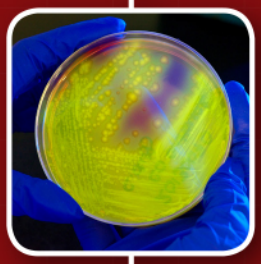

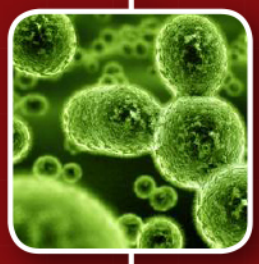

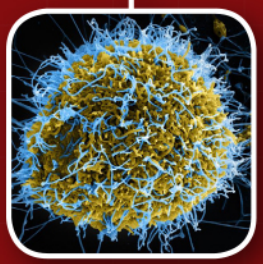

SELECT AGENTS AND TOXINS BIOSAFETY/ BIOCONTAINMENT PLAN GUIDANCE

7 CFR Part 331.12, 9 CFR Part 121.12, 42 CFR Part 73.12

JULY 2018

Centers for Disease Control and Prevention
Division of Select Agents and Toxins

Animal and Plant Health Inspection Service (APHIS)
Agricultural Select Agent Program

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Change/Highlight Section

Revisions: This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from entities registered with the Federal Select Agent Program, as well as the general public, are welcomed. Submit comments directly to the Federal Select Agent Program at:

DSAT: LRSAT@cdc.gov

AgSAS: AgSAS@aphis.usda.gov

Revision History:

March 2017: Initial posting
July 2018: Revised format, removed appendices 1 and 2 and added "Disinfectants" section to appendix.

Introduction

This document is intended to provide guidance and assist entities in developing and implementing a written biosafety/biocontainment plan, as required by section 12 of the select agent regulations (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73). This template summarizes current regulatory and procedural criteria for registered entities and provides examples for verifying compliance. It does not add to, delete from, or change current regulatory requirements or standards. For entities registered for Tier 1 select agents and toxins that require an occupational health program, reference the Occupational Health Program Guidance for more information. It should be noted that information regarding an occupational health program may be incorporated into the biosafety plan and that two separate plans are not required.

There are resources available to assist entities in the development of biosafety/biocontainment plans such as:

- "Biosafety in Microbiological and Biomedical Laboratories (BMBL),"
- "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines),"
- Occupational Safety and Health Administration, "Laboratory Safety Guidance,"
- "Containment Facilities and Safeguards for Exotic Plant Pathogens and Pests" (Robert P. Kahn and S.B. Mathur eds., 1999),
- "*A Practical Guide to Containment: Plant Biosafety in Research Greenhouses*" (Dann Adair and Ruth Irwin, 2008), and
- Detailed instructions on training requirements, including Biosafety/Biocontainment Training, can be found in Guidance for Select Agent Regulation Training Requirements.

These resources can be used as guidance to assist in the development of the biosafety/biocontainment plan. However, entities may use other comparable biosafety/biocontainment guidelines when developing and implementing a written plan. It should be noted that the Federal Select Agent Program inspects registered entities in accordance with the current versions of these nationally recognized standards.

Definitions

As used in this document the following terms have the following meanings:

Decontamination – Disinfection or sterilization of articles contaminated with toxins or agents to make the articles safe for use or disposal.

Disinfection – The elimination of nearly all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores) on inanimate objects.

Risk – The potential for an adverse outcome assessed as a function of threats, vulnerabilities, and consequences associated with an incident, event, or occurrence.

Risk Assessment – The process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable.

Select agents and toxins – A subset of biological agents and toxins that the Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The current list of select agents and toxins can be found at 42 CFR §§ 73.3, 73.4, 9 CFR §§ 121.3, 121.4, and 7 CFR § 331.3. Also see the current select agents and toxins list.

Sterilization – Any item, device, or solution is considered to be sterile when it is completely free of all living microorganisms and viruses. The definition is categorical and absolute (i.e., an item is either sterile or it is not). A sterilization procedure is one that kills all detectable microorganisms, including high numbers of bacterial endospores.

