Oklahoma State University

Biological Research Safety Plan
(for Select Agent & Toxin Use)

Revised February 2017

Certification and Approvals

The Biological Research Safety Plan for Oklahoma State University was prepared with the intent of it being compliant with the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* and 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. This plan must be reviewed at least annually and revised as necessary.

_____ _____

Signature of Authorized Official **Date**

ANNUAL REVIEW VERIFICATION	
VERIFICATION DATE	**SIGNATURE**
July 2009	
November 2009	
March 2010	
July 2010	
August 2010	
February 2011	
April 2011	
April 2012	
November 2012	
March 2013	
April 2014	
April 2015	
March 2016	
April 2017	

Chapter 1 Introduction

I. Preface

The Oklahoma State University (OSU) Biological Research Safety Plan, referred to throughout this document as the Biosafety Plan, is intended to serve as a resource of safety policies and procedures that is designed to enable and encourage those working with select agents and toxins (SATs) to work safely and reduce or mitigate any risk associated with the work. Federal and state regulatory requirements are presented in this plan. All OSU principal investigators (PIs) and laboratory workers must adhere to all campus biosafety policies and procedures in the course of conducting research and managing laboratories.

OSU is committed to ensuring that all activities with SATs are conducted safely. All university faculty, staff, and associated students are expected to engage in prudent practices necessary to protect people and the environment from SATs by adhering to biosafety regulations, policies, and required guidelines.

II. Scope

This plan applies to all personnel working with SATs on the OSU Stillwater campus. The current list of SATs can be found in Appendix A of this plan.

This plan does not address radiation or chemical safety. These areas are covered in the OSU Radiation Safety Handbook, which is the purview of the Radiation Safety Committee, and the OSU Chemical Hygiene Plan, which is the purview of Environmental Health and Safety.

III. Record Retention

All records/documents pertaining to SATs shall be maintained for at least three (3) years, as required by 42 CFR 73.17(c) unless the records/documents pertain to the Institutional Biosafety Committee's (IBC) review of activities, as required by the State of Oklahoma's General Records Disposition Schedules for State Universities and Colleges. Thus, each PI will maintain laboratory/facility specific records/documents accordingly. The Office of University Research Compliance will maintain all records related to biological safety on campus in accordance with pertinent laws, regulations, and statutes.

IV. Annual Review of the Biosafety Plan

The Responsible Official (RO) will engage appropriate individuals to review this plan at least annually and it will be reviewed and revised as necessary after a drill or exercise and after an incident. Specifically, in order to test and evaluate the effectiveness of OSU's Biosafety Plan, a tabletop exercise or drill will be conducted at least annually in adherence to the Select Agent Final Rule. All drills and/or tabletop exercises will be subjected to after action analysis to identify if any changes to OSU's Biosafety Plan are warranted.

V. Program Administration

A. Vice President for Research

The Vice President for Research (VPR) leads the effort to ensure that all research and teaching activities involving the use of biohazardous materials, and the facilities used to conduct such work, are in compliance with all external regulations and applicable University policies. The VPR has been designated by the President of OSU as the Responsible Official (RO) for the University's Select Agent Program.

B. Institutional Biosafety Committee (IBC)

The President has conferred upon the VPR the authority to appoint an IBC. The IBC has responsibility for approving research protocols and procedures related to biosafety. The IBC reviews and monitors all research projects involving SATs at least annually. The IBC's responsibilities are listed in the OSU Institutional Biosafety Policy (4-0301).

C. University Research Compliance

The Office of University Research Compliance (URC) has been designated as the office responsible for implementing the requirements of 42 CFR 73, 7 CFR 331, and 9 CFR 121. This responsibility includes

maintaining on file all records and documentation related to the Select Agent Program at OSU, providing these documents appropriately upon request per federal regulations, coordinating all communication with the Centers for Disease Control and Prevention (CDC) regarding the university's Select Agent Program on behalf of the RO, and communicating any changes in the Select Agent Final Rule to PIs.

This office is also responsible for ensuring compliance with the NIH Guidelines and all other applicable biosafety guidelines and policies.

E. Biological Safety Officer (BSO)

The BSO is also a designated ARO. He/she manages the SAT program. In addition to the BSO's responsibilities for biosecurity and incident response, the BSO is also responsible for:

- advising the IBC, administration, faculty, and staff on any concern regarding SATs and their control;
- performing routine inspections of all SAT facilities and laboratories;
- reporting any significant problems, violations, incidents or illnesses to appropriate University administrators, the IBC, and appropriate external agencies;
- serving as a first responder to all SAT incidents and emergencies;
- serving as a liaison between the University and regulatory agencies; and
- assisting in laboratory decontaminations.

F. Assistant Biological Safety Officer (ABSO)

The ABSO is also a designated ARO. He/she assists in the management of the SAT program. Additional responsibilities of the ABSO include:

- serving as a first responder to all SAT incidents and emergencies;
- assisting in laboratory decontaminations;
- assisting in advising the IBC, administration, faculty, and staff on any concern regarding biohazards and their control;
- performing routine inspections of all facilities and laboratories in which potentially biohazardous activities are being conducted.

G. Deans/Department Heads/Directors

Administrative heads of colleges, departments, and other units have primary responsibility for the biosafety of people, animals, and the environment within their purview. No activity involving the use of SATs is to be permitted at the University unless there is a commitment of effort and resources to ensure that it can be accomplished safely.

H. Principal Investigator (PI)

The PI is responsible for compliance with OSU biosafety policies and procedures and for the safe operation of his/her laboratory(s). His/Her knowledge and judgment are critical in assessing risks and in the appropriate application of biosafety guidelines.

Prior to initiating research, the PI will:

- conduct a thorough risk assessment to determine the proper work practices and containment requirements for work with biohazardous material;
- determine, with appropriate consultation with IBC and Occupational Health and Safety Program (OHSP) personnel, the usefulness of serological screening, the requirements of medical surveillance, and the availability of vaccination;
- assure that personnel working with SATs are enrolled in the OHSP (see Appendix E);

- assure that personnel working with biohazardous materials are appropriately trained (see training requirements in Section IIA);
- obtain appropriate IBC approval for all research projects that fall within the purview of the IBC; and
- obtain permits (if applicable) through the CDC, the Animal and Plant Health Inspection Service (APHIS), or other agencies as required for shipping biological material.

While the research is performed, the PI will:

- supervise the performance of his/her staff to ensure that the required safety practices and techniques are employed;
- strictly adhere to the research objectives outlined in the approved IBC protocol and strictly adhere to the items in the lab inspection checklist for the particular biosafety level for the project (Appendix H-K);
- communicate in writing to the IBC via the Modification Form any protocol changes that modify (e.g. changes in personnel, research location, agents/toxins, or objectives) the research procedures upon which approval was originally based prior to initiating the change;
- investigate and report in writing to the IBC any significant biosafety problems.

I. Laboratory/Facility Personnel

All persons involved in potentially biohazardous activities must share biosafety responsibility by ensuring appropriate conduct in research. Laboratory/facility personnel must adhere to the information in this plan as well as the laboratory-specific biosafety plan.

VI. Rules and Regulations

- ✓ **Biosafety in Microbiological and Biomedical Laboratories (BMBL),** Centers for Disease Control and Prevention and National Institutes of Health, U.S. Department of Health and Human Services
- ✓ **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines),** National Institutes of Health, U.S. Department of Health and Human Services
- ✓ **Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001**
- ✓ **Public Health Security and Bioterrorism Preparedness and Response Act of 2002**
- ✓ **42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121** "Final Rules"
- ✓ **OSU Institutional Biosafety Policy** (#4-0301)

References to each of the aforementioned documents, as well as other helpful resources, may be found on the biosafety webpages, which are available via the Office of University Research Compliance website: **http://compliance.okstate.edu**

Chapter 2 Project Assessment and Approval

I. Risk Assessment

A. Biological Safety Levels

Biosafety Level (BSL) is a description of the degree of physical containment being employed to confine biohazardous material and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. Four biosafety levels are specified in the BMBL and the NIH Guidelines (please see these references for specific guidance). Each BSL consists of a combination of laboratory practices and techniques, safety equipment, and laboratory facilities which are approved for research involving specific materials.

B. Risk Groups

Biological agents and toxins may be classified into risk groups based on their relative hazard. The table that follows, which was excerpted from the BMBL, describes classification of biological agents and toxins based on the risk to both humans and animals.

RISK GROUP CLASSIFICATION	NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLEUCULES 2002	WORLD HEALTH ORGANIZATION LABORATORY BIOSAFETY MANUAL 3RD EDITION 2004
Risk Group 1	Agents that are not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism that is unlikely to cause human or animal disease.
Risk Group 2	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measure are available.
Risk Group 4	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk)	(High individual and community risk) A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

The BMBL and the NIH Guidelines do not contain definitions for risk group classification of biological agents and toxins that pose a risk to plants. However, both documents define biosafety levels to contain agents that pose a threat to the environment. "**A Practical Guide to Containment**" will be used as a reference to determine risk group classification for biological agents and toxins that pose a risk to plants.

