Boston Public Health Commission

Biological Laboratory Safety Permit Application

SECTION 5: BSL-4 LABORATORY DECOMMISSIONING

Boston University

National Emerging Infectious Diseases Laboratories

October 2014

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1.0 PURPOSE AND APPLICABILITY

This policy is applicable to all BSL-4 laboratory suites and supporting containment systems of the National Emerging Infectious Diseases Laboratories. The purpose of decommissioning a BSL-4 laboratory suite is to make the space safe and accessible to repair or make improvements to a containment system (i.e., secondary barrier), or to make changes needed for future uses other than BSL-4 laboratory research. The process of decommissioning includes: the termination of research and animal care activities; removal of all chemical, radioactive, or biological materials, and sharps and other supplies; and the decontamination of all surfaces, equipment, and apparatus within (or interfacing with) the BSL-4 space prior to taking out or altering any containment system.

2.0 ROLES AND RESPONSIBILITIES

2.1 Director, Research Safety, Environmental Health & Safety

The Director of Research Safety of BU's Environmental Health & Safety department (EHS) is responsible for the management of the NEIDL Research Safety Program. This responsibility includes oversight of: 1) the development and execution of decommissioning plans for BSL-4 suites and containment systems; 2) the decontamination protocols for readying the suites and containment systems for decommissioning; and 3) the recertification protocols for bringing back online a repaired or replaced containment system. The Director of Research Safety is the Responsible Official (RO) for institutional compliance with the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) Select Agent Rules.

2.2 Principal Investigator

The Principal Investigator (PI) is an authorized individual approved by the Responsible Official (RO) who is responsible for the scientific and technical direction of a select agent or toxin project or program. The PI is responsible for: 1) notification of the IBC on the termination of the research and completion of required forms; 2) informing the RO of a decision to terminate a research program or convert the BSL-4 space to another purpose approved by NEIDL leadership ; 3)

terminating all research activities prior to a decommissioning activity; and 4) assisting EHS and Facilities Management & Planning (FMP) in preparing the space for decommissioning.

2.3 Responsible Official

The Responsible Official (RO) is an authorized individual with responsibility, authority, and control to ensure compliance with the CDC and APHIS Rules and Regulations pertaining to the possession, use, and transfer of select agents and toxins. BU/BMC designated the Director of Research Safety to serve as the RO. The RO will ensure the proper decontamination of all select agent materials. In the event of an incident, the RO will oversee the proper decontamination of materials or rooms involved and will report to DHHS and USDA the results of these efforts.

2.4 Associate Vice President for Research Compliance

The Associate Vice President for Research Compliance (AVP-RC) is responsible for oversight of the control of hazards in the research laboratories and for ensuring that comprehensive, enterprise-wide programs are in place for the safe handling of all hazardous materials (e.g., biological, chemical, radiological).

The AVP-RC will be informed by the Principal Investigator and the Director of Research Safety of a need for, or decision to, decommission a BSL-4 suite or supporting containment secondary barrier system. The AVP-RC serves as the RO for compliance with Boston Public Health Commission (BPHC) laboratory regulations and has the responsibility to certify the decommissioning plan for submittal to the BPHC and to ensure that Boston University informs the BPHC at least 30 days prior to any laboratory decommissioning activity.

2.5 Director, NEIDL Facilities, Facilities Management & Planning

The Director, NEIDL Facilities, is responsible for developing the decommissioning plan in coordination with Environmental Health & Safety and for managing the execution of the plan.

2.6 Facilities Operations Manager

The Facilities Operations Manager (FOM) is responsible for the evaluation of the physical components of the mechanical, electrical, plumbing, and HVAC systems that interface with a BSL-4 laboratory space, and coordination of the safe decommissioning of such components. The FOM works with Environmental Health & Safety and the BSL-4 suite authorized individuals to establish space-specific sequences and activities for implementing the decommissioning plan.