Tier 1 Select agents and toxins – A subset of select agents and toxins have been designated as Tier 1 because these biological agents and toxins present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety: *Bacillus anthracis*, *Bacillus cereus* Biovar *anthracis*, Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium*, *Burkholderia mallei, Burkholderia pseudomallei,* Ebola virus, *Francisella tularensis*, Foot-And-Mouth Disease virus, Marburg virus, Rinderpest virus, Variola major virus (Smallpox virus), Variola minor virus (Alastrim), and *Yersinia pestis*.

Biosafety/Biocontainment Plan Provision Requirements

Hazardous Characteristics of Select Agents and Toxins

It is important that the biosafety/biocontainment plan contain the hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety/biocontainment risk associated with laboratory procedures related to the select agent or toxin.

To assist with identifying the hazardous characteristics of each agent or toxin and the biosafety risk

associated with laboratory procedures related to the select agent or toxin, the BMBL is an excellent reference and includes agent summary statements that describe the hazards, recommended precautions, additional risks, and levels of containment appropriate for handling select agents and toxins in the laboratory. The BMBL also states that HEPA filtration of exhaust air should be required when working with all BSL-4 select agents, and other agents to include: Classical swine fever virus, Reconstructed 1918 influenza virus, Rift Valley fever virus, Venezuelan equine encephalitis virus, and Highly pathogenic avian influenza virus.

The NIH Guidelines provide further guidance on risk assessment, physical containment, and biological containment provisions relating to genetic elements, recombinant nucleic acids and recombinant select agents and toxins.

In addition, AgSAS has developed Guidelines for Avian Influenza Viruses to assist individuals and entities with developing policies and implementing procedures for working safely with these viruses.

In considering hazardous characteristics of each agent or toxin, the entity should discuss the hazards of agent cross-contamination in laboratories performing work with multiple select agents and agent strains to prevent the accidental transfer of agents. Areas to consider are:

- Characteristics of agent or toxin (e.g., virus, bacteria; [e.g., spore or non-spore forming], mode of transmission, etc.), and work being performed
- Work practices to prevent dissemination outside primary containment and exposure
- Engineering Controls to prevent dissemination
- Decontamination of laboratory work surfaces, equipment, and select agent and toxin waste to prevent dissemination

Safeguards for Protecting Against Exposure to Select Agents and Toxins

Section 12(a)(2) of the select agent regulations state that the biosafety/biocontainment plan must include Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to:

- Engineering controls such as containment equipment; including, but not limited to:
  - Biological safety cabinets
  - Animal caging systems
  - Centrifuge safety containers
- Administrative Controls such as vaccinations and the creation of biosafety plans and procedures
- Work Practices such as procedures that describes safe and proper work practices
- Personal protective equipment (PPE)

Please note that the entity should focus and think about the agents and procedures specific to their facility to ensure that they are using the appropriate equipment and practices for the conditions of their laboratory.

Engineering controls

The basic concept behind engineering controls is that, to the extent feasible, the work environment and the biosafety/biocontainment risk associated with the laboratory procedures should be designed to eliminate

hazards or reduce exposure to hazards. Engineering controls should be based on the following principles:

- If feasible, design the facility, equipment, or process to remove the hazard.
- If removal is not feasible, enclose the hazard to prevent exposure during normal operations.
- Where complete enclosure is not feasible, establish barriers or local ventilation to reduce exposure to the hazard during normal operations.

The basic types of engineering controls are:

- Process control
- Enclosure and/or isolation of source
- Ventilation

Some examples of engineering controls may include:

- Building ventilation/exhaust or HVAC (heating, ventilation and air conditioning) must provide safe, comfortable, breathable environments for all employees and the public, and to minimize exposures to hazardous air contaminants. At BSL-3 and BSL-4, exhaust laboratory air must be directly exhausted to the outside since it is considered potentially contaminated. The exhausted room air can be high-efficiency particulate air (HEPA)-filtered to prevent the hazards from being released to the outside environment. The HVAC exhaust system must be sized to handle both the room exhaust and the exhaust requirements of all containment devices that may be present. Adequate supply air must be provided to ensure proper function of the exhaust system.
- Biological safety cabinet (BSC) is an enclosed, ventilated laboratory workspace for safely working with materials contaminated with BSAT. The BMBL is an excellent reference to assist with identifying and selecting a BSC.
- Effluent Decontamination System (EDS) is defined as a system that sterilizes biohazardous liquid waste generated from biocontainment laboratories or other facilities prior to discharge.
- Pathological incinerators, alkaline hydrolysis digesters, or other approved means, must be provided for the safe disposal of the large carcasses of infected animals. Redundancy and the use of multiple technologies need to be considered and evaluated.
- Anaerobic digesters use a biochemical process in which organic matter is decomposed by bacteria in the absence of oxygen. Digesters must be airtight (no oxygen) for anaerobic digestion to occur.

Containment equipment

The containment equipment should focus on:

- Biological safety cabinets [1] Evers et. al. (2013) Laboratory Decontamination of HHS-listed and HHS/USDA Overlap Select Agents and Toxins. Applied Biosafety. 18: 2, pp. 59-72.
- Animal/arthropod caging systems
- Plant growth chambers
- Centrifuge safety containers

Secondary Containment

Secondary containment is the protection of the environment external to the laboratory from exposure to infectious materials and is provided by a combination of facility design and operational practices. Secondary containment may include separation of the laboratory work area from public access, availability of decontamination equipment (e.g., autoclave), separate clean and dirty corridors, double entry ways, air locks, hand washing facilities, etc.

Enclosure and Isolation

An enclosure keeps a selected hazard "physically" separated from workers. Enclosed equipment, for example, is tightly sealed and it is typically only opened for moving samples/cultures or for cleaning and maintenance. Examples include closed animal caging, "glove boxes" or Class III biosafety cabinets. Care must be taken when the enclosure is opened for maintenance as exposure could occur if adequate precautions are not taken. The enclosure itself must be well maintained to prevent leaks.

Isolation places the hazardous process "geographically" away from the majority of the workers. Common isolation techniques are to create a contaminant-free area either around the equipment or around the employee workstations.

Administrative Controls

Administrative controls are those that modify workers' work schedules and tasks in ways that minimize their exposure to workplace hazards. Examples include vaccinations and developing plans and procedures to reduce the risk to the worker. The plan should explain the following:

- Process controls should be appropriate for the activities performed and the select agent or toxin in use. Biosafety/biocontainment levels are dependent on the risks of the work being performed.
    - For example, the BMBL recommends BSL-3 practices, containment equipment and facilities for all manipulations of suspect cultures of *Francisella tularensis*. In contrast, BSL-2 practices, containment equipment, and facilities are recommended for diagnostic activities involving infectious cultures of *Bacillus anthracis, Burkholderia mallei, Burkholderia pseudomallei,* and *Yersinia pestis,* where there is no propagation of the agent or risk of aerosol or droplet formation only. All other activities with these agents are to be conducted at BSL-3.
- Describe detailed safety measures to ensure that primary and secondary containment are maintained during especially hazardous procedures (e.g., intentional production of select agent infectious aerosols or select toxin aerosols).

Work Practices

Work practices should involve procedures to reduce the risk of exposure (e.g., hand washing, spill procedures, using foot decontamination methods, maintaining the concept of clean and dirty spaces, etc.). Monitoring should be done before and after any change is implemented to make sure a change results in lower exposures. The plan should also describe the biosafety and containment procedures employed for experimentally exposed or infected animals or plants, if applicable:

- When animals or plants are to be infected with or exposed to select agents, describe the administration route(s) employed and the equipment used.
- Describe in detail appropriate containment of all organic material (select agent-infected carcasses, tissues, plant biomass) until final destruction (e.g., autoclave, incineration, etc.).
- Describe or reference procedures to monitor animals or plants for accidental infection.
- Describe procedures to ensure containment of animals accidentally exposed to or infected with select agents. Considerations for developing these procedures include but are not limited to, situations where an airflow reversal has occurred from a room harboring experimentally infected

animals to an adjacent room housing native animals; or movement of personnel, equipment, or laboratory waste from a select agent area to a non-select agent area has resulted in accidental exposure.