Risk groups and biological safety levels often correspond. However, the IBC may decide to raise or lower the biosafety level for work with a particular agent based upon risk assessment.

C. Agent Specific Risk Assessment

It is the responsibility of the PI or laboratory director to conduct a risk assessment to determine the proper work practices and containment requirements for work with biohazardous material. The risk assessment process should identify features of microorganisms as well as host and environmental factors that influence the potential for workers to experience a biohazard exposure. To document the risk assessment, the appropriate IBC forms and risk assessment forms must be filled out (see **http://compliance.okstate.edu/ibc/forms**). This responsibility cannot be shifted to inexperienced or untrained personnel. The IBC must approve the risk assessment before work may be conducted.

The PI or laboratory director should consult with the BSO to ensure that the laboratory is in compliance with established guidelines and regulations. When performing a risk assessment, it is advisable to take a conservative approach when the information available to you is incomplete. Factors to consider when evaluating risk include the following:

Host range: Note the susceptible hosts and whether susceptible hosts are in the vicinity of the proposed research.

Disease severity: Consider the symptoms that the agent or toxin causes. The potential to survive infection with and without medical treatment should also be described. Note that different strains of an agent may impact disease severity.

Route of transmission: Note how the agent causes infection (i.e. inhalation, ingestion, breaks in the skin, etc.). If a vector is needed for transmission, describe this relationship. Also note if infection can be spread from person to person, animal to animal, or plant to plant.

Agent stability: The greater the potential for an agent to survive in the environment, the higher the risk. Consider factors such as desiccation, exposure to sunlight or ultraviolet light, or exposure to chemical disinfections when looking at the stability of an agent. It is important to note the agent's ability to survive both on a surface in the lab and if it is accidentally released into the environment.

Form of agent: Note which developmental stages of the agent you are using if the agent has different forms (i.e. spores, vegetative cells, etc.).

Infectious dose: Consider the amount of an infectious agent needed to cause infection in a normal person. An infectious dose can vary from one to hundreds of thousands of organisms or infectious units. An individual's immune status can also influence the infectious dose.

Concentration and volume: Consider whether the organisms are in solid tissue, viscous blood, sputum, urine, feces, etc., the volume of the material and the laboratory work planned (amplification of the material, sonication, centrifugation, etc.). In most instances, the risk increases as the concentration of microorganisms increases.

Origin: This may refer to the geographic location (domestic or foreign), host (infected or uninfected human or animal), or nature of the source (potential zoonotic or associated with a disease outbreak).

Availability of data from animal studies: If human data is not available, information on the pathogenicity, infectivity, and route of exposure from animal studies may be valuable. Use caution when translating infectivity data from one species to another.

Drug resistance: Describe any drug resistance and note if the drug is commonly used to treat the disease the agent causes.

Availability of an effective prophylaxis or therapeutic intervention: Effective vaccines, if available, should be offered to laboratory personnel in advance of their handling of infectious material. However, immunization does not replace engineering controls, proper practices and procedures and the use of personal protective equipment (PPE). The availability of post-exposure prophylaxis should also be considered.

Medical surveillance: Medical surveillance programs may include monitoring employee health status, participating in post-exposure management, employee counseling prior to offering vaccination, and annual checkups. Personnel working with SATs must be enrolled in the university's occupational health and safety program.

II. Project approval

All projects involving SATs must be approved by the IBC and CDC/APHIS prior to initiation. Researchers may seek IBC and CDC/APHIS approval concurrently or separately depending upon the nature of the project. The BSO can provide guidance as to which approach is appropriate for a particular project. Aspects of certain projects may also require the approval of the Health and Human Services (HHS) Secretary/Administrator (APHIS), the NIH Director and NIH/Office of Biotechnology Activities (OBA), the Institutional Animal Care and Use Committee (IACUC), the Radiation Safety Committee (RSC), the Institutional Review Board (IRB), and Environmental Health and Safety (EHS), as well as others.

A. IBC

All research and teaching activities conducted by faculty, staff, students, post docs, visiting scientists or other temporary personnel on OSU property or involving the use of OSU-owned equipment are subject to IBC review if the activities involve the use of biohazardous materials.

Important information regarding the submission of a protocol application follows:

- All applicable sections must be completed; all signatures and initials obtained, and all required documentation must be provided to the IBC prior to its review of a protocol.
- The project summary must be easily understood by a diverse group of people, including individuals without expertise in the specific field. At the same time, it must provide enough detail for the committee to evaluate the work for the purpose of performing a risk assessment. Insufficient information will make it difficult for the IBC to assess the potential hazards and risks of the work which will result in approval delay. The following information should be included in the summary:
- primary hypothesis, objectives, and significance of the work;
- overall goals or specific objectives/phases;
- experimental procedures to be used;
- PPE, safety equipment, waste processing, disinfection procedures, transport procedures, sharp handling, and any other lab safety procedures; and
- specify locations for various steps if the research is to be conducted in multiple locations.

Note: It is not necessary to submit the SAT lab specific plans to the IBC for approval. The BSO reviews and approves the lab specific plans on behalf of the IBC.

After submission of the "complete" protocol, the IBC will review it to determine if the proposed project is in compliance with the appropriate policies and regulations. IBC review will consist of, but is not limited to:

- an overall assessment of the proposed project to determine if any conditions associated with the project would prohibit initiation of the proposed plan,
- an assessment of the containment levels proposed to ensure that the levels are sufficient for the type of activity being proposed, and
- an assessment of the facilities, procedures, practices, and training relative to the proposed level of containment.

The IBC, as part of its review of an application, will ensure that a biosafety inspection report for the particular space(s) listed in the application is current and any noted deficiencies from that inspection have been properly addressed.

No research employing biohazardous materials can commence prior to IBC approval, regardless of source of funding (if any). Any modification of the original protocol will require the approval of the Biological Safety Officer or the IBC depending upon the nature of the modification. Examples of project changes that require IBC approval include:

- change in scope of work,
- change in procedures or equipment,
- change in agents,
- addition of strains,
- change in drug resistance of strains,
- change in laboratory space, and/or
- change in personnel.

B. CDC/APHIS

All SAT work must be approved by CDC/APHIS prior to initiation. CDC/APHIS approval is requested by amending OSU's registration via Form 1. The BSO maintains OSU's Form 1 and requests for approval must be handled through him/her. Modifications to the work must also be approved by CDC/APHIS. If the BSO is unavailable, the ABSO will handle notifications via Form 1.

C. Health and Human Services (HHS) Secretary/Administrator (APHIS)
Restricted experiments, as defined by the Final Rule, require approval by the HHS Secretary or the Administrator (APHIS). These include:

- Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
- Experiments involving the deliberate formation of synthetic or recombinant nucleic acids containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD_{50} less than 100 ng/kg body weight.

D. NIH Director and NIH/Office of Biotechnology Activities (OBA)
In addition to IBC approval, some recombinant DNA experiments must also be approved by the NIH Director or by NIH/OBA. Major Actions, as defined by the NIH Guidelines, must be approved by the NIH Director. Experiments involving the cloning of toxin molecules with LD_{50} of less than 100 ng/kg body weight must be approved by NIH/OBA.

E. IACUC
All research involving live, vertebrate animals must be approved by the OSU IACUC prior to initiation. See **http://compliance.okstate.edu/iacuc/iacuc-index** for details.

F. Radiation Safety
All research involving radioactive materials and/or machines which produce ionizing radiation must be approved by the OSU Radiation Safety Committee prior to initiation. See **http://compliance.okstate.edu/rso/rso-index** for details.

G. IRB
All research involving human subjects must be approved by the OSU IRB prior to initiation. See **http://irb.okstate.edu/** for details. In addition, if the human subject research involves the deliberate transfer of recombinant DNA, the Recombinant Advisory Committee (RAC) of NIH OBA must also review and approve the project.

H. EHS

- Human Blood, Blood Products, Body Fluids, and Tissues

The federal regulation **"Occupational Exposure to Bloodborne Pathogens"** mandates a combination of engineering and work practice controls, training, Hepatitis B vaccination, and other provisions to help control the health risk posed to employees resulting from occupational exposure to human blood and other potentially infectious materials that may contain these or other specified agents.

Environmental Health and Safety (EHS) is responsible for facilitating compliance with Occupational Safety and Health Administration (OSHA) standards, including the bloodborne pathogen standard (29 CFR 1910.1030). Contact EHS for additional requirements for working with these materials.

- Occupational Health and Safety Program – see Appendix E
- Respiratory Protection Program – see Appendix F

III. Permits and Registrations

Special federal permits may be required for importing, exporting, and/or transporting human pathogens, animal pathogens, animals or animal products, plant pathogens or plant pests, and plants or plant products.

Permit requirements should be verified well in advance of needing the material in question because some permits can take 60-180 days to receive. The Biosafety Office personnel can provide assistance with any questions about shipping and/or required permits for biological materials.

When applying for permits for SATs, the name of the permittee should be that of the PI. However, the RO's address must be used: 203 Whitehurst Hall, Stillwater, OK 74078.

