Boston Public Health Commission

Biological Laboratory Safety Permit Application

SECTION 17: BSL-4 WASTE DISPOSAL PLAN

Boston University

National Emerging Infectious Diseases Laboratories

November 2014

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1.0 PURPOSE AND APPLICABILITY

The purpose of the BSL-4 Waste Disposal Plan for the National Emerging Infectious Diseases Laboratories (NEIDL) located at the Boston University Medical Campus is to describe the processes through which all waste (non-infectious and infectious) will be removed from the BSL-4 containment laboratories for disposal. This plan identifies the mechanisms employed, the responsible individuals, and the processes that are followed to ensure proper removal and efficacy of the waste disposal procedures.

2.0 ROLES AND RESPONSIBILITIES

2.1 Director, Research Safety Division, Environmental Health & Safety

The Director of Research Safety in the Environmental Health & Safety (EHS) department is responsible for the management of the NEIDL Research Safety Program. This responsibility includes: 1) oversight of the planning and execution of waste disposal procedures in the BSL-4 suite; 2) oversight of all training on waste disposal procedures; and 3) oversight of EHS functions such as waste processing and record keeping.

2.2 Principal Investigator

The Principal Investigator (PI) is an authorized individual approved by the Responsible Official (RO). The PI is responsible for the scientific and technical direction of a Select Agent or Toxin project or program. The waste disposal responsibilities of the PI include ensuring that all authorized individuals under his or her direction understand and comply with BU waste management requirements, which include 1) waste disposal training and practice exercises; waste disposal policies and operating procedures, including preparation of waste materials inside BSL-4 laboratories; 3) chemical inventory management and approval policies; and 4) reporting all

accidents, spills, incidents, and exposures to the RO and the Research Occupational Health Program as described in Section 7 Disease Surveillance Plan.

2.3 Responsible Official

The Responsible Official (RO) is an authorized individual with responsibility, authority, and control to ensure compliance with the Centers for Disease Control and Prevention (CDC) and Animal and Plant Health Inspection Services (APHIS) Rules and Regulations pertaining to the possession, use, and transfer of Select Agents and Toxins. Boston University Medical Center (BUMC) has designated the Director of Research Safety to serve as the RO. The RO will ensure the proper disposal of all Select Agent materials. In the event of an incident, the RO will oversee the proper disposal of materials involved and will report the results of these efforts to CDC and APHIS.

2.4 Associate Vice President for Research Compliance

The Associate Vice President for Research Compliance (AVP-RC) is responsible for: 1) oversight of the control of hazards in the research laboratories and ensuring that comprehensive, enterprise-wide programs are in place for the safe handling of all hazardous materials (e.g., biological, chemical, radiological) and 2) all non-financial research compliance at BU and Boston Medical Center (BMC). The AVP-RC has direct functional responsibility for EHS and the Biosafety Program, the Institutional Biosafety Committee (IBC), the Charles River Institutional Review Board (IRB), laboratory safety committees, the Institutional Animal Care and Use Committees (IACUC) and laboratory animal use and care programs, the responsible conduct of research, and other research-related oversight committees.

The AVP-RC will be informed by the Responsible Official (CDC, APHIS required) of normal waste disposal operations and will be immediately informed of all incidents involving waste management.

2.5 Director, NEIDL Facilities

The Director of NEIDL Facilities is responsible for maintaining the building systems and equipment necessary for the decontamination and disposal of wastes generated in the BSL-4 laboratories. The Director will assist the Director of Research Safety with all building operational issues concerning waste disposal.

2.6 Core Supervisors

The supervisor for each of the NEIDL scientific cores shall be responsible for daily operations for that core, including oversight of waste disposal practices that are carried out by BSL-4 laboratories

authorized individuals. The core supervisor acts as an operations manager for waste disposal and other functions of each NEIDL core.

2.7 BSL-4 Laboratory Authorized Individuals

All authorized individuals of the BSL-4 suite will abide by all requirements set forth by the PI, RO, AVP-RC, and EHS and work according to all appropriate standard operating procedures (SOPs). This will include: 1) compliance with all safety training; 2) compliance with all chemical inventory approval and management policies; 3) adherence to established waste disposal practices; 4) knowledge of notifications and response actions in emergencies or incidents involving waste disposal; and 5) initiation of autoclave operation cycles and maintenance of an operational log.