- When animals infected with select agents are either loosely housed or housed in open caging, there is an increased potential of room-level select agent contamination. Unless it can be demonstrated that the animal model does not shed the agent, the increased hazard of not using containment caging must be mitigated by procedural or facility enhancements.

Personal protective equipment (PPE)

In determining the PPE and other safety equipment needed, consider the hazardous characteristics of each agent or toxin listed on the entity's registration and the risk associated with laboratory procedures related to the select agent or toxin. The PPE and other safety equipment should focus on:

- Breathing or respiratory protection
- Eye and face protection
- Head protection
- Hearing protection
- Hand/arm protection (gloves, sleeves)
- Foot protection
- Full body protection

When considering laboratory clothing, the entity needs to determine what PPE should be worn to prevent hazards from leaving the laboratory (i.e., how clothing can be a fomite to carry BSAT out of laboratories and how the clothing should be cleaned, disinfected, or disposed, should street clothes being worn or wearing scrubs or full body PPE, should individuals shower out, include general principles for separation of clean and dirty boundaries). Employees should be educated that PPE must not be worn outside the containment laboratory except when transporting samples between laboratories within containment. It must not be worn (or stored) in break rooms, office areas, toilets, or outside the building. Employees must be properly instructed on how to don (put on) required PPE before entering an area with a potential hazard that requires the use of the PPE. Procedures for employees to remove (doff) required PPE before leaving the area of potential exposure should be structured to prevent transfer of infectious material outside laboratory room, as well as protect workers from exposure to infectious agents during exit procedures.

Biological Safety - Personal Protective Equipment (PPE) Requirements*

BSL-1	BSL-2	BSL-3	BSL-4
• **Protective laboratory coats, gowns, or uniforms** recommended to prevent contamination of personal clothing. • **Protective eyewear** worn when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Personnel who wear contact lenses in laboratories should also wear eye protection. • **Gloves** must be worn to protect hands from exposure to hazardous materials.	• **Protective laboratory coats, gowns, smocks, or uniforms** must be worn while working with hazardous materials. • **Eye and face protection** (goggles, mask, face shield or other splatter guard) must be used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms are handled outside the Biological Safety Cabinet (BSC) or physical containment device. Personnel who wear contact lenses in laboratories should also wear eye protection. • **Gloves** must be worn to protect hands from exposure to hazardous materials. • **Eye, face and respiratory protection** should be used in rooms containing infected animals.	• **Protective laboratory clothing with a solid-front**, such as tie-back or wrap-around gowns, scrub suits, or coveralls must be worn. • **Eye and face protection** (goggles, mask, face shield or other splash guard) must be used for anticipated splashes or sprays of infectious or other hazardous materials. [All procedures involving the manipulation of infectious materials must be conducted within a BSC, or other physical containment devices.] Personnel who wear contact lenses in laboratories must also wear eye protection. • **Gloves** must be worn to protect hands from exposure to hazardous materials. • **Eye, face, and respiratory protection** must be used in rooms containing infected animals.	• Cabinet Laboratory: All work is conducted in a class III biosafety cabinet, • All materials appropriately decontaminated (disinfectant tank) prior to removal from biosafety cabinet. • The class III biosafety cabinet serves as engineering control to prevent worker exposure to infectious agents and material. • Protective Suit Laboratory: All work is conducted within a class II biosafety cabinet with the Use of a positive pressure suit connected to a HEPA filtered airline. The positive pressure suit completely isolates the laboratory worker from the laboratory environment, ensuring there is no contact with potentially hazardous material. Laboratory personnel who work in positive pressure suits require significant training.

Disinfection, Decontamination or Destruction of Select Agent and Toxin[1]

See the Inactivation guidance for more information on the inactivation of and rendering samples free of select agents and select toxins for future use. In addition, reference Appendix I: Principles of decontamination, sterilization, and disinfection provides additional information regarding decontamination and disinfection.