A. Animals, Plants, Introduction of Genetically Modified Organisms

The USDA-APHIS regulates the transport of materials that could potentially harm U.S. agricultural products, such as livestock or crops. For this reason, APHIS permits may be required for import, export and/or transport of animal or plant pathogens, soil samples, insects, import or export of animals, animal products, plants or plant products, or introduction of genetically modified organisms into the environment. The information provided by the APHIS websites listed below can help determine if a permit is required. You may also contact Biosafety Office personnel for information or assistance with the application process.

USDA-APHIS-Plant Protection and Quarantine
(permits for the import and interstate transport
of plant materials, plant pests, plant pathogens and soils)
See: **http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth**

USDA-APHIS Biotechnology Regulatory Services
(permits and notification for the import and interstate movement
of Genetically Modified Plants, Plant Pests, or Plant Pathogens)
See: **http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology**

USDA-APHIS Veterinary Services
(permits for the import and interstate transport of pathogens of livestock and poultry, and anything biological derived from or exposed to pathogens of livestock and poultry)
See: **http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth**

The USDA APHIS does not require a Veterinary Services permit for importation or interstate movement of select agents listed in 9 CFR Parts 121.3 and 121.4 provided that the importation and/or interstate movement of the materials is authorized in accordance with 42 CFR Part 73 and 9 CFR Part 121.16.

The following SATs require an APHIS Plant Protection & Quarantine (PPQ) permit to ship/receive:

- *Peronosclerospora philippinesis* (*Peronosclerospora sacchari*)
- *Phoma glycinicola* (*Pyrenochaeta glycines*)
- *Ralstonia solanacearum*
- *Rathayibacter toxicus*
- *Sclerophthora rayssiae*
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*

B. Human Pathogens or Biological Toxins

HHS, through the CDC, regulates the import and transport of biological materials that could cause illness in humans. These regulated biological materials include pathogenic bacteria or viruses, toxins from biological sources (for example, tetanus toxin, aflatoxin, etc.), blood or tissues capable of containing pathogens transmissible to humans and certain animals, and insects that may harbor disease-causing organisms. Information presented via the CDC website and OSU biosafety staff can help determine if a permit is required and assist you with the application process.

CDC Importation Permits for Etiologic Agents
See: **http://www.cdc.gov/od/eaipp/**

IV. Reporting SATs identified in diagnosis, verification or proficiency testing

The Oklahoma Animal Disease Diagnostic Laboratory (OADDL) and the Plant Disease and Insect Diagnostic Laboratory (PDIDL) are exempt from adherence to the regulations governing SATs, except in situations when a positive diagnosis is confirmed. Although diagnostic labs are exempt from the SAT regulations, biosafety precautions must still be taken when working with samples suspected of containing SATs. The CDC document, "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories" should be used to develop proper biosafety procedures.

To ensure appropriate tracking and monitoring of activities that may result in human, animal or economic harm or loss at OSU, the OADDL and PDIDL will provide to URC copies of any relevant reports required by the CDC and/or the State of Oklahoma.

When OADDL or PDIDL or any other outside entity, transfers a specimen suspected of containing a select agent or toxin to an approved OSU PI, the following procedure must be followed.

- A specimen (tissues, organs, blood, etc.) <u>suspected</u> of containing a SAT may be transferred from OADDL or any other entity to an approved OSU PI without prior notification to or approval from the Office of University Research Compliance or the CDC provided that the suspect specimen is transported in a primary non-breakable, leak-proof, sealed container and then enclosed in a non-breakable, sealed secondary container.
- The "Reporting the Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen" (APHIS/CDC Form 4) must be completed by the OSU PI in conjunction with the OSU BSO upon the identification of a SAT from that transferred specimen.
- If the entity that transferred the "suspect" specimen to the OSU PI has kept any of that specimen and has possession of it at the time of a positive identification by the OSU PI, then that entity must also submit APHIS/CDC Form 4 as described above.

When a clinical or diagnostic laboratory has identified a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing, the following procedure must be followed:

- Upon the identification of a SAT from a specimen presented for diagnosis, verification, or proficiency testing, proper notification must be made to CDC.
- The following select agents and toxins are required to be immediately (i.e. within 24 hours) reported to CDC or APHIS:
  - African horse sickness virus
  - African swine fever virus
  - Avian influenza virus (highly pathogenic)
  - *Bacillus anthracis*
  - Botulinum neurotoxins
  - Botulinum neurotoxin producing species of *Clostridium*
  - *Burkholderia mallei*
  - *Burkholderia pseudomallei*
  - Classical swine fever virus
  - Ebola viruses
  - Foot-and-mouth disease virus
  - *Francisella tularensis*
  - Marburg virus
  - *Peronosclerospora philippinensis (Peronosclerospora sacchari)*
  - *Phoma glycinicola* (formerly *Pyrenochaeta glycines*)
  - *Ralstonia solanacearum*, race 3, biovar 2
  - *Rathayibacter toxicus*
  - Rinderpest virus
  - *Sclerophthora rayssiae*
  - Swine vesicular disease virus
  - *Synchytrium endobioticum*
  - Variola major virus (Smallpox virus)
  - Variola minor (Alastrim)
  - Virulent Newcastle disease virus
  - *Xanthomonas oryzae*
  - *Yersinia pestis*
- All other SATs must be reported to the CDC within seven calendar days after identification. The SAT contained in the specimen presented for diagnosis or verification must be transferred in accordance with federal regulations or destroyed on-site.
  - OADDL or PDIDL must complete APHIS/CDC Form 4 within seven days after identification. The BSO is available to assist as needed.
  - "Request to Transfer Select Agents and Toxins" form (APHIS/CDC Form 2) may be required in addition to Form 4 if the entity intends to transfer the select agent or toxin.
- Form 4 must be completed in instances where the SAT contained in a specimen is presented for proficiency testing within 90 days of receipt of the sample. [More information regarding any of these procedures may be obtained from URC personnel and/or the BSO.]

Chapter 3 Biosafety Containment, and Practices & Procedures

I. Containment

The term "containment" is used to describe the safe methods for managing infectious agents in the laboratory environment where they are being handled or stored. The purpose of containment is to reduce or eliminate

exposure of laboratory workers, other people, and the outside environment to potentially hazardous agents. The three elements of containment are 1) laboratory practice and technique, 2) safety equipment, and 3) facility design.

A. Primary Containment

The protection of personnel and the immediate laboratory environment from exposure to infectious agents is considered primary containment. It is attained by good microbiological technique and the use of appropriate safety equipment.

- Primary Containment Equipment:

  Safety equipment includes Class II and III biological safety cabinets (BSC), HEPA-filtered fermenters, enclosed containers (i.e., safety centrifuge cups) and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The BSC is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures.

  Safety equipment may also include items for PPE such as protective clothing, respirators, face shields, safety glasses or goggles. PPE is often used in combination with other safety equipment when working with biohazardous materials. In some situations, personal protective clothing may form the primary barrier between personnel and the infectious materials.

  In some cases, the laboratory itself can be considered primary containment (i.e. a laboratory housing animals exposed to SATs in open cages).

B. Secondary Containment

The protection of the environment external to the laboratory from exposure to infectious materials is considered secondary containment. It is attained by a combination of facility design and operational practices. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of work practices, safety equipment, and facility design to provide adequate containment.

- Facility Design:

  The design of a facility is important in providing a barrier to protect people working inside and outside the laboratory, and people, plants, and animals in the community from infectious agents by reducing the probability of them being released from the laboratory. Facilities must be commensurate with the laboratory's function and the recommended biosafety level for the agent being manipulated.

  The recommended secondary barrier(s) will depend on the risk of transmission of specific agents. For example, the exposure risks for most laboratory work in Biosafety Level 1 and 2 facilities will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments. Secondary barriers in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave), and hand washing facilities.

  As the risk for aerosol transmission increases, higher levels of primary containment and multiple secondary barriers may become necessary to prevent infectious agents from escaping into the environment. Such design features could include specialized ventilation systems to assure directional airflow, air treatment systems to decontaminate or remove agents from exhaust air, controlled access zones, airlocks at laboratory entrances, or separate buildings or modules for isolation of the laboratory.

C. Laboratory Practice and Technique:

The most important element of containment is strict adherence to standard microbiological practices and techniques. Individuals working with infectious agents or infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The PI or laboratory supervisor is responsible for providing or arranging for appropriate training of personnel.

The following standard microbiological practices must be adhered to at all times:

- Lab personnel must wash their hands after handling biohazardous materials, removing gloves, or leaving the containment area.
- Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas.
- Mouth pipetting is prohibited; mechanical pipetting devices must be used.
- Perform all procedures in a way that minimizes the creation of splashes and/or aerosols.
- Decontaminate work surfaces after completion of work with biohazardous materials and after any spill or splash of potentially infectious material with appropriate disinfectant.
- Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method.
- An effective integrated pest management program is required (see Appendix G for details).
- The PI or laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.

