

OCCUPATIONAL HEALTH AND SAFETY PLAN
Working with *Bacillus Anthracis* in BSL-3 Laboratories
University of Minnesota, Office of Occupational Health and Safety

Background Information

Anthrax is caused by *Bacillus anthracis*, a gram-positive bacterium that causes an acute bacterial disease of mammals, including humans. *B. anthracis* has the ability to produce spores that allow the organism to persist for long periods of time. Numerous cases of laboratory-associated anthrax (primarily cutaneous) have been reported. The clinical forms of anthrax in humans that result from different routes of exposure are 1) cutaneous (via broken skin), 2) gastrointestinal (via ingestion), and 3) respiratory (via inhalation). Cutaneous anthrax is the most common and readily treatable form of the disease. It is believed that very few spores (10 or less) are required for cutaneous anthrax. Inhalation of spores from virulent strains of *B. anthracis* may cause severe respiratory distress and can be fatal. The infective dose via inhalation is estimated to be 8,000 to 50,000 organisms. Estimates vary greatly but the lethal dose (LD50) is likely within the range of 2,500-55,000 spores.

A licensed vaccine for anthrax (BioThrax anthrax vaccine adsorbed) and both the Advisory Committee on Immunization Practices (ACIP) and the Occupational Health and Safety Administration recommend vaccination for individuals involved in laboratory activities that present an increased risk for repeated exposures to *B.anthraxis* in vegetative or spore form. The currently approved schedule for intramuscular administration of the vaccine is 0, 1, and 6 months for the primary series, and intramuscular injections of booster doses at 12 and 18 months after initiation of the primary series, and at one year intervals thereafter.

Following exposure to anthrax, prophylactic antibiotics are typically started and may be continued for 60-100 days depending on previous anthrax vaccine status and type of exposure. Ciprofloxacin or doxycycline are commonly used and recommended antibiotics. Workers who have already received the full series of anthrax vaccine may be treated with shorter courses of antibiotics or not treated, depending on the type of exposure. Anthrax vaccine may also be administered after an exposure if the entire series of vaccines has not been completed. If a very significant exposure occurs or if symptoms develop additional measures may include anthrax immune globulin, monoclonal antibodies or anthrax antitoxin.

Occupational Health Requirements for ALL Work in BSL-3 Laboratories

The following summarizes the general requirements for all BSL-3 work. **Refer to the BSL-3 Laboratory Operations Manual as well as the facility's manual and laboratory safety plan for more details on occupational health and safety policies and procedures.** Prior to starting research, a Principal Investigator (PI) is responsible for completing risk assessments for biological, chemical, and physical hazards, as well as for project-specific protocols, in consultation with the Laboratory and BSL-3 Facilities Managers. Decisions about methods for ensuring employee health and safety should be made in consultation with the Office of Occupational Health and Safety (OHS). OHS must approve all decisions about personal protective equipment, medical evaluation, treatment, and medical surveillance.

Training: Prior to beginning work in a BSL-3 facility, research personnel must receive training about the potential health effects of exposure to all biological and chemical hazards associated with their research work in the facility, necessary precautions to avoid exposures, initial medical evaluation requirements, vaccine requirements, importance of monitoring and reporting exposures and symptoms, and post-exposure medical evaluation and treatments, as appropriate to their research project and activities.

Preliminary Medical Evaluation: Prior to beginning research, the BSL-3 Facilities Manager, Laboratory Manager, and Supervisor (PI or Facilities Management Team Leader) must complete a BSL-3 Medical Evaluation Authorization Form for each individual requiring access to a BSL-3 facility. Each employee and visitor must enroll in the Office of Occupational Health and Safety (OHS) medical surveillance program and complete a BSL-3 Medical Questionnaire. Any employee who uses a respirator will be required to complete a Respirator Medical Evaluation Form and be medically

cleared to wear a respirator. Some individuals may need to complete a medical evaluation conducted by an occupational health physician at the occupational health clinic designated by OHS (www.ohs.umn.edu). The occupational health physician will issue a Work Ability Report indicating medical and respirator clearance for work and respirator use; a copy of this report will be sent to the employee, the employee's supervisor, the Office of Occupational Health and Safety, and the BSL-3 Facilities Manager. Some individuals may be placed on work restrictions or require additional evaluation. Each employee will receive a card that identifies his/her work with specific organisms; this card should be presented to a health care provider if the employee is seeking medical attention for symptoms related to a possible exposure.

A tetanus vaccine is recommended for all personnel. Depending on the research activities, employees will require additional immunizations and, in some cases, periodic follow-up blood titers to measure antibody production. Employees choosing not to receive recommended vaccines or follow-up titers must sign a declination form. **Declination may prevent work with a BSL-3 agent or result in work restrictions from the occupational health physician. In many instances University policy does NOT permit an individual who declines immunization to work in some specified environments.**

Ongoing Medical Evaluations: BSL-3 employees must complete a medical re-evaluation at least every two years. More frequent evaluation may be necessary, depending on the organism, change in the health of the employee, or at the discretion of the evaluating physician. Updated medical evaluations may be required if there are changes in research processes identified by an updated risk assessment. Any medical condition that increases risk following exposure (e.g., immunosuppression, chemotherapy, pregnancy, significant injury) must be reported to the Office of Occupational Health and Safety to ensure appropriate evaluation.