For material that is disinfected, decontaminated, or destroyed as waste, section 12(a)(3) states that the biosafety/biocontainment plan must contain written procedures for each validated method used for disinfection, decontamination, or destruction, as appropriate, of all contaminated or presumptively contaminated material including, but not limited to:

- Cultures and other materials related to the propagation of select agents or toxins
- Items related to the analysis of select agents and/or toxins

[1] Evers et. al. (2013) Laboratory Decontamination of HHS-listed and HHS/USDA Overlap Select Agents and Toxins. Applied Biosafety. 18: 2, pp. 59-72.

- Personal protective equipment
- Animal caging systems and bedding (if applicable)
- Animal carcasses or extracted tissues and fluids (if applicable)
- Plant biomass (if applicable)
- Laboratory surfaces and equipment
- Surfaces of transport containers
- Effluent material

The plan should describe the following:

- Adherence to the concentration and contact time specified by the manufacturer of a disinfectant during laboratory surface decontamination procedures to be effective in decontaminating the select agent and toxin material.
- Ensure that procedures follow any equipment manufacturer guidance on the disinfectants compatible with their equipment.
- Define waste management procedures based on the types of waste generated (e.g., PPE, plates, liquids, eggs, animal caging, carcasses, sharps) and the containers most appropriate for the types of waste being produced.
- Describe in detail safety procedures for decontaminating reusable sharps.
- Describe the procedure for safe transport of waste to the decontamination site, including the location of the decontamination equipment in relation to the laboratory generating the waste. Transport procedures must take into account any safety requirements to protect personnel and the environment during transport.
- Specify the actual method(s) used to decontaminate select agent and toxin waste (e.g., autoclave, incinerators, renderers, tissue digester, chemical, etc.).
- Describe the means of verifying that decontamination equipment is operating correctly, and how often verification is performed (i.e., biological indicators [BIs], confirmation of cycle parameters).
    - For autoclave verification, BIs or parametric monitors should be placed in the center of the load in a manner expected to provide the maximum challenge for steam penetration. When BIs are used, they should be incubated for the length of time stated by the manufacturer and a positive control should be used. The temperature of the material to be autoclaved must be considered when verifying the autoclave parameters (e.g., frozen carcasses will require a longer sterilization time than non-frozen carcasses).
    - For chemical decontamination, the chemical used must be appropriate for the select agent or toxin (Manufacturers normally test surrogates and not select agents and toxins. This would be acceptable), and the chemical concentration and contact time must be defined in the procedure. The procedure should also address whether chemicals used for decontamination must be freshly prepared or can be stored, and the shelf life if stored.
- Describe the method(s) used to decontaminate laboratory surfaces and equipment (e.g., chemical surface decontamination, or space fumigation using Vaporized Hydrogen Peroxide, paraformaldehyde, or chlorine dioxide). The method selected must be appropriate for the

equipment and the select agents and toxins used in the laboratory. Procedures should indicate contact time required which may be variable depending on agent and equipment.
    - Fumigation used as a means to inactivate select toxins requires the use of a published method or method validation.
    - Fumigation procedures for select agent inactivation should include the use of biological indicators to verify adequate decontamination.
- Describe how entity personnel are notified of the status of decontamination of laboratory surfaces and equipment.
- Describe how entity personnel are notified of ongoing or completed decontamination activities for laboratory spaces.
- Describe when laboratory surfaces and equipment should be decontaminated.

Note: Although the regulations require written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials, an entity does not have to validate the method in-house. A validated method is a method that has been shown to render materials safe to handle (i.e., safe in the context of being reasonably free from a risk of disease transmission). The validation of methods for disinfection, decontamination or destruction of select agent waste does not have to occur in-house since this material is not for future use. Further, validation does not have to be performed on select agents but can be performed on surrogates. However, entities must use the concentrations and conditions prescribed by manufacturers, the BMBL, or other government regulations, such as those promulgated by the Environmental Protection Agency (EPA). The inactivation provisions for future use material do not apply to disinfection, decontamination or destruction of select agent waste.

Handling Select Agents and Toxins in Shared Spaces

Section 12(a)(4) of the regulations requires the entity to describe procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins in order to prevent unintentional contamination. For example:

- Laboratory work surfaces, equipment, and all select agent and toxin waste that must be decontaminated prior to transitioning to work with non-select agents or toxins.
- How personnel are made aware of the status of any particular room or laboratory at any given time.
- Spatial and/or temporal considerations when performing tissue culture studies.
- Any concurrent work with Reconstructed 1918 Influenza virus and highly pathogenic avian influenza virus.
- Sterilization of all samples at the end of the study/experiment/procedure.