Each laboratory must develop an operational manual that identifies specific hazards that will or may be encountered, and that specifies practices and procedures designed to minimize or eliminate risks. Personnel should be advised of special hazards and should be required to read and follow the required practices and procedures.

Laboratory personnel safety practices and techniques must be supplemented by appropriate facility design and engineering features, safety equipment, and management practices as determined by risk assessment.

II. Biosafety Practices & Procedures

Members of the IBC will inspect the research facility (visual inspection) to ensure that the space meets regulatory standards. SAT facilities are inspected annually.

The inspectors will ask the PI who is responsible for the space a series of questions (verbal inspection) to verify that the proper biosafety procedures are being adhered to by all laboratory personnel. The visual and verbal inspection checklists for each type of SAT containment facility can be found in Appendices H-K. Noncompliance with the items in the checklists will result in suspension or termination of IBC approval. The checklist items are self-explanatory; however the following sections provide further details for some of the items.

A. Biosafety Training

Training requirements are dependent upon the individual's role in the select agent program. The following table dictates training requirements for various groups. A description of OSU's SAT training program follows.

Training Requirements

	Researchers	Animal Handlers	Bio Emergency Responders	Maintenance	UMS	Support Staff	Administration
Select Agent Training	x	x	x	x	x	x	x
Agent Specific Training	x	x_2	x	x	x_3	N/A	N/A
Lab Specific Procedures Training	x	x_2	N/A	N/A	N/A	N/A	N/A
Project Specific Proficiency Training	x	x_2	N/A	N/A	N/A	N/A	N/A
Respiratory Training	x_1	x_1	x	N/A	N/A	N/A	N/A
Bloodborne Pathogen Training	x_1	x_1	N/A	N/A	N/A	N/A	N/A
Chemical Hygiene Training	x_1	x_1	N/A	N/A	N/A	N/A	N/A

Support staff = OSUPD, radiation safety, IT , key shop, building security personnel

Bio Emergency Responders = individuals who may enter SAT spaces to respond to an emergency (e.g., Biosafety Office personnel, Radiation Safety Office personnel, Laser Safety Officer)

x_1= if needed for the project
x_2=not required until initiation of a project
x_3=required before shipping/receiving SAT package

Required training must be completed within 12 months of an individual's anniversary of receiving access approval from the HHS Secretary or the APHIS Administrator, or prior to his or her entry into an area where any select agents and toxins are used or stored, whichever occurs first. Refresher training must be completed on an annual basis.

Select agent training is conducted by the BSO at least annually. The training session is recorded and those who miss the training event or enter the program mid-year can schedule a time to view the training with Biosafety Office staff.

Agent specific training includes: the potential hazards, the signs and symptoms the agents/toxins cause, the route of exposure, precautions to prevent exposures, and exposure evaluation procedures. The PIs provide this training for their personnel on an annual basis. The BSO provides this training for qualifying emergency responders, maintenance personnel, and university mailing services personnel.

Respiratory training is required for personnel who must wear a respirator to carry out aspects of their job. This training can be provided either by EHS or by the PI. Details regarding respiratory training requirements can be found in Appendix F.

Lab specific procedures training covers the lab specific plans (biosafety, biosecurity, and incident response) and includes training on spill procedure and how to open packages containing biohazards. The PIs provide this training for their personnel on an annual basis.

Project specific proficiency training involves the individual demonstrating that they can perform project specific tasks safely. Typically, the procedures are conducted with a non-select agent or toxin until the individual demonstrates proficiency. The trainer is someone who has experience working with the agent/toxin and the procedure. This should be performed initially and when new procedures are used.

Bloodborne pathogen training is required if an individual is working with or may be exposed to human blood or other potentially infectious bodily fluids. This training is provided by EHS and is required annually.

Chemical hygiene training is required for those working with biological toxins or other hazardous chemicals. The training should cover the lab specific Chemical Hygiene Plan. The PIs provide this training for their personnel on an annual basis.

B. Biohazard Warning Signs and Postings

Anyone entering areas where biohazardous materials are used must be aware of the potential hazards. All biosafety laboratories/facilities will display the same type of signage. The sign or door placard will include the biohazard symbol, the biosafety containment level, the PI's contact information and any required procedures for entering and/or exiting the laboratory. Additionally, visitors to SAT labs/facilities must follow the visitor guidelines that are outlined in the Biosecurity Plan.

C. Syringes and Needles

Written policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. The greatest risks when using sharps are accidental injection and the creation of aerosols. Laboratory supervisors should adopt engineering and work practice controls that reduce the risk of sharps injuries.

- Needles and syringes may only be used when there is no reasonable alternative. Safety needles and syringes must be used in these instances.
- Sharps must be kept away from fingers as much as possible. Sharps must never be bent, sheared, or recapped. Needles should never be removed from syringes after use. If a contaminated needle must be recapped or removed from a syringe, a mechanical device, such as forceps, must be used.
- Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
- Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
- Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps.
- A modified excerpt from the "Biohazard Waste Disposal Guidelines For the OSU-CVHS Veterinary Teaching Hospital," which may be used by **any** OSU employee for sharps follows.

  Check Out or Purchase Procedure of Biohazard and Sharps Boxes from Central Supply in the VTH – Personnel will purchase boxes from Central Supply for use in their own sections/department. Central Supply will write the section/department name on the box with a Sharpie at the time of box purchase from non-VTH units. This will allow the VTH to call the specific section or department responsible for the box if a box has not been properly assembled, packaged, or is returned in poor condition. The VTH cannot accept any over-stuffed boxes, leaking boxes, or poorly taped boxes.

  Proper Use of Sharps Containers - All sharps containers have a maximal fill level designated on the container. DO NOT over fill. Filled sharps containers must be autoclaved or decontaminated by an approved method before disposal.

  Proper Use of Box - Decontaminated sharps containers shall be properly closed and disposed of in cardboard biohazard box lined with a red bag. The red bag must be free of holes and closed with a goose-neck tie or taped shut. This box will be picked up by Stericycle for incineration.

Full biohazard boxes that are being returned should be brought to Central Supply in the VTH and Central Supply personnel will assist you in where to place the box. Alternatively, researchers can call EHS to transport the container from the lab to the VTH for proper disposal. * DO NOT bring sharp containers to the VTH as a separate item, the sharps containers must be placed in a cardboard biohazard box. Due to federal regulations, the full boxes must be stored in a locked fenced-in area until pick up by the vendor. Central supply personnel have the key to this area and will assist you in getting the key that unlocks the door to room 011 and the gate lock.

Since all boxes will be identified by the department or section, if the box begins to leak or have significant odor, the responsible department/section will be called to resolve those issues. Note: it is the department/section responsibility to assure proper care and use of these boxes.

Cost of Boxes and Pick-Up Day – The cost of boxes includes disposal charge, energy charge, and fuel charge from Stericycle and a minimal handling fee by Central Supply. Each department outside of the VTH must give Central Supply an account number so that appropriate charges can be levied at the time personnel purchase the boxes. Contact the VTH for current costs and Stericycle pick-up times.

D. Safe and Effective Use of Biological Safety Cabinets

All SAT manipulations must be performed inside a biological safety cabinet (BSC) or other primary containment device unless a project has been approved by the IBC and CDC with the room serving as primary containment. All BSCs must be certified annually.

BSCs are designed to protect personnel, research products, and the environment. The BSC accomplishes this protection by directional airflow and HEPA filters. HEPA stands for high efficiency particulate air and can filter 0.3 micron particles at 99.97% efficiency. HEPA filters are even more efficient at trapping both smaller and larger sized particles. The HEPA filter removes airborne particles from the air but does not remove chemical fumes. Some chemicals may even compromise the HEPA filters. The BMBL provides more detailed information on the different types of BSCs.

There are other types of hoods that share some similarities with a BSC, but cannot protect all three categories. For example, a chemical fume hood is designed to protect personnel by removing chemical vapors and aerosols away from the work area. However, it does not protect the environment from biohazardous materials because it does not typically have a HEPA filter. Laminar flow hoods should also not be used when working with biohazardous materials because these types of hoods can only protect the research product, as they do not protect the researcher or others in the vicinity.

If your cabinet is hard-ducted to an in-house exhaust system, then you will want to keep your BSC running at all times and you will need to leave the sash up to ensure proper exhaust of your laboratory. Contact your building manager or the Biosafety Office if you are unsure about whether you need to leave your BSC on or if you need to turn it off. If your BSC can be turned off, always make sure it is disinfected prior to shutting it down (refer to "Disinfection and cleanup of the BSC" for details, which follows). For the most consistent contamination control and safe operation, BSCs should be operating 24 hours a day, 7 days a week.

Preparation for Work in a BSC

- Turn on the BSC and wait for the air to purge (10 minutes) to prevent product contamination.
- Put on a lab coat or solid front gown and gloves (additional PPE such as eye or respiratory protection may be required based upon risk assessment).
- Check to make sure the BSC has been certified within the last 365 days.
- Make sure the drain valve is closed so that the BSC can contain a spill within the cabinet.
- Check the height of the seat (armpits should be level with the view screen; feet should be on the floor or foot rest).
- Disinfect all surfaces within the BSC (work surface, walls, interior of sash). (*Note bleach can be corrosive. Rinse with sterile water if bleach is used.)