3.0 WASTE DISPOSAL METHODS

3.1 Basic Concepts

Management of wastes from a BSL-4 laboratory involves two principal steps.

1. Decontamination of all waste materials generated within a BSL-4 laboratory through a containment barrier decontamination process.
2. Disposal of waste materials.

The first step, removing wastes from containment, is achieved only through waste decontamination. All waste generated in a BSL-4 laboratory is considered to be contaminated. Therefore, the process of waste disposal cannot begin until each waste product has been completely decontaminated. No product or waste can be removed from a BSL-4 laboratory unless it has gone through one of the following processes:

- Steam decontamination in a pass-through autoclave;
- Chemical decontamination and flushing to the liquid effluent decontamination tanks;
- Chemical decontamination via the pass-through chemical “dunk tank”. or
- Chemical or gaseous decontamination in the airlock or as part of laboratory decontamination.

The determination of methods to decontaminate BSL-4 laboratory waste materials requires an evaluation of the characteristics of each waste stream generated. No single method is appropriate for all BSL-4 waste. A combination of methods may be required to render wastes safe for removal from containment. Four general categories of waste streams exist in a BSL-4 laboratory, and each is described in more detail later in this plan:

- Biological Wastes
- Chemical Wastes

- Radioactive Wastes
- General Laboratory Wastes

The decontaminated waste streams that exit a BSL-4 laboratory are ready for final disposal. General disposal methods include:

- Off-site incineration for decontaminated biological waste;
- Sanitary sewer discharge for decontaminated liquid wastes;
- Sanitary sewer discharge for decontaminated animal carcasses and tissues following alkaline hydrolysis tissue digestion treatment to solubilize the waste;
- Management of decontaminated hazardous chemical and radioactive wastes according to federal, state, and local regulations.

3.2 Decontamination of Waste Materials

3.2.1 Autoclaving

Most solid laboratory wastes can be effectively decontaminated in a "pass-through" type autoclave utilizing heat, steam, and vacuum pressure to destroy microorganisms. Operating parameters for autoclaves are set by establishing standard load sizes, types, and processing times for different types of waste. The operating parameters are validated using chemical and biological indicators placed within test loads.

During daily operations, each load of autoclaved waste that comes from a BSL-4 laboratory includes both chemical and biological indicators to ensure full destruction of microorganisms and to verify that the loads are safe to handle for final treatment and disposal. Autoclave cycles are documented on an autoclave log sheet with data that includes the amount of waste, the actual autoclave parameters attained, and the success of validation.

With the exception of animal carcasses and tissues, all waste autoclaved from a BSL-4 laboratory is further packaged for shipment and disposal as medical waste. Once properly packaged, the shipping containers are catalogued on a shipping manifest and transported by an authorized third-party handler for final disposal. EHS manages the shipping documents and verifies that each container was successfully destroyed.

All animal carcasses, parts, and tissues are collected for final treatment on-site by alkaline hydrolysis tissue digestion. These wastes exit the autoclave, are transferred to a closed transportation cart, and are brought to the digestion chamber. Tissue digestion uses high temperature potassium hydroxide to convert animal and tissues to a sterile, neutral, aqueous solution that is safe for discharge to the sanitary sewer. Loads of animal wastes processed in the tissue digester are documented.

3.2.2 Chemical Decontamination

Chemical decontamination is used for waste items that are not safe for autoclaving, for liquid wastes, and as an extra step in the decontamination of some solid wastes that are generated inside a biological safety cabinet.

Some small items that cannot be autoclaved, such as chemical waste containers, are chemically disinfected in dunk tanks prior to removal from a BSL-4 laboratory. Waste materials are inactivated inside the BSL4 laboratory according to established protocols and placed in sealed, leak-proof containers which are completely submerged in the bath of disinfectant liquid at the dunk tank. The chemical disinfectant is replenished routinely and the concentration is monitored by measuring the chemical's conductance. In some instances, it is preferable to chemically decontaminate larger non-autoclavable wastes and then process them out via the fumigation airlock. Solid items with direct contact to live agents inside a biological safety cabinet, such as pipette tips, are chemically decontaminated prior to entering the autoclave waste stream.

Chemical decontamination of liquids involves the mixing of a chemical disinfectant with a potentially contaminated liquid waste. The disinfectant concentration, mixing process, and contact time are predetermined by validation.

