposal for exception and shall designate the time during which such filings may be made. After consideration of the application and any comments on or objections to the proposal for exception, the board shall issue its findings on the application.

10.37(2) *Designation of new controlled substance.* The board may designate any new substance as a controlled substance to be included in any of the schedules in Iowa Code chapter 124 no sooner than 30 days following publication in the Federal Register of a final order so designating the substance under federal law. Designation of a new controlled substance under this subrule shall be temporary as provided in Iowa Code section 124.201, subsection 4.

10.37(3) *Objection to designation of a new controlled substance.* The board may object to the designation of any new substance as a controlled substance within 30 days following publication in the Federal Register of a final order so designating the substance under federal law. The board shall file objection to the designation of a substance as controlled, shall afford all interested parties an opportunity to be heard, and shall issue the board's decision on the new designation as provided in Iowa Code section 124.201, subsection 4.

657—10.38(124) Temporary designation of controlled substances.

10.38(1) Amend Iowa Code section 124.204 by adding the following new subsection 9:

9. Temporary listing of substances subject to Schedule I. Any material, compound, mixture, or preparation which contains any quantity of the following substances:

a. (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: UR-144, 1-pentyl-3-(2,2,3,3-tetramethylcyclopropoyl)indole.

b. [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 5-fluoro-UR-144, 5-F-UR-144, XLR11, 1-(5-fluoro-pentyl)-3-(2,2,3,3-tetramethylcyclopropoyl)indole.

c. N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: APINACA, AKB48.

10.38(2) Amend Iowa Code subsection 124.204(4) by adding the following new paragraphs:

al. 4-methyl-N-ethylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 4-MEC, 2-(ethylamino)-1-(4-methylphenyl)propan-1-one.

am. 4-methyl-alpha-pyrrolidinopropiophenone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 4-MePPP, MePPP, 4-methyl-[alpha]-pyrrolidinopropiophenone, 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one.

an. Alpha-pyrrolidinopentiophenone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: [alpha]-PVP, [alpha]-pyrrolidinovalerophenone, 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one.

ao. Butylone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: bk-MBDB, 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one.

ap. Pentedrone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: [alpha]-methylaminovalerophenone, 2-(methylamino)-1-phenylpentan-1-one.

aq. Pentylone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: bk-MBDP, 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one.

ar. 4-fluoro-N-methylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 4-FMC, flephedrone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one.

as. 3-fluoro-N-methylcathinone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 3-FMC, 1-(3-fluorophenyl)-2-(methylamino)propan-1-one.

at. Naphyrone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: naphthylpyrovalerone, 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one.

au. Alpha-pyrrolidinobutiophenone, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: [alpha]-PBP, 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one.

10.38(3) Amend Iowa Code subsection 124.204(9) by adding the following new paragraphs:

g. Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: PB-22, QUPIC.

h. Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate, its optical, positional, and geometric isomers, salts and salts of isomers. Other names: 5-fluoro-PB-22, 5F-PB-22.

i. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: AB-FUBINACA.

j. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers. Other name: ADB-PINACA.

[**ARC 7906B**, IAB 7/1/09, effective 6/22/09; **ARC 8411B**, IAB 12/30/09, effective 12/1/09; **ARC 8989B**, IAB 8/11/10, effective 7/21/10; **ARC 9091B**, IAB 9/22/10, effective 8/30/10; **ARC 0893C**, IAB 8/7/13, effective 7/9/13; **ARC 1408C**, IAB 4/2/14, effective 3/13/14]

657—10.39(124,126) Excluded substances. The Iowa board of pharmacy hereby excludes from all schedules the current list of "Excluded Nonnarcotic Products" identified in Title 21, CFR Part 1308, Section 22. Copies of the list of excluded products may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

657—10.40(124,126) Anabolic steroid defined. Anabolic steroid, as defined in Iowa Code section 126.2, paragraph 2, includes any substance identified as such in Iowa Code section 124.208, paragraph 6, or in Iowa Code section 126.2, paragraph 2.

657—10.41(124A) Designation of imitation controlled substances.

10.41(1) *Synthetic cannabinoids.* The following synthetic cannabinoids, including products by whatever trade name that are treated, sprayed, or saturated with these synthetic cannabinoids, are designated imitation controlled substances subject to the provisions of Iowa Code chapter 124A:

a. Dexanabinol, (6aS, 10aS)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a, 7, 10, 10a-tetrahydrobenzo[c]chromen-1-ol, also known as HU-211.

b. 1-butyl-3(1-naphthoyl) indole, also known as JWH-073.

c. 1-pentyl-3-(1-naphthoyl) indole, also known as JWH-018.

d. Phenol, CP 47, 497 and homologues, or 2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol, where side chain n=5, and homologues where side chain n=4, 6, or 7.