2.7 BSL-4 Suite Authorized Individuals

Authorized individuals assigned to the BSL-4 suite will assist in the preparation of the BSL-4 suite for decommissioning.

2.8 EHS Staff

EHS is responsible for scheduling and coordinating the biological decontamination activities for decommissioning BSL-4 laboratory spaces. EHS works with the research and facilities staff in developing the decommissioning plan, and is responsible for documenting all decontamination procedures and validating the results; scheduling and coordinating the removal of chemical supplies from the space and managing chemical abatement activities associated with decommissioning; and identification, remediation, and removal of all radioactive hazards associated with a BSL-4 laboratory space in preparation of the decommissioning initiative.

3.0 PROTOCOL METHODOLOGY

3.1 Notification

The decommissioning planning by Environmental Health & Safety and Facilities Management & Planning begins with the notification by the RO of a decision to take off-line a BSL-4 laboratory, or a containment barrier system integral to the operation of that laboratory. The RO will notify and submit reports and amendments to the BPHC and CDC that will: 1) state the purpose of the decommissioning, which includes the reason for the decomissioning, whether termination of research work, new research purpose, or change in use of the space; 2) identify the location of the BSL-4 laboratory as described in the project permit application; 3) estimate start and completion times; and 4) identify the selected decontamination methods, the agent to be used and effectiveness against the agent/s being decontaminated, and validation of successful decontamination procedures.

3.2 Delineation and Documentation

Environmental Health & Safety, in collaboration with Facilities Management & Planning, delineates and documents the physical boundaries of the BSL-4 laboratory space scheduled for decommissoning. This process requires extensive plan review including the physical inspection and identification of contaminted spaces and systems, and documentation of the components of each containment barrier system of the space.

3.3 Material Audit

Environmental Health & Safety maintains records of biological agents, chemicals, and radioactive materials and containment equipment that are present in the BSL-4 laboratory. The material audit is reviewed with the BSL-4 suite authorized individuals, and plans are made for the disposition of equipment, select agents, animals, and surplus materials that are not to remain in the BSL-4 suite.

3.4 Removal of Materials, Select Agents, Equipment, and Wastes

Select agents will be moved into designated areas upon approval by CDC. The BSL-4 suite authorized individuals, with the guidance and assistance of EHS, will remove all materials,

equipment, select agents, and wastes from the BSL-4 suite following estabished practices for packaging and decontamination prior to removal of materials from the suite. The removal procedures will follow established policies and reporting requirments that are in compliance with CDC, APHIS, and BPHC regulations. The RO will document the removal of all items from the suite, including validation data of the decontamination protocol.

3.5 System Lockout

Facilities Management & Planning will physically secure the BSL-4 suite in prepararion for decontaminating the laboratory space and integral secondary barrier systems. This process will result in de-energizing, purging, and capping all utility services connected to the BSL-4 laboratory space. The system lockout is performed by FMP in conjunction with EHS and the BSL-4 authorized individuals. The system lockout renders all utility feeds unusable in the space and isolates the space from the rest of the building systems.

3.6 Decontamination

The decontamination of a BSL-4 laboratory, its built-in surfaces, and systems supporting the space are the last physical activity to take place prior to a final inspection, with the exception of a system lockout that must be performed post-decontamination. Decontamination of the BSL-4 suites and contaminated systems, including the effluent decontamination systems, uses validated processes to effectively sterilize and/or disinfect a BSL-4 laboratory space, rendering its occupancy status biologically safe without personal protective equipment. Selection of the decontamination process in BSL-4 laboratories is based on the BSL-4 research risk assessment. The process is performed by BSL-4 authorized individuals working in conjunction with EHS and FMP. For more information on BSL-4 decontamination means and methods, reference the BPHC Biological Laboratory Safety Permit Application, Section 6: “BSL-4 Laboratory Decontamination Plan.”

