

**641—112.4(135) Biological agent risk assessment.****112.4(1) Questionnaire.**

*a. Duty to complete and submit.* Any laboratory, clinic, research facility, commercial enterprise, or other entity which possesses select biological agents shall complete and submit to EMD a biological agent risk assessment questionnaire on an annual basis or more frequently as requested by EMD. The questionnaire shall identify the select biological agents possessed and shall contain such other information as required by the department and EMD.

*b. Purpose and use.* The questionnaires shall be used in the development of the critical asset protection plan prepared pursuant to Iowa Code section 29C.8. EMD shall provide the department with the completed questionnaires for the purpose of preparing relevant security guidelines. The department shall not disseminate the information contained in the questionnaires.

**112.4(2) Assessment criteria.** The criteria for assessing the risk of a select biological agent shall be based on, but not limited to, current CDC guidelines, recommendations from USAMRIID, recommendations from the biosecurity council, and this subrule. The biosecurity council may modify the criteria based on new scientific information, treatments, or public perceptions, or any combination thereof.

*a. Biological agent rating criteria.* Biological agents shall be rated by the department based on the following three categories:

(1) Transmissibility (T). 0 = nontransmissible, 1 = transmissible only by injection, sexual interface or bite, 2 = transmissible by ingestion, 3 = transmissible by air or touch.

(2) Lethality (L). 0 = nonlethal, 1 = 0-25 percent mortality, 2 = 26-50 percent mortality, 3 = 51-100 percent mortality.

(3) Suitability for or degree of weaponization (S). 0 = not suitable, 1 = suitable but not modified, 2 = modified for antibiotic resistance or improved environmental resilience, 3 = modified and packaged for effective delivery on a mass scale.

*b.* The final rating for a biological agent is determined by adding the score the biological agent received in each of the three categories (T + L + S = biological agent rating).

**112.4(3) On-site examination.**

*a. Notification.* The department or its designee may conduct an on-site examination of any premises containing select biological agents. Prior to conducting the on-site examination, the department shall notify the owner or person in charge of the premises.

*b. Examination.* An on-site examination shall include each of the following components:

- (1) A review of laboratory safety and security policies and procedures;
- (2) A review of external and internal access to the premises;
- (3) A review of access controls to areas where select biological agents are used and stored;
- (4) A review of employee, student and visitor access to the premises, including the identification required to access the premises and the method of recording access to the premises;
- (5) A review of background and security clearance measures implemented;
- (6) A review of the screening process for packages brought into or taken out of the premises;
- (7) A review of the emergency plan;
- (8) A review of appropriate biocontainment within a laboratory;
- (9) A review of the training and knowledge of research staff;
- (10) A review of the process for reporting and investigating breach-of-security incidents;
- (11) A review of disposal procedures; and
- (12) A tour of the premises to view access security, select biological agent locations, storage, inventory, records, coding and database procedures.

*c. Administrative search warrant.* If the owner or person in charge of the premises refuses the department's employee or designee admittance or if the department's employee or designee is not permitted to conduct a full examination, the department may obtain an administrative search warrant under Iowa Code section 808.14.

**112.4(4) Security guidelines.** After a biological agent risk assessment questionnaire has been completed and the on-site examination has been conducted, the department shall provide the entity

with a biological agent risk assessment report and security guidelines. A select biological agent which is listed as a CDC Category A biological agent or as determined by the biosecurity council shall be maintained in accordance with maximum security guidelines as established by the biosecurity council and the director.

**112.4(5) Confidentiality.** The biological agent risk assessment questionnaire, the biological agent risk report and security guidelines, and any other information if it relates to the imminent threat of death, disease, biological malfunction in a human, animal, plant or other living thing, deterioration of food, water, equipment, supplies, or a deleterious alteration of the environment provided to or by EMD or the department pursuant to this chapter may be considered critical asset protection plan information and may be maintained as confidential pursuant to Iowa Code section 22.7(43).