10.41(2) *Product examples.* Some currently marketed products containing the imitation controlled substances identified in subrule 10.41(1) include K2, Red Dragon Smoke, Spice, K2 Spice, Mojo, Smoke, Skunk, K2 Summit, and Pandora Potpourri.

[**ARC 9000B**, IAB 8/11/10, effective 7/22/10]

These rules are intended to implement Iowa Code sections 124.201, 124.301 to 124.308, 124.402, 124.403, 124.501, 126.2, 126.11, 147.88, 147.95, 147.99, 155A.13, 155A.17, 155A.26, 155A.37, and 205.3.

[Filed 9/29/71; amended 8/9/72, 12/15/72, 11/14/73, 8/14/74, 4/8/75]
[Filed 11/24/76, Notice 10/20/76—published 12/15/76, effective 1/19/77]

[Filed 11/9/77, Notice 8/24/77—published 11/30/77, effective 1/4/78]
[Filed 10/20/78, Notices 8/9/78, 9/6/78—published 11/15/78, effective 1/9/79]
[Filed 8/28/79, Notice 5/30/79—published 9/19/79, effective 10/24/79]
[Filed 2/12/81, Notice 12/24/80—published 3/4/81, effective 7/1/81]
[Filed 7/24/81, Notice 5/13/81—published 8/19/81, effective 9/23/81]
[Filed emergency 12/14/81—published 1/6/82, effective 1/6/82]
[Filed emergency 10/6/82—published 10/27/82, effective 10/27/82]
[Filed 6/16/83, Notice 5/11/83—published 7/6/83, effective 8/10/83]
[Filed 2/23/84, Notice 11/23/83—published 3/14/84, effective 4/18/84]
[Filed emergency 8/10/84—published 8/29/84, effective 8/10/84]
[Filed emergency 6/14/85—published 7/3/85, effective 6/14/85]
[Filed emergency 8/30/85—published 9/25/85, effective 9/6/85]
[Filed emergency 12/4/85—published 1/1/86, effective 12/5/85]
[Filed emergency 5/14/86—published 6/4/86, effective 5/16/86]
[Filed 5/14/86, Notice 4/9/86—published 6/4/86, effective 7/9/86][◊]
[Filed 1/28/87, Notice 11/19/86—published 2/25/87, effective 4/1/87]
[Filed emergency 7/24/87—published 8/12/87, effective 7/24/87]
[Filed 8/5/87, Notice 6/3/87—published 8/26/87, effective 9/30/87]
[Filed emergency 1/21/88—published 2/10/88, effective 1/22/88]
[Filed 3/29/88, Notice 2/10/88—published 4/20/88, effective 5/25/88]
[Filed emergency 8/5/88—published 8/24/88, effective 8/5/88]
[Filed emergency 10/13/88—published 11/2/88, effective 10/13/88]
[Filed emergency 5/16/89—published 6/14/89, effective 5/17/89]
[Filed emergency 9/12/89—published 10/4/89, effective 9/13/89]
[Filed 1/19/90, Notice 11/29/89—published 2/7/90, effective 3/14/90]
[Filed 8/31/90, Notice 6/13/90—published 9/19/90, effective 10/24/90]
[Filed emergency 1/29/91—published 2/20/91, effective 2/27/91]
[Filed 1/29/91, Notice 9/19/90—published 2/20/91, effective 3/27/91]
[Filed emergency 2/27/91—published 3/20/91, effective 2/27/91]
[Filed 4/26/91, Notice 2/20/91—published 5/15/91, effective 6/19/91]
[Filed emergency 5/10/91—published 5/29/91, effective 5/10/91]
[Filed 7/30/91, Notice 5/29/91—published 8/21/91, effective 9/25/91[1]]
[Filed emergency 9/23/91—published 10/16/91, effective 9/23/91]
[Filed emergency 10/18/91—published 11/13/91, effective 10/21/91]
[Filed 3/12/92, Notice 1/8/92—published 4/1/92, effective 5/6/92]
[Filed 5/21/92, Notice 4/1/92—published 6/10/92, effective 7/15/92]
[Filed emergency 8/10/92—published 9/2/92, effective 8/10/92]
[Filed 10/22/92, Notice 9/2/92—published 11/11/92, effective 1/1/93]
[Filed 9/23/93, Notice 5/26/93—published 10/13/93, effective 11/17/93]
[Filed emergency 3/21/94—published 4/13/94, effective 3/23/94]
[Filed 3/21/94, Notice 10/13/93—published 4/13/94, effective 5/18/94]
[Filed 4/22/94, Notice 11/10/93—published 5/11/94, effective 6/15/94]
[Filed 6/24/94, Notice 4/13/94—published 7/20/94, effective 8/24/94]
[Filed 3/22/95, Notice 11/9/94—published 4/12/95, effective 5/31/95]
[Filed 12/6/95, Notice 8/16/95—published 1/3/96, effective 2/7/96]
[Filed 11/19/97, Notice 10/8/97—published 12/17/97, effective 1/21/98]
[Filed 4/24/98, Notice 3/11/98—published 5/20/98, effective 6/24/98]
[Filed 7/31/98, Notice 5/20/98—published 8/26/98, effective 9/30/98]
[Filed emergency 8/18/99—published 9/8/99, effective 8/18/99]
[Filed emergency 10/6/99—published 11/3/99, effective 10/11/99]
[Filed emergency 7/18/00—published 8/9/00, effective 7/18/00]
[Filed 8/14/02, Notice 6/12/02—published 9/4/02, effective 10/9/02]