Decontaminated liquid waste flows from the sinks and floor drains to a secondary barrier Liquid Effluent Decontamination System. The Liquid Effluent Decontamination System consists of three, redundant 1,500-gallon decontamination tanks. Pressurized steam heats the transfer jackets, increasing the temperature of the waste in an inner chamber to a validated sterilizing temperature for a predetermined cycle. The tank's validated cycle is monitored and verified before discharging the waste to the sanitary system.

3.2.3 Gaseous and Vapor Decontamination

Gaseous and vapor decontamination is used when it is necessary to ensure decontamination of all surfaces within a space, to ensure decontamination of a piece of equipment or a waste product that has difficult-to-reach surfaces, or to decontaminate waste items which cannot be safely autoclaved or passed through the dunk tank. The process of gaseous and vapor decontamination consists of the generation and dispersal of a gas or vapor chemical agent, such as chlorine dioxide or hydrogen peroxide. The compound effectively diffuses throughout a space coming into contact with every exposed surface. Parameters of this process are validated with biological indicators. An important requirement prior to gaseous or vapor decontamination is the preparation of the equipment or waste product by opening

equipment panels, removing closures and caps to ensure contact, and thoroughly pre-cleaning all surfaces.

Gaseous or vapor decontamination can be accomplished on a small scale to sterilize a single piece of equipment or on a laboratory-wide scale to sterilize the entire BSL-4 laboratory.

3.3 Initial Validation and Continual Verification

All methods of decontamination undergo a validation process to design effective processes and are continuously verified to ensure efficacy over time. To validate a decontamination process, physical parameters must be established in advance. These parameters include: the nature of the material being decontaminated, exposure time, and method-specific limits such as temperature or chemical concentration. A biological indicator is then employed to test that the specific set of physical parameters allows for complete decontamination. After a decontamination cycle, the biological indicator is examined to determine the efficacy of the process. The biological indicator is processed by incubation at an appropriate temperature for the biological indicator to validate the process. The absence of growth indicates confirmation that the indicator was inactivated and assurance that the material was decontaminated.

In the case of a liquid chemical application, a concentration minimum must be maintained and documented, along with the contact time of the chemical to the material being decontaminated. In a heat cycle, the validated parameters are the maximum mass of the material, type of container or packaging, load placement, and the temperature and time period of the cycle. Additional factors that may impact gaseous or vaporous chemical decontamination include room temperature and relative humidity.

Initial validation test results will be provided to the Boston Public Health Commission (BPHC).

3.3.1 Autoclaving

Each autoclave cycle is validated by temperature mapping of the entire chamber and using multiple biological indicators and temperature data-loggers in test loads representing the waste type being decontaminated. Three consecutive runs with complete biological indicator destruction are necessary before an autoclave cycle is considered validated.

Each load of autoclaved waste is verified using chemical and biological indicators placed within a load of waste. The chemical indicator is immediately examined following an autoclave cycle to confirm that the required heat parameters were met. The biological indicator, such as *Geobacillus stearothermophilus*, is then separated from the load and incubated at 55°–60°C for 24 hours. The absence of growth verifies that the waste has been decontaminated using the chosen autoclave cycle parameters.

3.3.2 Validation of Chemical Decontamination and Gaseous Decontamination

The efficacy of chemicals as disinfectants is established through a combination of factors: chemical manufacturer efficacy data, Environmental Protection Agency (EPA) registration and efficacy data, relevant scientific literature, and empirical data (including use of biological indicators) collected in-house at other BSL-4 laboratories. EHS evaluates chemical efficacy data, which is considered validated only upon approval by the IBC. Decontamination procedures using gas or vapor agents are also validated through the use of biological indicators.

Verification of chemical decontamination is accomplished by ensuring that validated parameters, such as chemical concentration, contact time, and chemical shelf life are rigorously maintained and monitored during laboratory operations. All decontamination events that use gas or vapor agents are verified using biological indicators.

3.3.3 Liquid Effluent Decontamination System

The validation process for the Liquid Effluent Decontamination System relies on data-logging temperature sensors and biological indicators deployed throughout the interior of each vessel. Cycle parameters are approved when temperatures and biological indicator destruction at each tank location confirm effective decontamination.