Precautions should be taken to prevent cross-contamination of viral select agents in cell cultures. Some means of preventing accidental transfer of agents between cultures include:

    - Working with only one select agent at a time.

- Decontaminating biosafety cabinet with a surface disinfectant between select agents and toxins.
- Allowing a certain amount of time to pass between decontamination and beginning work with another select agent.
- Changing gloves when changing from one select agent to another.
- Aliquoting growth medium and other reagents so that the same vessel is not used for more than one select agent.

Appendix I: Principles of decontamination, sterilization, and disinfection

Decontamination

Decontamination can include a number of processes that render an area, device, item, or material safe to handle (i.e., safe in the context of being reasonably free from a risk of disease transmission). The primary objective is to reduce the level of microbial contamination so that infection transmission is eliminated. The decontamination process may include a cleaning step prior to disinfection or sterilization.[2]

Cleaning

Cleaning is a process that can be an important adjunct in the decontamination process by removal of organic and inorganic materials from objects and surfaces prior to sterilization or disinfection. This process can remove a large number of microorganisms as well and the organic matter protecting them. Cleaning is normally accomplished manually or mechanically using water with detergents or enzymatic products. Liquid for cleaning should be treated as liquid biohazardous waste.

Disinfection

Some chemical germicides used as disinfectants do, in fact, kill large numbers of spores, though high concentrations of the chemical germicides and several hours of exposure may be required. Non-sporicidal disinfectants may differ in their capacity to accomplish disinfection. Some germicides rapidly kill only the vegetative forms of bacteria such as staphylococci and streptococci, some forms of fungi, and lipid-enveloped viruses, whereas others are effective against such relatively resistant organisms as *Mycobacterium tuberculosis* var. *bovis*, non-lipid viruses, and most forms of fungi.[3]

The effectiveness of a disinfection procedure is controlled by several factors, including:

- Nature and number of contaminating microorganisms (especially the presence of bacterial spores)
- Amount of organic matter present (e.g., soil, feces, and blood)
- Type and condition of instruments, devices, and materials to be disinfected
- Temperature
- Time
- pH
- Water hardness
- Other chemicals used (e.g., mixing with certain detergents)

Sterilization

Results from sterilization procedures, however, can only be expressed in terms of the probability of viable

[2] Fraise, AP. (2004) Decontamination of the environment and medical equipment in hospitals. In *Principles and Practices of Disinfection, Preservation and Sterilization,* 4th edition eds Fraise, AP, Lambert, PA and Maillard J-Y, p 565.
[3] BMBL, p 327

organisms surviving after a sterilization procedure.[4] A probability level of less than one in one million microbial survivors (10^{-6}) after treatment is a commonly accepted measure of sterility. This is referred to as the "sterility assurance level."[5]

Decontamination of Solid and Liquid Wastes

All laboratory waste materials, contaminated animal or plant materials, and personal protective equipment (PPE) that are contaminated with BSAT should be decontaminated prior to removal from BSAT registered containment areas. However, there are situations when equipment used for terminal decontamination such as autoclaves, incinerators, digesters, renderers, or effluent decontamination systems (EDS), are located outside of registered BSAT spaces.

If the solid waste decontamination area (e.g., such as autoclave rooms, digester or renderer rooms, and incinerator facilities) is not inside the containment barrier of the laboratory, an entity should ensure the following practices are in place (Note: The area would not need to be listed on an entity registration or separately registered as long as the area is not used for the storage of BSAT solid waste):