[Filed emergency 12/13/02—published 1/8/03, effective 12/13/02]
[Filed emergency 7/16/04 after Notice 6/9/04—published 8/4/04, effective 7/16/04]
[Filed 10/22/04, Notice 3/31/04—published 11/10/04, effective 12/15/04]
[Filed emergency 5/3/05—published 5/25/05, effective 5/21/05]
[Filed emergency 6/30/05 after Notice 5/11/05—published 7/20/05, effective 7/1/05]
[Filed 8/9/05, Notice 5/25/05—published 8/31/05, effective 10/5/05]
[Filed 3/22/06, Notice 12/21/05—published 4/12/06, effective 5/17/06]
[Filed 3/22/06, Notice 1/18/06—published 4/12/06, effective 5/17/06]
[Filed 5/17/06, Notice 4/12/06—published 6/7/06, effective 7/12/06]
[Filed 2/7/07, Notice 10/25/06—published 2/28/07, effective 4/4/07]
[Filed 5/14/07, Notice 2/28/07—published 6/6/07, effective 7/11/07]
[Filed emergency 8/2/07—published 8/29/07, effective 8/2/07]
[Filed emergency 11/13/07 after Notice 8/29/07—published 12/5/07, effective 11/13/07]
[Filed ARC 7636B (Notice ARC 7448B, IAB 12/31/08), IAB 3/11/09, effective 4/15/09]
[Filed Emergency ARC 7906B, IAB 7/1/09, effective 6/22/09]
[Filed ARC 8172B (Notice ARC 7908B, IAB 7/1/09), IAB 9/23/09, effective 10/28/09]
[Filed Emergency ARC 8411B, IAB 12/30/09, effective 12/1/09]
[Filed ARC 8539B (Notice ARC 8269B, IAB 11/4/09), IAB 2/24/10, effective 4/1/10]
[Filed ARC 8892B (Notice ARC 8667B, IAB 4/7/10), IAB 6/30/10, effective 9/1/10]
[Filed Emergency ARC 8989B, IAB 8/11/10, effective 7/21/10]
[Filed Emergency ARC 9000B, IAB 8/11/10, effective 7/22/10]
[Filed Emergency ARC 9091B, IAB 9/22/10, effective 8/30/10]
[Filed ARC 9410B (Notice ARC 9196B, IAB 11/3/10), IAB 3/9/11, effective 4/13/11]
[Filed ARC 9912B (Notice ARC 9671B, IAB 8/10/11), IAB 12/14/11, effective 1/18/12]
[Filed ARC 0504C (Notice ARC 0351C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13]
[Filed ARC 0749C (Notice ARC 0652C, IAB 3/20/13), IAB 5/29/13, effective 7/3/13]
[Filed Emergency ARC 0893C, IAB 8/7/13, effective 7/9/13]
[Filed Emergency ARC 1408C, IAB 4/2/14, effective 3/13/14]

◊ Two or more ARCs

[1] Effective date delayed 70 days by the Administrative Rules Review Committee at its meeting held September 11, 1991.

TRANSPORTATION DEPARTMENT[761]

Rules transferred from agency number [820] to [761] to conform with the reorganization numbering scheme in general IAC Supp. 6/3/87.

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Rescinded **ARC 1395C**, IAB 4/2/14, effective 5/7/14