Each cycle of decontamination through the Liquid Effluent Decontamination System is monitored for proper operation, pressure, time, and temperature. To further verify the efficacy of this system, biological indicators are added through specific ports in the tanks. Incubation and examination of growth/no growth from the biological indicators is used with recorded cycle parameters to verify effective decontamination.

3.3.4 Tissue Digester System

The tissue digester is used for final processing and disposal of animal carcasses, tissues, and organs. Validation of this system is achieved using biological indicators processed with large animal carcasses, such as turkey breasts or pigs. The indicators are not digested during the tissue digestion process and are retrieved for incubation and to confirm agent destruction.

Verification of tissue digester cycles is accomplished by documenting cycle parameters for each load and with quarterly placement and incubation of biological indicators.

3.3.5 Chemical Dunk Tank

Chemical decontamination is validated as described in section 3.3.2. In the case of the dunk tanks, Microchem Plus has been established as the decontamination chemical. A 5% solution, measured as 3,500 micro Siemens via a conductivity test, is the effective concentration. This concentration of Microchem Plus has been tested and verified by the manufacturer to be effective for the disinfection of lipid enveloped viruses and has been used effectively for several years by other BSL-4 laboratories.

Verification of the disinfectant chemical in the dunk tank is accomplished as part of the daily safety checks performed by EHS. The conductance of the disinfectant is checked using a conductance meter to verify appropriate chemical concentration. Furthermore, the chemical in the dunk tank is refreshed monthly to ensure that the disinfectant is kept fresh.

4.0 WASTE DISPOSAL APPLICATIONS

This section catalogues the categories and subcategories of waste that may be generated in a BSL-4 laboratory. Waste materials are removed from the laboratory at the end of each day. After decontamination, wastes are stored outside the laboratory to await final disposal.

4.1 Biological Waste

4.1.1 Solid and Semi-solid Waste

Description of Waste: Includes animal bedding and feces, solid growth media containing infectious agents, and solid wastes generated in a biological safety cabinet (BSC).

Generation and Accumulation: The manipulation of microbial agents occurs only inside a BSC. All solid wastes generated in the BSC are collected inside a container filled with approved disinfectant chemical or collected within an autoclave bag. All solid wastes generated inside a biological safety cabinet which have had direct contact with a live agent must be soaked in disinfectant (e.g., pipettes, pipette tips, tubes, etc.). All other solid wastes (e.g., pipette wrappers, paper towels, etc.) must be collected in an autoclave bag and sprayed with disinfectant prior to being removed from the BSC.

In animal facilities, solid or semi-solid animal wastes, including bedding and feces, are sprayed with chemical disinfectant while still in the cages and trays they were generated in. The entire cage is staged for autoclaving in a dedicated autoclave unit.

All containers and bags for the collection of biological waste are labeled with the biohazard symbol. When approximately 50% full, bags are loosely closed (to allow a free exchange of

steam during the autoclave cycle) with autoclave tape, and staged inside a BSL-4 laboratory for decontamination.

Decontamination: At the end of each workday, all loosely closed bags and cages are decontaminated in the autoclave as described in sections 3.2.1 and 3.3.1 of this Plan. Bags and cages are loaded into the autoclave on the containment side of a BSL-4 laboratory, decontaminated, and then removed from the autoclave from the non-containment side of the BSL-4 laboratory. Autoclave runs are recorded on an autoclave log sheet.

Final Disposal: Decontaminated animal bedding and solid wastes are removed from the cages and double-bagged in a biohazard bag. These bags, along with other decontaminated autoclave bags, are packaged for shipment and disposal as regulated medical or biological waste. This process involves bags being secured in rigid boxes that are packed and labeled for transport according to Massachusetts Department of Public Health and U.S. Department of Transportation (DOT) regulations.

Full boxes are sealed with tape and stored in a dedicated waste storage area. The storage area has restricted access and is posted with the biohazard sign and the words "biological waste." Boxes are removed from this room and shipped off-site for final destruction by an authorized third-party biological waste disposal company. Boxes containing animal bedding are routed for incineration as the only acceptable means of destruction.

4.1.2 Animal Carcasses, Parts, and Tissues

Description of Waste: Includes whole animal carcasses, animal parts, and tissues.

Generation and Accumulation: Animal carcasses are generated any time an animal expires during research. Animal parts and tissues are generated during necropsy or during the processing of animal tissues inside the BSL-4 suite.