- Place an absorbent plastic-backed mat on the work surface with the plastic side down (optional).
- Disinfect materials to be placed inside BSC and place only the necessary items in the BSC, as BSCs are not to be used for storage.
- Set up work items so that clean items are on one side and dirty items are on the other, leaving the middle section for your work area.
- Check to make sure nothing is blocking the front grill of the BSC.
- The view screen should be in the proper position (determined by the manufacturer).

Working in a BSC

- Limit traffic in the area when the BSC is in use.
- Conduct work in the center as far into the cabinet as comfortably possible.
- Move slowly and deliberately while working.
- Move arms straight in, perpendicular to the opening and wait for 1 minute to start manipulations; do not use sideways or sweeping motions in order to prevent airflow disruption.
- Use good aseptic microbial techniques.
- Do not use open flames or flammable gas in the BSC. Open flames inside of a BSC disrupt the airflow, compromising protection of both the work and the material being handled. Open flames are extremely dangerous around flammable materials, such as ethanol, which is often found in a BSC. Electric incinerators, touch plate microburners, and sterile disposable instruments are excellent alternatives.
- Only use grounded electrical equipment inside the cabinet.
- If a spill occurs, follow the spill procedures outlined in Appendix L of this document.
- If the BSC alarm sounds while the cabinet is in use, close or cover vessels containing biohazardous material and report the problem to the PI or lab manager.

Disinfecting and cleanup of the BSC

- Place all disposable items that have been exposed to biohazardous material in a biohazard bag within the cabinet.
- Disinfect items before bringing them outside of the BSC, including the outside of the biohazardous waste bag and PPE.
- Be sure to allow adequate disinfection time for the disinfectant used. Alternatives for bleach or alcohol are preferred. Bleach has a tendency to corrode stainless steel, and even 70% alcohol evaporates too quickly to be effective.
- Disinfect all surfaces in the cabinet, including the work surface, interior walls, and inside of sash with a disinfectant and proper contact time that is appropriate for the particular biohazardous material used. Never put your head inside the BSC!
- UV lights should not be the only means used to disinfect a BSC because the light cannot penetrate organic material and its efficiency decreases over time. Be sure the UV light is turned off before beginning work and when occupants are in the laboratory because exposure to UV light for a prolonged period will cause burns.
- Schedule routine thorough cleanings of the BSC to include cleaning the pan underneath the work surface.

- Leave blower on for an additional 5-10 minutes once disinfection is complete, if your BSC is not one that needs to remain on at all times.

E. Laundry

The OSU IBC recognizes that all University employees have the right to know and the need to know the properties and potential safety issues and health problems associated with the substances to which they may be exposed.

Therefore, all materials such as lab coats must be autoclaved or treated with an appropriate disinfectant for the appropriate contact time prior to being taken to any laundry facility.

F. Housekeeping

Custodial Services personnel do not have access to any SAT space. The PI, or his/her research team, is responsible for housekeeping inside SAT spaces.

G. Biohazard Spill Cleanup Kits

Each laboratory in which biohazardous materials are used must have appropriate equipment and supplies on hand for managing spills and incidents involving biohazardous materials. Permanent equipment should include a safety shower (if appropriate), eyewash, and a hand-washing sink and supplies. A Biohazard Spill Kit should also be kept on hand and immediately accessible. The supplies available in a Biohazard Spill Kit should include, but are not limited to:

- a copy of the biohazard spill clean-up protocol,
- disposable shoe covers (booties),
- absorbent material, such as absorbent paper towels, granular absorbent material, etc. (a disposable or cleanable scoop will be needed for granular absorbent material),
- all-purpose disinfectant, such as normal household bleach (freshly diluted 1:10) or other appropriate disinfectant,
- something disposable or easily disinfected such as tongs, forceps, manila folders, etc. for picking up broken glass, other contaminated sharps, or contaminated absorbent material,
- autoclavable biohazard waste bags, and
- biohazard spill warning signs.

  NOTE: All non-disposable items should either be autoclavable or compatible with the disinfectant to be used.

H. Biohazard Spill Clean-up Protocol for laboratories that fall within the IBC's purview see Appendix L.

I. Laboratory Decontamination for SAT Laboratories

Each SAT laboratory will undergo an annual decontamination procedure to allow for preventative maintenance, annual recertifications, and IBC laboratory inspection. The method for decontamination will be determined by risk assessment and will be based upon the agents and procedures used in a space. At a minimum, each SAT laboratory shall disinfect all of the horizontal surfaces in a space where SATs have been used:

- on an annual basis;
- following any major spills outside of primary containment; and
- when the space will be decommissioned or downgraded to a lower biosafety level.

For some projects, it will be appropriate to use vaporized hydrogen peroxide (VHP) to decontaminate a SAT space. When VHP is used, the dampers must be closed and the laboratories must be sealed with tape. It is recommended that conventional fans be set up to help distribute the VHP gas throughout the space. The instruction manual for the specific VHP unit will be consulted and followed. The

concentration of VHP will be tested and verified to be under the allowable amount prior to reentering the space. Spore strips will be used to determine if the VHP was effective. The number of spore strips used will be based upon the size of the laboratory. The required PPE for the space will be worn until the spore strips verify that the decontamination was successful. The Biosafety Office is responsible for VHP decontamination in SAT spaces.

J. Laboratory Recertification

SAT facilities must be recertified on an annual basis. BSL-2 SAT labs are recertified through the IBC inspection and are not required to perform any additional recertification. The NIH BSL-3 Certification Checklist as well as the CDC document "Policy on BMBL 5th edition Laboratory Facilities (Secondary Barriers) Standards" will be used as guides for the annual recertifications.

K. Personal Exposure to Infectious Material

See the SAT Incident and Emergency Response Plan for details.

L. Decontamination

All employees who through their work generate biohazardous waste must strictly adhere to the OSU waste disposal guidelines delineated below.

All biohazardous waste must be decontaminated before disposal. Common decontamination methods include heat sterilization (e.g. autoclaving), chemical disinfection, incineration, or tissue digestion. The decontamination of SAT waste must be validated on a monthly basis at a minimum. When using an autoclave for steam sterilization, the waste should be treated for a minimum of 15 minutes at 121 ºC at 15 psi. The sterilization time will be dependent upon the volume of the waste and the concentration of organisms.

a. Animal carcasses, tissues, and bedding

All animal carcasses, tissues, and bedding used in a SAT project must be decontaminated before disposal. The waste should be autoclaved, incinerated, or tissue digested as dictated by risk assessment.

b. Liquids

Decontaminate all liquid biohazardous materials by autoclaving or treating with the appropriate chemical disinfectant if autoclaving is not an option. Once the decontamination has been validated, liquids may be disposed of by pouring them down the drain to the sanitary sewer with cold running water.

c. Disposable solid items

Collect all non-sharp disposable items (such as gloves, plasticware, Kimwipes, etc.) contaminated with biohazardous materials in leak proof autoclavable biohazard bags. Decontaminate the bags by autoclaving when they are ready for disposal. After autoclaving, the biohazard bag should be labeled in accordance with EHS policy. After labeling, the waste should be double-bagged in dark trash bags and placed in a solid waste container.

d. Non-disposable or reusable items

Decontaminate non-disposable or reusable items (such as equipment, glassware, benchtops, etc.) contaminated with biohazardous materials by using a chemical disinfectant (such as 10% bleach, a quaternary ammonium compound, an alcohol, etc.). Choose a chemical disinfectant appropriate for the specific biohazardous material being used and make sure to use the appropriate contact time for each disinfectant.

e. Sharps and broken glass

Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Collect all sharps in an approved, rigid, leak proof, puncture-resistant, autoclavable, plastic sharps container. Decontaminate the containers by autoclaving when they are ready for disposal. Broken glassware must be collected in a similar type of container that is autoclavable if contaminated with biohazardous material. After decontamination, the sharps containers will be picked up on request by EHS. For broken glassware that is not contaminated with biohazardous material, collect in a rigid, leak proof container labeled broken glass. Package it in a cardboard box that has been sealed and labeled "broken glass," and discard in regular trash.

M. Transportation of SATs

When transporting SATs, materials must be placed in a primary non-breakable, leak-proof, sealed container and enclosed in a non-breakable, secondary container. Special security procedures must be followed when shipping or receiving SATs. These procedures are outlined in the Biosecurity Plan. Please contact the BSO for details.

N. Compromised Immune Systems

The following may make individuals more susceptible to infection: disease, other medical conditions, or drugs that alter host defense; allergic hypersensitivity; inability to receive a specific vaccination; and reproductive issues. Skin diseases such as chronic dermatitis, eczema, and psoriasis can create breaks in the skin that will allow pathogens to penetrate. Antibiotic or antimicrobial treatment can change the composition of the natural microbial flora of your mucous membranes or digestive system, leaving you more susceptible to colonization by infectious microorganisms. Other conditions and treatments such as diabetes mellitus, cancer chemotherapy, steroid treatments, or HIV infection may also cause immunodeficiencies.