3.7 Final Inspection

Environmental Health & Safety will conduct a final inspection of the decommissioned space including the integral containment barrier systems and verify that the decommissioning activities were executed effectively by both internal staff and contracted decommissioning agents. The RO will notify in writing the BPHC, CDC, and other regulatory agencies as applicable, within 48 hours of completing the decommissioning of the BSL-4 laboratory space. The BPHC may inspect the facility within 30 days of completion of decommissioning.

4.0 TRAINING

All staff participating in the decommissioning of a BSL-4 laboratory space must be trained in the activities undertaken. This includes training staff on BSL-4 laboratory inspections, proper handling

methods, waste removal, and various methods of decontamination. Training is a mandatory prerequisite for working in or supporting BSL-4 operations, and is documented.

5.0 RECURRING REVIEW OF PROTOCOL

EHS will conduct a decommissioning assessment following the completion of each decommissioning activity. Revisions to the decommissioning plan will incorporate lessons learned to improve the decommissioning process. Training programs will be updated accordingly.

6.0 DEFINITIONS

Certification: Verification that a BSL-4 laboratory and operational protocols meet the requirements of regulatory guidelines.

Commissioning: Verification of the design intent, physical construction, and performance of critical containment barrier components.

Decommission: The BPHC guidelines for implementing the biological laboratory regulation state that decommission shall mean to take off-line, out of use, or change use. It is a systematic review and documentation process signifying that specified laboratory components, systems, and/or system components have been removed or changed, inspected, tested, and verified to meet national and international standards. Decommissioning includes taking off-line the mechanical systems – such as HEPA filters, ductwork, and primary and secondary barriers. If an entity converts a laboratory space to or from BSL-4, the intended decommissioning shall be reported to the BPHC.

Decontamination: The process of treating the BSL-4 space, equipment, and containment barrier systems with a gaseous or vapor phase chemical disinfectant to ensure that no surface, equipment, or barrier containment system is contaminated with an infectious agent once stored, used, or handled in the BSL-4 laboratory space.

7.0 KEY REFERENCE

Biosafety in Microbiological and Biomedical Laboratories (BMBL), U.S. Department of Health and Human Service Centers for Disease Control and Prevention and National Institutes of Health, 5th Ed., Dec. 2009.

APPENDIX A

Decommissioning Plan Summary Checklist

The decommissioning process of the BSL-4 ensures that the facility and the related infrastructures are successfully decontaminated and achieves the environmental health and safety requirements for its next intended use. Decommissioning is a risk-based approach and takes into account the type hazardous materials used and stored within the facility along with the safeguards employed to protect human health and the environment. Decommissioning of the BSL-4 requires characterization of all hazardous materials, mitigation of these hazards by employing methods proven to be effective, and as applicable, validation of these methods to ensure that the resulting materials are safe. The decommissioning is established for the types of contamination and equipment involved. Regulated wastes generated during the process are treated on site or disposed of by licensed contractors. This checklist provides the overarching roadmap to perform the decommissioning of the BSL-4 facility.

Steps encompassing the decommissioning process include:

- Determine the scope of decommissioning project.
- Identify the area/s for decommissioning.
- Collect historical information about the area/s (i.e. use of space, routine cleaning and disinfection) to be decommissioned.
- Perform site survey and conduct sampling as necessary.
- Complete the review of the survey and analytical sampling results.
- Develop decontamination and remediation strategy.
- Develop validation of decontamination strategy.
- Perform decontamination remediation and validations based on developed plan.
- Conduct a final survey to confirm that all remediation have been completed.
- Document final results.
- Release of facility to its next intended use.

A. Defining the Decommissioning Scope of Work

The scope of work describes the process and extent of the decommissioning project. The scope of work includes the following information:

	SCOPE OF WORK
	Description and intent of the proposed decommissioning
	Areas to be decontaminated (i.e. suites, rooms)
	Support areas to be decontaminated (i.e. waste room)
	Use of the areas to be decontaminated (i.e. animal holding)
	Systems to be decontaminated (i.e. exhaust duct work)
	Equipment to be decontaminated (i.e. Biological Safety Cabinet)
	Goals of the decontamination

B. Site Survey and Risk Assessment and Characterization

The purpose of the site survey is to verify the planned scope of work developed; characterize the hazards within the facility; identify any potential process contaminants that may require further investigation; and as needed, perform material sampling.