Specific Occupational Health Requirements for Work with Virulent *Bacillus anthracis*

The following are required before an employee will be cleared to work with virulent strains of *B. anthracis* and applies to all employees whose job duties may involve their presence in the laboratory when the organism is being used in research activities. These requirements do not apply to individuals who may encounter the organism only during a medical or other emergency or to individuals whose job duties involve their presence when research activities are not being conducted. An occupational health physician will make the final determination about the application of these requirements for each individual. Changes in these requirements may be made only for **compelling** medical reasons and in consultation with the OHS Director.

Preventing Exposures: In addition to the required facility-specific personal protective equipment, nitrile gloves and Powered Air Purifying Respirators (PAPR) with a full facepiece or hood and equipped with N100 filters must be worn during all tasks that involve handling material that contains or may contain *B. anthracis*. The same requirements for personal protective equipment pertain to all personnel present in the room during these activities. Skin defects must be covered with an impermeable occlusive bandage. It is strongly recommended that all work is performed in a single room, and all procedures must be performed in a certified Biological Safety Cabinet, when possible. Tasks must be performed in a manner that prevents or minimizes the generation of aerosols. Careful hand washing must be undertaken after removing personal protective equipment and personal protective equipment must be immediately and carefully disposed of or properly decontaminated. **Anyone responding to a medical or other emergency must wear personal protective equipment that prevents skin or respiratory system exposures.**

Preliminary Medical Evaluation and Vaccinations: Each employee must receive an initial medical evaluation and vaccination with the primary series consisting of three doses of anthrax vaccine administered intramuscularly before work with the agent can be started. Booster doses must be received at 12 months, 18 months, and annually thereafter. Employees must be cleared to receive prophylactic antibiotics (ciprofloxacin [500 mg bid] and/or doxycycline [100 mg bid]) following an exposure. This requirement for immunization may change as new series of immunizations are developed (e.g., BioThrax) or protocols are modified by the Centers for Disease Control and Prevention or the *Advisory Committee on Immunization Practices (ACIP)*. The following precautions are noted for BioThrax:

- May cause fetal harm and should not be used during pregnancy
- May contain small amounts of latex
- Immune response may be diminished among immune-compromised individuals

- Caution is advised when used on nursing mothers

Ongoing Medical Evaluation: Employees working with virulent anthrax bacilli must complete annual medical re-evaluations and receive annual anthrax vaccine boosters.

Post-Exposure Reporting and Medical Evaluation: Any known or suspected exposure to *B. anthracis* must be treated as a medical emergency and employees must seek immediate medical care through HealthPartners or University of Minnesota Medical Center - Fairview. The employee should show his/her BSL-3 card, the agent hazard information sheet, and this Anthrax Occupational Health and Safety Plan (if available) to the medical provider. Prophylactic antibiotics may be prescribed for 60-100 days, depending on the employee's vaccine status and the nature of exposure. If the employee has received the full series of vaccines and was wearing personal protective equipment, shorter courses of antibiotics or no antibiotics may be necessary, depending on the level and nature of exposure. If the full course of vaccinations has not been received, an anthrax vaccine may be administered in addition to antibiotics. For a very significant exposure or if symptoms develop, additional measures could include anthrax immune globulin, monoclonal antibodies, or anthrax antitoxin. After medical care is received, all exposures and treatment must be reported to OHS and the IBC and a First Report of Injury form must be completed and submitted to the University's Risk Management Office.

Symptom Monitoring and Reporting Employees must continuously self-monitor for skin lesions and other symptoms, including cough, fatigue, fever, sweats, muscle aches, chest pain, nausea or vomiting, headache, abdominal pain, and shortness of breath. Employees who develop these signs or symptoms should seek immediate medical care and show their BSL-3 card to the medical provider. All treatment received for symptoms consistent with anthrax exposure must be reported to OHS and a First Report of Injury form must be completed and submitted to the University's Risk Management Office (an electronic form is available online at <https://webapps-prd.oit.umn.edu/froi/index.html>). ALL symptoms consistent with possible anthrax exposure must be reported to a supervisor and/or OHS. Symptoms that occur after completing or leaving the project should also be reported to OHS.

Describing an Occupational Health Plan in a Project-Specific Standard Operating Procedure

The Principal Investigator must include the following information in the Occupational Health Plan Appendix as part of their Project-Specific Standard Operating Procedure(s) for a BSL-3 workplan:

1. Identify the type of respiratory protection that will be worn by all personnel.
2. List by name and job title all personnel who will receive:
 - a. Health and safety training
 - b. Medical evaluation
 - c. Respirator clearance
3. Identify who has responsibility for conducting health and safety training and describe how training records will be maintained.
4. Identify who has responsibility for reporting exposures (suspected or real).