Women who are pregnant are also considered to be immunocompromised. The mother's body has to lower its defenses to make sure that it does not reject the baby. This leaves pregnant women more susceptible to infections and some of these infections can be passed along to the fetus.

Being aware of your health status can reduce your risk of contracting a laboratory acquired infection (LAI). If you have any concerns regarding your immune system and the hazards you are exposed to in the workplace, please contact University Health Services or your own personal physician for medical advice.

O. Exclusion & Inactivation

The following are excluded from the requirements of the select agent regulations:

- a select agent or regulated nucleic acid that has been subjected to a validated inactivation procedure and confirmed through a viability testing protocol; and
- a select toxin that has been rendered non-toxic by a validated procedure.

Select agents or regulated nucleic acids are considered non-viable or non-infectious only after being subjected to an in-house validated inactivation procedure that is confirmed through a viability or infectivity testing protocol. A select toxin is considered non-toxic only after it has been subjected to a procedure that has been validated to be effective on a specific toxin. The entity possessing the regulated material is responsible for assuring non-viability, non-infectivity, or non-toxicity.

A PI must render a select agent, select toxin, or regulated nucleic acids non-viable, non-toxic, or non-infectious using a validated inactivation procedure for which the efficacy has been confirmed by data generated from a viability testing protocol. Validation of an inactivation procedure may include:

1) use of the **exact** conditions of a commonly accepted procedure that has been validated in-house;

2) use of a published procedure with adherence to the exact published conditions that has been validated in-house as applied;

3) use of in-house derived procedures with specific conditions that will be used to prepare subsequent samples to verify that the inactivation procedure would be an effective procedure each time it is performed.

For materials subjected to a validated inactivation procedure, the following records must be kept:

- A written description of the:
    - validated inactivation procedure or viable select agent removal method used, including validation data; and
    - viability testing protocol used.
- The name of each individual performing the validated inactivation or viable select agent removal method.
- The date(s) the validated inactivation or viable select agent removal method was completed.
- The location where the validated inactivation or viable select agent removal method was performed.
- A certificate, signed by the PI, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the individual who carried out the inactivation protocol. A copy of the certificate must accompany any transfer of these materials.

Each validated inactivation protocol will be reviewed by the BSO on an annual basis.

Appendix A – Select Agent and/or Toxin List

HHS AND USDA SELECT AGENTS AND TOXINS
7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus[3]
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus[3]
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
- Chapare
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
- Far Eastern subtype
- Siberian subtype

Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis *
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus[3]

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus[3]
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum[3]
Mycoplasma mycoides[3]
Newcastle disease virus[2,3]
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

*Denotes Tier 1 Agent

[1] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnlA, α-CnlB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[2] A virulent Newcastle disease virus (avian paramyxovirus serotype 2) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[3] Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus , west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, and Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3, provided that the individual or entity can verify that the agent is within the exclusion category.

9/10/13

Appendix B – Permissible Toxin Amounts

The following toxins are not regulated if the amount under the control of a PI does not exceed, at any time, the amounts indicated in the table below.

HHS Toxins [§73.3(d)(3)]	Amount
Abrin	1,000 mg
Conotoxins (short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)	100 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1,000 mg
Saxitoxin	500 mg
Tetrodotoxin	500 mg
HHS / USDA Overlap Toxins [§73.3(d)(3)]	**Amount**
Botulinum neurotoxins	1.0 mg
Staphylococcal enterotoxins (subtypes A-E)	100 mg
T-2 toxin	10,000 mg

Appendix C – Hazardous Characteristics of Select Agents & Toxins at OSU

Select Agent or Toxin	Mode of Transmission	Infectious Dose	Lab Safety & Containment Recommendations	Treatment	Disinfectants
Bacillus anthracis	Direct contact via skin abrasions, ingestion, inhalation	8,000 to 50,000 organisms by inhalation; very few spores (10 or less) are required for cutaneous anthrax	BSL-3/ABSL-3 practices & facilities	Susceptible to penicillin (except for inhalation anthrax), ciprofloxacin, doxycycline, tetracyclines, erythromycin, & chloramphenicol	Spores are resistant to many disinfectants; susceptible to 2% glutaraldehyde formaldehyde & 5% formalin
Botulinum neurotoxin producing species of *Clostridium*	Direct contact via skin abrasions, ingestion	Cells/spores are not toxic for healthy adults	BSL-2/ABSL-2 practices & containment for activities involving the organism; BSL-3/ABSL-3 practices & containment for activities with high potential for aerosol or droplet production, or for those requiring handling of larger quantities of the organism	Susceptible to penicillin, metronidazole, clindamycin, cephalothin, cefoxitin, cefotaxime, chloramphenicol, tetracycline, erythromycin, rifampin, & vancomycin;	Vegetative cells are susceptible to 70% ethanol, 0.1% sodium hypochlorite, & 0.1N NaOH; spores may be resistant to disinfectants
Botulinum neurotoxin	Ingestion, injection, inhalation	Estimated oral or injected toxin dose of 0.001 ug/kg body weight; estimated lethal dose by inhalation of 0.07 ug/kg body weight	BSL-2/ABSL-2 practices & containment for activities involving the toxin; BSL-3/ABSL-3 practices & containment for activities with high potential for aerosol or droplet production, or for those requiring handling of larger quantities of the organism	Botulinum antitoxin	Inactivated by 20 minutes exposure to 3 mg/L free available chlorine (FAC)
Brucella abortus *Brucella melitensis* *Brucella suis*	Direct contact via skin abrasions, mucous membrane exposure, ingestion, inhalation	10-100 organisms by aerosol route	BSL-3/ABSL-3 practices & facilities for manipulations of cultures and experimental animal studies	Susceptible to tetracyclines and streptomycin; therapy usually consists of a doxycycline and streptomycin combination	Susceptible to many disinfectants; 1% sodium hypochlorite, 70% ethanol, iodine/alcohol solutions, glutaraldehyde, & formaldehyde

Select Agent or Toxin	Mode of Transmission	Infectious Dose	Lab Safety & Containment Recommendations	Treatment	Disinfectants
Burkholderia mallei	Direct contact with nasal secretions of infected equines, inhalation	Unknown	BSL-3/ABSL-3 practices & facilities	Sensitive to ceftazidime, imipenem, doxycycline, minocycline, ciprofloxacin, & gentamicin	Susceptible to many disinfectants; 1% sodium hypochlorite, 70% ethanol, & 2% glutaraldehyde
Burkholderia pseudomallei	Direct contact via skin abrasions, ingestion, inhalation	Unknown	BSL-3/ABSL-3 practices & facilities	Susceptible to ceftazidime, imipenem, doxycycline, ciprofloxacin, sulphas, chloramphenicol, & tetracycline; TMP-SMX is most effective	Susceptible to many disinfectants; 1% sodium hypochlorite, 70% ethanol, glutaraldehyde, & formaldehyde
Coxiella burnetii	Inhalation, direct or indirect contact with infected animals or their dried excreta, ingestion, bite of infected insect	1-10 organisms	BSL-3/ABSL-3 practices & facilities	Susceptible to cotrimoxazole, rifampin, doxycycline, minocycline, tetracycline, clarithromycin, sparfloxacin, & quinolones	Resistant to many chemical disinfectants; inactivated by 30 minutes exposure to 70% ethanol, 5% chloroform, or 5% Enviro-Chem
Francisella tularensis	Direct contact via skin abrasions, conjunctival sac, or mucous membranes, ingestion, inhalation, bite of infected insect or animal	5-10 organisms by the respiratory route; 10^6-10^8 organisms by ingestion	BSL-3/ABSL-3 practices & facilities	Susceptible to aminoglycosides, streptomycin, gentamycin, tobramycin, kanamycin, tetracyclines, chloramphenicol; streptomycin for severe disease and tetracycline for less severe	Susceptible to many disinfectants; 1% sodium hypochlorite, 70% ethanol, glutaraldehyde, & formaldehyde
Peronosclerospora philippinensis (*Peronosclerospora sacchari*)	Spread of spores from infected plants via rain & wind dispersal	Unknown	BSL-2	No treatment; control via removal and destruction of infected hosts, adherence to sanitary practices, and quarantine of infested areas	Susceptible to 10% bleach & 70% ethanol