	SITE SURVEY
	Historical analysis of the areas to be decommissioned
	Characterization and evaluation of contaminants
	Criteria for decontamination and clean up
	Sampling and analysis (as necessary)
	Applicable regulatory requirements

	Documented final survey report

C. Contaminated Laboratory Systems

Laboratory systems that support the containment facility will be assessed for contamination and decontaminated as part of the decommissioning process. Each system will be assessed to characterize the contaminant and once determined, the appropriate decontamination method is employed. Only the method proven to be effective will be used to treat and decontaminate the system to ensure that it safe to dispose, transfer or use by the next occupants of the space. Such methods include formaldehyde, vaporized hydrogen peroxide, chlorine dioxide, steam, microchem plus solution and bleach solution.

	LABORATORY SYSTEMS
	Exhaust Air system
	Supply Air system
	Plumbing system
	Sewer system
	Lighting system
	Autoclave sterilizers
	Effluent Decontamination System
	Tissue Digester

D. Contaminated Laboratory Equipment

Laboratory equipment used in the facility will be assessed for contamination and decontaminated as part of the decommissioning process. The equipment will be assessed to characterize the contaminant and once determined, the appropriate decontamination method is employed. Only the method proven to be effective will be used to treat and decontaminate the equipment to ensure that it safe to dispose, transfer or use by the next occupants of the space. Such methods include formaldehyde, vaporized hydrogen peroxide, chlorine dioxide, steam, microchem plus solution and bleach solution.

	LABORATORY EQUIPMENT
	Biological Safety Cabinets
	Down Draft Table
	Ventilated Animal Cage Racks
	Centrifuges
	Imaging Equipment
	Freezers
	Incubators

E. Contaminated Suites, Rooms and Storage Spaces

Laboratory and animal spaces within the facility will be assessed for contamination. Each area will be decontaminated with a method that is known to be effective in decontaminating microbiological agents used in the facility. These methods include formaldehyde, vaporized hydrogen peroxide, chlorine dioxide, steam, microchem plus solution and bleach solution.

	LABORATORY SPACES

	Laboratory rooms
	Animal procedure rooms
	Animal holding rooms
	Necropsy
	Agent storage room
	Dry and supplies storage rooms
	Fumigation airlocks
	Hallway
	Animal rack staging areas

F. Preparation for Decontamination of Laboratory Space and Equipment

The areas to be decontaminated as part of the decommissioning process must initially be prepared in order to perform a successful and completed decontamination. Established procedures will be followed when conducting initial preparations to clear the space of wastes, and perform preliminary surface decontamination.

	LABORATORY AND EQUIPMENT DECONTAMINATION PREPARATION
	Autoclave and dispose all biological wastes
	Decontaminate and dispose all chemical wastes
	Spray and disinfect all equipment surfaces
	Spray and disinfect equipment interior surfaces
	Disinfect and wipe all bench top work surfaces

	Disinfect and wipe all chair surfaces

G. Post Laboratory and Equipment Decontamination

The following will be perfumed after successfully completing the decontamination of the laboratory spaces and equipment:

	POST LABORATORY AND EQUIPMENT DECONTAMINATION
	Remove all Biohazard stickers on all equipment
	Remove Biohazard signs on doors
	Affixed equipment decontamination labelling on all equipment

H. Documentation for facility or space decommissioning shall consist of the following records:

	RECORDS AND DOCUMENTATIONS
	Decommissioning plan
	Site survey
	Sampling reports
	Decontamination validation reports
	Site maps
	Photographs
	Safety Data Sheets (SDS)
	Hazardous waste manifest
	Contractor pre-qualification (as needed)
	Agent destruction record