Carcasses, waste parts, and tissues are collected in containers that are double-lined with disposable biohazard bags. As wastes are added to the bags, chemical disinfectant is sprayed over the top. Both the bags and the containers are labeled with the biohazard symbol. Non-animal wastes such as contaminated absorbent materials and bench chucks are discarded into separate biohazard bags for autoclaving and disposal as biological wastes. No aluminum or metal tags or objects can be placed in the bags with animal tissues.

Decontamination: All loosely closed bags are decontaminated in the autoclave according to predetermined and validated parameters and cycle times, depending on species type and load size.

Final Disposal: Decontaminated biohazard bags are removed from the autoclave, placed in closed transport containers, and brought to a freezer for staging. When a full load is generated, bags of waste are brought from the freezer to the tissue digester room, loaded into the digestion basket, and lowered into the tissue digestion unit. The unit weighs and records each load, and uses high-temperature potassium hydroxide to digest the animal material into a sterile, neutral, aqueous solution that is safe for discharge to the sanitary sewer system.

4.1.3 Cultures, Stocks, and Contaminated Liquids

Description of Waste: Includes liquid cultures, stocks of agents, and blood and bodily fluids from research specimens.

Generation and Accumulation: Cultures and stocks of microbiological agents are only manipulated inside BSCs. These wastes are collected and chemically disinfected inside the BSC before removal from the BSC.

Animal blood and bodily fluids are generated during necropsy or during animal care in the animal facility. Fluids that are collected via collection trays at necropsy areas or underneath animal cages are chemically disinfected prior to disposal into sinks or drains. Fluids that are absorbed into bench chucks are placed in biohazard bags for autoclaving and disposal as biological wastes, as described above.

Decontamination: Chemical disinfection of liquid material(s) in the BSC or other point of generation is left to occur for an appropriate contact time. Subsequently, all wastes are disposed of into the sinks or floor drains in a BSL-4 laboratory.

Final Disposal: Downstream of the BSL-4 sinks and floor drains are three, 1,500-gallon Liquid Effluent Decontamination System tanks. The tanks' successful cycle completion is monitored and verified before discharging to the building's sanitary drainage system.

4.1.4 Sharps

Description of Waste: Sharps should not be used in the BSL-4. In the event that no safer substitute is feasible, any sharp use will be reviewed and approved by EHS. Disposable items include syringes, needles, scalpel blades, glass slides and cover slips, and broken glass. Not included in this section are reusable necropsy instruments.

Generation and Accumulation: Sharps and glass objects are used sparingly and only when absolutely necessary in a BSL-4 laboratory. At each location where disposable sharps are used, rigid plastic containers are provided for waste sharps.

When these containers become approximately 50% full, a chemical disinfectant is sprayed onto the container top. The containers are then closed and staged inside the BSL-4 laboratory for decontamination by autoclaving.

Decontamination: Closed sharps containers are placed in trays and decontaminated by autoclaving.

Final Disposal: Decontaminated sharps containers are packaged for shipment and disposal as regulated biological waste. The containers are sealed in bags and packed into rigid boxes appropriate for transport according to Massachusetts Department of Public Health and DOT regulations.

Full, closed boxes are stored in a dedicated waste storage area. The storage area has restricted access and is posted with the biohazard sign and the words 'biological waste'.

Full boxes are catalogued on shipping documents and transported by an authorized third-party handler for final disposal.

4.2 Chemical Waste

Chemical use inside a BSL-4 laboratory is kept to a minimum compared to most other laboratory facilities. A chemical is brought into the laboratory only if it is an absolutely necessary component in a process. EHS reviews any chemical for safety before it is brought into the laboratory for the first time. The majority of materials that can be considered chemical in nature are brought into a BSL-4 laboratory for one of two reasons:

1. To keep cells or microbial agents alive, or
2. As a disinfectant to ensure the destruction of cells or microbial agents.

Inventories are maintained of all chemicals that are brought into a BSL-4 laboratory. Environmental Health & Safety works with researchers to identify disposal options for each chemical on the inventory and for any chemical that is to be added to the inventory.

As with all other materials generated in a BSL-4 laboratory, chemicals must be free of contamination before they can be removed from the laboratory for disposal.