Select Agent or Toxin	Mode of Transmission	Infectious Dose	Lab Safety & Containment Recommendations	Treatment	Disinfectants
Phoma glycinicola (formerly *Pyrenochaeta glycines*)	Spread locally by rain splash & movement by contaminated animals; long distance spread may occur by transport of infected plant material & seeds	Unknown	BSL-2	No treatment; control via removal and destruction of infected hosts, adherence to sanitary practices, and quarantine of infested areas	Susceptible to 10% bleach & 70% ethanol
Ralstonia solanacearum race 3, biovar 2	Spread by contaminated soil, irrigation & surface water, equipment, personnel, & infected plant material	Unknown	BSL-2	No treatment; control via removal and destruction of infected hosts, adherence to sanitary practices, and quarantine of infested areas	Susceptible to 10% bleach & 70% ethanol
Rathayibacter toxicus	Spread to new fields via nfected seeds and by *Aguina* sp. nematodes; corynetoxin produced by the organism is spread by ingestion of infected plant material	Unknown	BSL-2	No treatment for plant disease; control via removal and destruction of infected hosts, adherence to sanitary practices, and quarantine of infested areas; toxicosis may be treated with toxin-binding agents	Susceptible to 10% bleach & 70% ethanol
Rickettsia prowazekii	Direct contact via skin abrasions, inhalation	<10 rickettsial particles	BSL-3/ABSL-3 practices & facilities	Susceptible to tetracyclines, chloramphenicol & doxycycline	Susceptible to 1% sodium hypochlorite, 4% formaldehyde, 2% glutaraldehyde, 70% ethanol, 2% paracetic acid, 3-6% hydrogen peroxide, & 0.16% iodine
Sclerophthora rayssiae	Transmitted via wind & rain dispersal or in infected soil	Unknown	BSL-2	No treatment; control via removal and destruction of infected hosts, adherence to sanitary practices, and quarantine of infested areas	Susceptible to 10% bleach & 70% ethanol

Select Agent or Toxin	Mode of Transmission	Infectious Dose	Lab Safety & Containment Recommendations	Treatment	Disinfectants
Synchytrium endobioticum	Local spread occurs via movement of spores in soil and water & by contaminated machinery; long-distance spread occurs via infected seed potatoes	Unknown	BSL-2	No treatment; control via removal and destruction of infected hosts, adherence to sanitary practices, and quarantine of infested areas	Susceptible to 10% bleach & 70% ethanol
Yersinia pestis	Direct contact via skin abrasions, inhalation, bit of infected insect	Unknown	BSL-3/ABSL-3 practices & facilities	Susceptible to streptomycin, tetracycline, chloramphenicol & kanamycin	Susceptible to many disinfectants; 1% sodium hypochlorite, 70% ethanol, 2% glutaraldehyde, iodines, phenolics, & formaldehyde
Xanthomonas oryzae	Spread via infected seeds, irrigation water containing infected plant material, & weather events	Unknown	BSL-2	No treatment; control via removal and destruction of infected hosts, adherence to sanitary practices, and quarantine of infested areas	Susceptible to 10% bleach & 70% ethanol

Appendix D – Procedural Risks

	Procedure	Mitigating Factors				Notes
		PPE	Primary Containment (BSC, etc.)	Secondary Containment (Engineering Controls)	SOPs/Training	
Aerosol Producing	Propagation	✓	✓	✓	✓	
	Culture Manipulation	✓	✓	✓	✓	
	Vortexing	✓	✓		✓	
	Centrifugation	✓	✓	✓	✓	Use safety cups or sealed rotor
	Pipetting	✓	✓		✓	
	Blending	✓	✓	✓	✓	
	Shaking	✓	✓	✓	✓	
	Automated Plating/Washing	✓	✓	✓	✓	
Animal Work	Injection Procedures	✓	✓	✓	✓	
	Aerosol Exposure	✓	✓	✓	✓	
	Bedding/Cage Changes	✓	✓		✓	
	Necropsy/Tissue Harvesting	✓	✓	✓	✓	
	Sharps Usage	✓		✓	✓	
	Surface Decontamination	✓			✓	Use effective disinfectant
	Waste Handling	✓			✓	
	Spills/Splashes/Sprays	✓			✓	Use effective disinfectant & approved SOP

Appendix E - Occupational Health & Safety Program for Biosafety

All personnel listed on the University's SAT registration shall be enrolled in and comply with the OSU Occupational Health and Safety Program, aspects of which have been tailored for Biosafety.

The IBC will review protocols and determine if other personnel are required to enroll in the program.

The policy and forms can be found on the Environmental Health and Safety (EHS) Occupational Health and Safety Program webpage: **https://ehs.okstate.edu/content/ohsp-biological-safety**

Personnel working with animals will also be required to enroll in the Occupational Health and Safety Program. Allergy risk assessment and counseling will be provided by a health care provider at University Health Services for each individual working with animals. Additional details for animal handlers can be found in IACUC Policy No. 007.

Appendix F – Respiratory Protection for Select Agent and Toxin Laboratories

I Purpose and Scope

A. The purpose of the university's respiratory protection program is to ensure that all employees have adequate respiratory protection when working in laboratories on the OSU campus where engineering controls or work practices may not fully protect employees from hazards associated with the work they are performing. The respiratory protection program applies to all employees who are required to wear respirators during normal operations, non-routine tasks, or emergency operations such as a spill of a hazardous substance. For the purpose of this program, the wearing of N-95 respirators is deemed to be within the scope of this document and proper medical evaluations and fit testing shall be performed.

B. In all cases, engineering controls will be the first line of protection and must be implemented to the extent that they are feasible.

II Responsibilities

A. OSU shall provide respirators, training, fit testing, and medical evaluations at no cost to the employee. The respiratory program is not paid for with Occupational Health and Safety Program (OHSP) funds however; the respiratory program is typically paid for by the PI's department.

B. Each department, unit, office, laboratory, etc. will have a program administrator who is responsible for overseeing the respiratory protection program in their respective area. PIs typically serve as program administrators for the research labs they manage. Duties of the program administrator include:

- Identifying work areas, processes or tasks that require workers to wear respirators, and evaluating hazards
- Selection of respiratory protection options
- Monitoring respiratory use to ensure that respirators are used in accordance with their certifications
- Arranging for and/or conducting training
- Ensuring proper storage and maintenance of respiratory protection equipment
- Arranging for fit testing through Environmental Health and Safety (EHS)
- Administering the medical surveillance program
- Maintaining records required by the program
- Evaluating the program
- Updating written program as needed
- Ensuring that employees under their supervision (including new hires) have received appropriate training, fit testing, and medical evaluation
- Ensuring the availability of appropriate respirators and accessories
- Being aware of tasks requiring the use of respiratory protection
- Enforcing the proper use of respiratory protection when necessary
- Ensuring that respirators are properly cleaned, maintained, and stored according to the respiratory protection plan
- Ensuring that respirators fit well and do not cause discomfort
- Continually monitoring work areas and operations to identify respiratory hazards
- Addressing respiratory hazards or other concerns regarding the program

C. Each employee has the responsibility to wear his or her respirator when and where required and in the manner in which they were trained. Employees must also:

- Care for and maintain their respirators as instructed and store them in a clean sanitary location
- Inform their supervisor if the respirator no longer fits well, and request a new one that fits properly

- Inform their supervisor or the Program administrator of any respiratory hazards that they feel may not be adequately addressed in the workplace and of any other concerns that they have regarding the program

D. PIs will utilize the process flow diagram below to evaluate, develop, and maintain a respiratory protection program for their SAT laboratories.

E. The IBC shall review respiratory protection, as well as other forms of personal protective equipment (PPE) recommended by the PI, for adequacy and for compliance with institutional standards.

F. University Health Services personnel shall make the determination of whether an employee is medically fit to wear respiratory protective equipment (see Respiratory Program Medical Evaluation Process Flow). The frequency of a medical evaluation for each individual will be determined by a health care provider and will be based upon age and health status.

G. University Health Services shall maintain all medical records pertaining to the respiratory protection program as outlined in part V of this appendix.

H. EHS personnel shall perform fit testing for employees who have been deemed medically fit to wear tight fitting respirators such as an N-95. Fit testing is required to be performed annually.

III Training and Information

A. Prior to being permitted or required to wear respiratory protective equipment, the employee must successfully complete the appropriate respiratory training requirements.

B. EHS shall provide training as required by the OSHA 1910.134 Respiratory Protection Standard and shall ensure that each employee can demonstrate knowledge in the following areas:

1. Why respiratory protection is necessary.
2. The limitations and capabilities of the respirator.
3. How to inspect, put on, and remove a respirator, as well as how to perform user check seals.
4. The procedures for maintenance and storage of respiratory equipment.
5. How to recognize medical signs and symptoms.

C. The PI or program administrator shall provide lab-specific training in the following areas:

1. The laboratory's respiratory protection program requirements.
2. How to recognize medical signs and symptoms associated with exposure to the select agents and/or toxins used in the laboratory. Other respiratory hazards encountered and their health effects, as well as medical signs and symptoms limiting the effective use of respirators.
3. The OSHA Respiratory Protection Standard.
4. Proper selection and use of respirators.
5. Limitations of respirators.
6. Respirator donning and user seal (fit) checks.
7. Fit testing.
8. Emergency use procedures.
9. Maintenance and storage.

