

CHAPTER 112
BIOLOGICAL AGENT RISK ASSESSMENT

641—112.1(135) Purpose. The purpose of a statewide biological agent risk assessment is to protect the citizens of Iowa from exposure to biological agents which are or have the potential to be biological weapons. In order to protect the public health, the department is charged with identifying sources, locations, safety and security of select biological agents.

641—112.2(135) Definitions. For the purposes of these rules, the following definitions shall apply:

“Biological agent” means any microorganism (including bacteria, viruses, fungi, rickettsiae or protozoa), pathogen, or infectious substance, toxin, or any naturally occurring, bioengineered or synthesized component of any such microorganism, pathogen or infectious substance, whatever its origin or method of production.

“Biosecurity council” or *“council”* means a council established by the director to advise the department on biosecurity issues and to recommend guidelines to protect the citizens of Iowa from exposure to select biological agents.

“CDC” means the Centers for Disease Control and Prevention.

“Department” means the Iowa department of public health.

“Director” means the director of the Iowa department of public health.

“DOJ” means the federal Department of Justice.

“EMD” means the emergency management division of the department of public defense.

“FBI” means Federal Bureau of Investigation.

“HHS” means the federal Department of Health and Human Services.

“Laboratory” means a facility for the examination of biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological or pathological materials or other materials derived from humans, animals, or plants to provide information for the diagnosis, prevention or treatment of any disease or impairment of, or for the assessment of the health of, humans, animals, or plants.

“Lethality” or *“L”* means the relative power and degree of pathogenicity possessed by organisms to produce disease.

“Select biological agent” means a biological agent identified by the director, upon recommendation from the biosecurity council, for heightened monitoring and security, including but not limited to any biological agent that is listed as a Category A, B, or C biological agent by the Centers for Disease Control and Prevention, any agent identified as a select agent in the Code of Federal Regulations, Title 42, Part 72, Appendix A, and any biological agent identified by the United States Army Medical Research Institute of Infectious Diseases as appropriate for a heightened level of monitoring and security.

“Suitability” or *“S”* means suitability for weaponization.

“Transmissibility” or *“T”* means degree of contagion.

“USAMRIID” means the United States Army Medical Research Institute of Infectious Diseases.

“Weaponization” means manipulation of a biological agent to increase the potential for use as a weapon.

641—112.3(135) Biosecurity council established. The director shall appoint a biosecurity council to advise the department on biosecurity issues and to recommend guidelines to protect the citizens of Iowa from exposure to select biological agents.

112.3(1) The council shall, at a minimum, consist of the following members:

- a. The director of the department of public health;
- b. The governor’s homeland security advisor;
- c. The director of the University of Iowa Hygienic Laboratory;
- d. A representative from the FBI as made available by the director of the FBI or a representative of the U.S. Secret Service as made available by the director of the U.S. Secret Service;
- e. A representative appointed by the Iowa adjutant general;

- f.* A representative from the Iowa attorney general's office;
- g.* The medical director of the department of public health;
- h.* The executive director of the office of disease epidemiology and disaster preparedness, department of public health;
- i.* A microbiologist at the master's or doctorate level who has expertise in human microbiology;
- j.* A microbiologist at the master's or doctorate level who has expertise in zoonosis;
- k.* A biological safety professional; and
- l.* The emergency management division administrator.

112.3(2) The council shall make recommendations to the department on classification of select biological agents, select biological agent risk assessment guidelines, and security guidelines.

112.3(3) Security guidelines shall be consistent with applicable state and federal laws, including but not limited to specific antiterrorism regulations of HHS and DOJ.

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).

641—112.5(135) Requests for biological agent information. A laboratory, clinic, research facility, commercial enterprise, or other entity which possesses select biological agents shall respond to written requests from the department regarding the presence, location, and security of biological agents within 30 days of the request. In the event of a disaster emergency, a laboratory, clinic, research facility, commercial enterprise, or other entity which possesses select biological agents shall immediately respond to a request from the department or its designee regarding the presence, location, and security of biological agents.

641—112.6(135) Exceptions.

112.6(1) The requirements of this chapter are not applicable to hospital laboratories which possess select biological agents solely as a result of a patient culture provided that the culture is destroyed within 14 days after referral to and confirmation by the University of Iowa Hygienic Laboratory or other laboratory approved by the council.

112.6(2) The requirements of this chapter are not applicable to a person who detects a biological agent in a clinical or environmental sample for the purpose of diagnosing disease, epidemiological surveillance, exposure assessment, reference, verification or proficiency testing, and who discards the agent within 14 calendar days. If a biological agent is kept for more than 14 calendar days, the laboratory shall provide written notice to the department identifying the agent and reason for continued or extended possession.

These rules are intended to implement Iowa Code Supplement section 135.11(28).

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