4.2.1 Disposal of Chemical Wastes to the Sanitary Sewer System via the Liquid Effluent Decontamination System

Description of Waste: Includes any chemical material which is NOT regulated by the Environmental Protection Agency, the Massachusetts Department of Environmental Protection, or the Massachusetts Water Resources Authority AND which can be safely

discharged through the liquid effluent treatment tanks. Examples include growth media, salt solutions, buffers, and most disinfectant materials.

Generation and Accumulation: Generation of chemical waste materials occurs during BSL-4 laboratory operations. Chemicals are collected in the flasks and containers in which they are generated.

Decontamination: Chemicals that are brought into the laboratory as decontamination reagents, such as quaternary ammonium compounds, and for which efficacy of microbial destruction has been validated, can be considered free of microbiological agent contamination. When a validated decontamination concentration and contact time are reached, these materials are considered decontaminated and are poured into the sinks which convey them to the Liquid Effluent Decontamination System tanks.

Chemical materials with known or suspected direct microbial contamination, such as those which are part of cultures, are decontaminated using disinfectant materials, for example by adding quaternary ammonium compounds. Chemical compatibilities are determined ahead of time to identify proper decontamination and disposal methods. After achieving an approved concentration and contact time for chemical disinfection, these chemicals can be poured into the sinks and flow to the Liquid Effluent Decontamination System tanks.

Because of the presence of chemical traps in all sink and floor drains in a BSL-4 laboratory, any material that enters the drain contacts a chemical disinfectant prior to exiting the laboratory. Chemical traps are wide sections of pipe immediately downstream from sink and floor drains. Typical plumbing traps contain water, to prevent noxious sewer gases from migrating from the sewer and entering spaces through the drains. Chemical traps use chemical disinfectant instead of water to provide an extra margin of disinfection safely.

Final Disposal: Final disposal of chemicals that can be safely sink-disposed is discharge into the sanitary sewer system.

4.2.2 Chemical Wastes Not Disposed of Through the Sanitary Sewer System

Description of Waste: Includes any chemical waste regulated by the EPA, the Massachusetts Department of Environmental Protection, or the Massachusetts Water Resources Authority, or which cannot safely be discharged via the Liquid Effluent Decontamination System. Examples include concentrated alcohols and solvents and formaldehyde solutions.

Generation and Accumulation: Regulated chemicals that are needed for a research protocol are brought into a BSL-4 laboratory in quantities that will satisfy the protocol

requirement but eliminate or minimize residual chemical waste. Inventory controls will eliminate the generation of chemical wastes that cannot be disposed of in sinks. All chemical wastes that cannot be sink-disposed are collected in plastic containers that have tight-fitting closures and are labeled according to federal, state, and local regulations. These collection containers are kept closed at all times.

Decontamination: Chemicals that are brought into a BSL-4 laboratory for the purpose of fixing tissues or decontamination, and which are present as wastes in concentrations that have been shown and validated to destroy microbial agents, are considered to be decontaminated.

Waste chemicals that have not been validated to destroy microbial agents are decontaminated. The chemical agent used for decontamination is determined to be compatible with the waste chemical, with an approved final concentration and contact time established. After decontamination of the contents of a chemical waste container is assured, external decontamination of the chemical container must be completed prior to removal from the laboratory. External decontamination of chemical containers is achieved by chemical disinfection. Small chemical containers are disinfected and removed through the dunk tank. .

In rare circumstances, internal and external decontamination of a chemical waste container can be accomplished by autoclaving the container. Environmental Health & Safety must be consulted prior to placing any chemical material into an autoclave.

Final Disposal: Regulated chemical waste containers that have been internally and externally decontaminated and removed from a laboratory are transported in a secondary container to a designated chemical waste storage room. The room is designed to provide fire resistance, ventilation, equipment, and signage for the safe storage of chemical wastes until they are shipped off-site.

Environmental Health & Safety manages and inspects the chemical waste storage room. Chemical wastes stored in this room are shipped off-site for incineration or treatment by a contracted vendor of hazardous waste disposal services. All wastes are stored, packed, and shipped according to federal, state, and local regulations. EHS releases the chemical waste by signature on the shipping documents and monitors all chemical wastes during transport to their final destruction.

4.3 Radioactive Waste

In the event that radioactive materials must be introduced to a BSL-4 laboratory space, the types and amounts of isotopes are strictly controlled through an internal approval and

licensing process. Disposal of radioisotopes inside a BSL-4 laboratory is performed in a similar fashion as in BSL-1 and BSL-2 laboratories including the use of sink and solid waste disposal logs, with the additional step of decontamination to destroy any biological organisms.