- Ensure that a person who has FSAP approved access to BSAT (approved by FSAP to have access to BSAT subsequent to a FBI security risk assessment) transports solid BSAT waste. For a Tier 1 BSAT, or material contaminated with a Tier 1 BSAT, the person also must be enrolled in the entity's personnel suitability program.
- Transport waste by FSAP approved staff using personal protective equipment (PPE) deemed appropriate for the agent or toxin as determined by a risk assessment.
- Transport solid waste to the decontamination unit in leak-proof sealed containers. The outside surface of these containers must be decontaminated with an appropriate disinfectant before being removed from containment. Place the container in the decontamination apparatus. The container must remain sealed until the decontamination cycle is completed.
- Start the decontamination unit as soon as the material is placed in the unit. The FSAP approved person must confirm to his satisfaction that the decontamination cycle has begun. This person is not required to remain in the area during the entire decontamination cycle but only to be reasonably assured that the cycle has begun.
- The FSAP approved person confirms that the decontamination cycle, using system settings validated to render the contaminated material non-infectious or non-toxic, has been completed according to system specifications.
- Keep the decontamination unit on a maintenance schedule. Maintenance schedules usually include periodic spot-checks for problems, semi/annual service, and re-certification by a qualified technician.
- Create a process for verifying all parameters of the decontamination cycle have been attained (e.g., recording tape, biological indicators, probes, etc.).
- Maintain written documentation that the decontamination procedure is validated for the specific agent, toxin, and/or material decontaminated.
- Maintain a chain of custody document for solid waste that leave registered spaces for decontamination.
- Check if the decontamination apparatus is working properly and is adequately maintained.

The entity incident response plan should include a plan for material that leaves the laboratory to be

[4] Lambert, PA. (2004) Sterilization. In *Principles and Practices of Disinfection, Preservation and Sterilization,* 4th edition eds Fraise, AP, Lambert, PA and Maillard J-Y, p 389.
[5] Baird, RM. (2004) Sterility assurance: concepts, methods and problems. In *Principles and Practices of Disinfection, Preservation and Sterilization,* 4th edition eds Fraise, AP, Lambert, PA and Maillard J-Y, p 526-539.

decontaminated offsite and for material that remains in the building. Ideally, waste should not be transported through an unregistered area. If the entity has no other option, include a description in the entity's incident response plan addressing how the entity will deal with a spillage or release. The plan must also include procedures for documenting unintended spills or accidents during transport. There is a requirement for the notification of the appropriate Federal, state, and/or local officials and first responders in the event of an offsite spill.

Ensure that procedures are in place for decontamination of personnel and the PPE worn by personnel responding to a spill. As needed, include medical surveillance after potential exposure to select agents and toxins during the clean-up process.

Any departure from a standardized method protocol should be revalidated. The entity could validate the autoclaved decontamination method used with a biological indicator, such as *Geobacillus stearothermophilus*.

Liquid waste that is not decontaminated in the solid waste decontamination stream may be decontaminated by several means. Contaminated liquid from showers may be disinfected by chemical disinfectant following manufacturer's specifications including purging the plumbing trap before and after the shower. Contaminated liquid waste may be decontaminated by holding in a container or sink with a chemical disinfectant for the appropriate amount of time. An EDS, while not required, may also be utilized if large amounts of liquid waste, such as liquid from showers and from animal holding facilities, are generated. If the entity has an EDS, the entity should conduct the following practices:

- Restrict access to the EDS. Non-FSAP-approved staff or visitors should be monitored and allowed controlled access for official duties only.
- Create and maintain written documentation that the decontamination procedure is validated for the specific agent, toxin, and/or material being decontaminated.
- Validate any changes in standardized methods.
- Keep a regular maintenance schedule. Maintenance schedules may include daily or monthly checks or regular service.
- Validate the EDS system under actual in-use conditions that may include high levels of bioburden or high matrix content, such as in infected animal holding areas.
    - This may include use the solid waste decontamination process above for disposing of animal bedding and/or high volume of fecal matter.
- Maintain training records that the EDS operation staff have been trained on how to respond to leaks and spills.
- Inspect the pipe leading from the containment area to the EDS to ensure it is sealed at least annually. A double walled pipe is preferred.
- Put procedures and structures in place to contain more liquid than the EDS system would process in the event a spill of the liquid from the EDS tanks (e.g. a berm surrounding the EDS tanks that holds greater volumes than the tanks).
- Ensure that procedures are in place for the cleanup and decontamination of a spill from the EDS.