Any liquid radioactive wastes suitable for sink disposal must be disinfected prior to disposal through the addition of a disinfectant chemical. Solid wastes which contain radioisotopes must be autoclaved prior to disposal. In the event an autoclave must be used for the treatment of solid wastes which contain radioisotopes, that autoclave will be monitored and tested for radioactive contamination. Solid wastes which have been autoclaved will be sent off-site for proper disposal.

Solid wastes containing radioactive nucleotides that may potentially produce volatile hazards will not be autoclaved. Such wastes will be handled and treated by other methods, including decay or treatment with a compatible chemical, to properly inactivate viable biological materials.

4.4 Other Laboratory Waste

Much of the waste generated inside a BSL-4 laboratory does not pose any risk by itself, but because it is generated inside the laboratory, it must be considered biologically contaminated. The principles of management for these materials are similar to those for other wastes described in this Plan: only bring into a BSL-4 laboratory what is absolutely necessary and completely decontaminate all wastes before their removal. The following sections describe the processes for managing some specific types of waste.

4.4.1 Miscellaneous Solid and Semi-solid Laboratory Waste

Description of Waste: Paper and office products, non-directly contaminated labware such as plastic flasks and beakers, packaging materials, and other general waste products.

Generation and Accumulation: General laboratory wastes are generated throughout a BSL-4 laboratory. These wastes are managed as solid biological waste. Collection is in containers that are double-lined with autoclave bags.

Decontamination: Biohazard bags are loosely closed with autoclave tape and staged for decontamination by autoclaving.

Final Disposal: Successfully decontaminated bags of waste are packaged and shipped as medical or biological waste by a third-party waste disposal vendor.

4.4.2 Large Objects and Equipment

Description of Waste: Waste equipment and objects that are too large or otherwise not suitable for autoclaving.

Generation and Accumulation: In the event that a broken piece of equipment or large object must be removed from a BSL-4 laboratory as waste, the external surfaces of the equipment or large object are gently washed and wiped with a chemical disinfectant. All removable panels and parts are removed to expose the internal components.

Decontamination: The cleaned, partially disassembled equipment or large object is decontaminated using a validated gaseous decontamination procedure as described in section 3.2.3 of this Plan.

Final Disposal: Decontaminated equipment is disposed of as non-hazardous, non-infectious waste.

4.4.3 Batteries

Description of Waste: Batteries from equipment in a BSL-4 laboratory.

Generation and Accumulation: Battery-operated equipment is not common in a BSL-4 environment and will only be introduced when necessary.

Decontamination: Batteries are never decontaminated in an autoclave. Batteries are wiped with a chemical disinfectant inside a laboratory and then passed through the dunk tank for removal from the laboratory.

Final Disposal: Decontaminated batteries are considered non-infectious and sent for recycling through an EHS-approved vendor.

4.4.4 Gas Cylinders

Description of Waste: Small lecture-bottle sized cylinders of compressed gas or air.

Generation and Accumulation: While the gases most often used in research are provided through plumbed fixtures into a BSL-4 laboratory, the potential exists for a research protocol to require the addition of a compressed gas cylinder. Prior to being introduced into a laboratory, all cylinders will be equipped with an in-line backflow preventer connected to the outlet valve. Cylinders will always be secured in an upright position when inside a BSL-4 laboratory.

Decontamination: Any cylinder to be removed from a BSL-4 laboratory as waste must undergo decontamination. Under no circumstances are cylinders decontaminated in an autoclave. Whenever possible, cylinders are not allowed to become completely empty. They are removed with some charge left inside.

For cylinders that are not completely empty, the valve is closed and the regulator is removed to expose the outlet so that it can be chemically decontaminated up to, and including, the backflow preventer. The outside of the cylinder is then chemically decontaminated by spraying with chemical disinfectant. The cylinder is then passed out of a BSL-4 laboratory through the dunk tank as described in section 3.2.2 of this plan. A special need for use of a large cylinder would require a decontamination procedure within an airlock prior to disposal.

For cylinders that are completely empty (i.e., have no charge left inside), the valve is removed inside a BSL-4 laboratory. The cylinder, both inside and out, is chemically decontaminated by spraying with chemical disinfectant, and then is passed out through the dunk tank.

Final Disposal: Decontaminated cylinders are disposed as non-hazardous, non-infectious waste.

5.0 EMERGENCY RESPONSE APPLICATIONS

Spills of waste materials inside a BSL-4 laboratory are considered emergencies and have the potential for release from containment. Spills of blood or biological wastes are cleaned up using a chemical disinfectant. Solid materials are disposed of in biohazard bags and then autoclaved. The closely controlled, small volumes of chemicals inside a laboratory ensure that a spill involving a chemical is minimal. These spills are cleaned up using absorbent spill equipment present in the laboratory. These wastes are decontaminated and removed from the laboratory by autoclaving or by chemical disinfection and passage through the dunk tank.

Waste decontamination systems are designed and operated to be able to effectively and safely manage incidents, malfunctions, or interruptions. When an autoclave malfunctions during a decontamination cycle, the door to the autoclave that is outside of containment is never opened. Instead, wastes are removed from the autoclave inside the laboratory and transferred to a functioning autoclave unit. The tanks of the Liquid Effluent Decontamination System allow for effluent in a malfunctioning tank to be pumped directly to a functioning tank for heat treatment prior to disposal. If a malfunction of the tissue digester is encountered, the autoclave-decontaminated animal carcasses and tissues are sent for incineration at an approved facility.

6.0 TRAINING

All EHS and Facilities staff who manage waste or decontamination systems waste will undergo training prior to working in a BSL-4 laboratory or on any system. Operators of autoclaves and the tissue digester will receive annual retraining on the proper operation and maintenance of these systems. Research staff will be trained annually on routine research practices, including waste management and disposal, as part of their required BSL-4 training. No member of the research team or support staff will handle any BSL-4 materials or enter a laboratory without first completing all required training.

7.0 ANNUAL REVIEW

An annual review will be completed of all waste disposal systems and standard operating procedures relating to these systems. All research teams and support staff will be retrained on any changes made to any procedure as part of their annual refresher training.

8.0 DEFINITIONS

Authorized Individual: "Authorized Individual" means a person who the Department of Health and Human Services (DHHS) Secretary or U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Administrator, and the BU Responsible Official have approved to have access for the possession and use of Select Agents at the NEIDL based on a Security Risk Assessment by the Attorney General.

Decontamination: As defined in Section 6 BSL-4 Laboratory Decontamination Plan, "decontamination," is described by Block (2001) as "disinfection or sterilization of infected articles to make them suitable for use" (Block, p. 22).

Disinfection: As defined in Section 6 BSL-4 Laboratory Decontamination Plan, "disinfection" is the reduction of certain undesirable microorganisms in order to prevent their transmission.

Equipment: Laboratory "equipment" consists of mechanical components and fixtures that assist researchers with complex functions. Examples of equipment include biological safety cabinets, tabletop or floor model centrifuges, and incubators.

Principal Investigator: "Principal Investigator" means an authorized individual approved by the Responsible Official to direct a Select Agent or Toxin project or program and who is responsible for the scientific and technical direction of that project or program.

Responsible Official: The CDC "Responsible Official" (RO) is an authorized individual with responsibility, authority, and control to ensure compliance with the DHHS and USDA Rules and Regulations pertaining to the possession, use, and transfer of Select Agents and Toxins.

Select Agent: As defined in Section 6 BSL-Laboratory Decontamination Plan, "Select Agent" means a biological agent or toxin that has the potential to pose a severe threat to public health and safety. The DHHS Secretary and the USDA Animal and Plant Health Inspection Service Administrator have responsibility for determining Select Agents. Select Agents are listed in 42 CFR Part 73 and 9 CFR Part 121.

Sterilization: Sterilization is the complete killing of all microorganisms. Sterilization is a process used to remove or destroy all viable forms of microbial life.

9.0 KEY REFERENCES AND RESOURCES

Biosafety in Microbiological and Biomedical Laboratories, 2009. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention and National Institutes of Health. 5th Edition. Washington: U.S. Government Printing Office.

Block, Seymour S. 2001. *Disinfection, Sterilization, and Preservation*. 5th edition. Philadelphia: Lippincott Williams & Wilkins.

Boston University Biosafety Manual. 2014. Boston University Office of Research Compliance

105 CMR 480. 2008 Minimum Requirements for the Management of Medical or Biological Waste. Massachusetts Department of Public Health.