D. The training shall be understandable to the employee.

E. Employees shall be trained annually by either the PI or EHS and whenever one or more of the following situations occur (Note: Training conducted by the PI cannot take the place of the OSHA 1910.164 Respiratory Protection training, which is provided by EHS on an annual basis):

1. There are changes in the workplace environment where respiratory protection is used (e.g. addition or deletion of a select agent or toxin, changes in engineering controls, etc.)
2. There are changes in the procedures or policies in respiratory equipment usage.
3. Whenever the employee demonstrates inadequacies in knowledge, as determined by a supervisor or the PI.
4. Any other situation that might warrant retraining.

IV Program Evaluation

The PI shall evaluate the respiratory protection program for his/her lab at least annually. The PI will also routinely evaluate the following:

1. The proper respirator fit on the employee.
2. Whether the respirator in use is interfering with the effective work performance.
3. Whether appropriate respiratory protection has been selected.
4. Whether the respiratory equipment is used properly.

V Recordkeeping

A. At a minimum, the PI of the laboratory shall maintain the following documents:

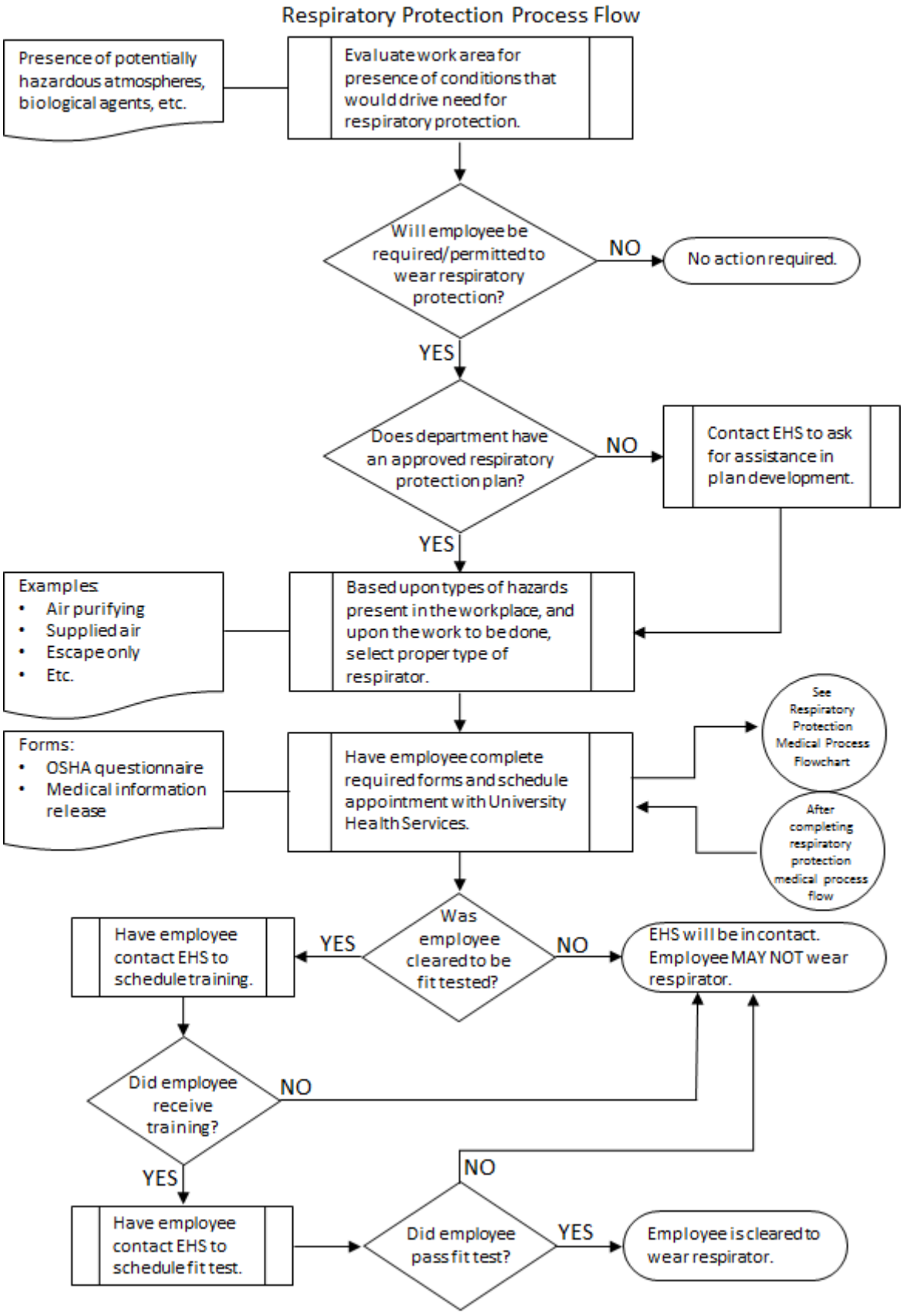
1. A written record from UHS that certifies that an employee is medically fit to wear a respirator.
2. A written record of the last respiratory fit test administered to the employee.
3. A current, written copy of the respiratory protection program for the laboratory.

B. University Health Services, serving as the Physician or Other Licensed Health Care Professional (PLHCP), shall maintain all written medical records of the employees who wear respiratory equipment. Only the affected employee and the PLHCP shall have access to the employee's medical record, unless the employer has authorized the release of medical information to a third party or if some aspect of the employee's medical history is important to a worker's compensation claim.

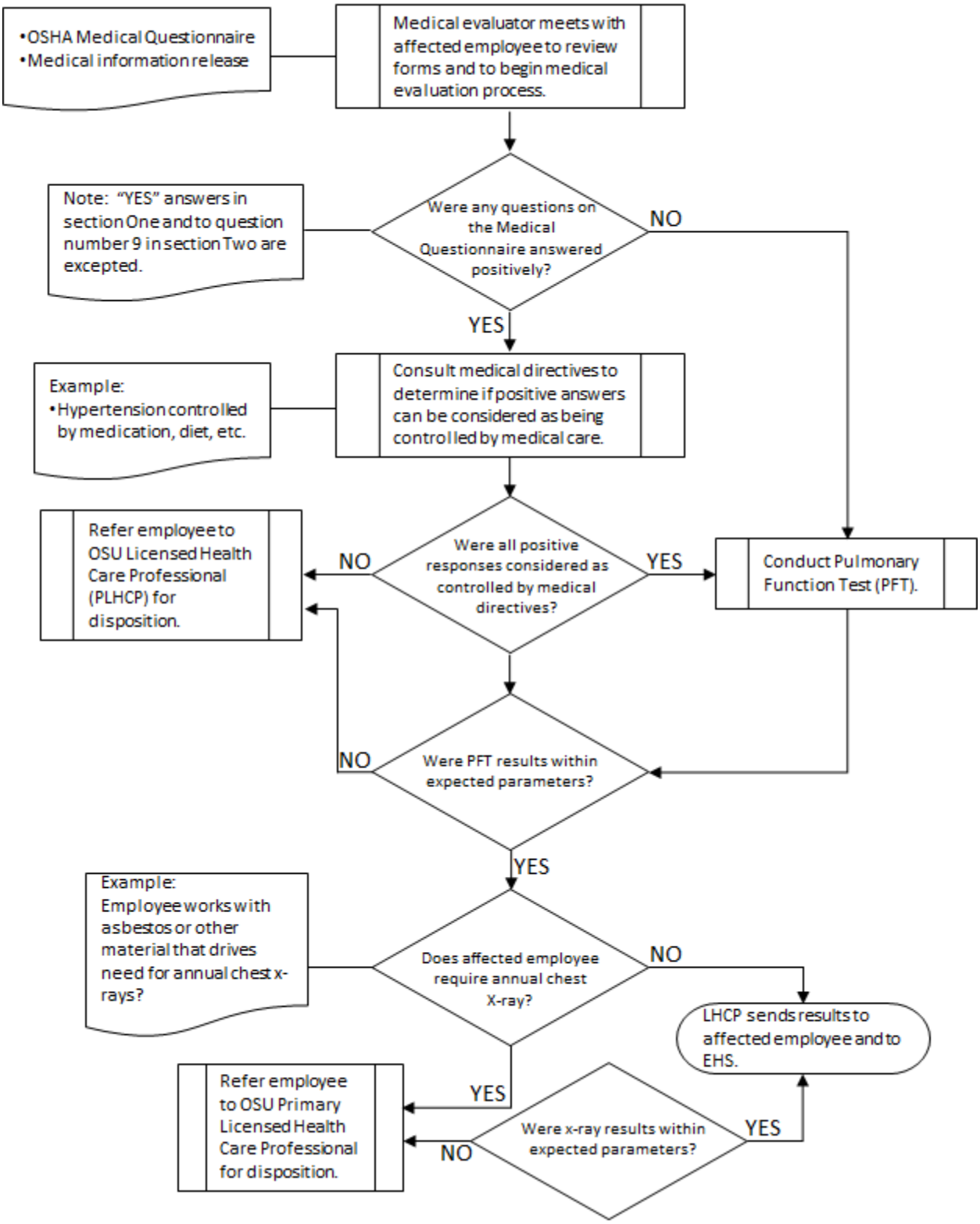
C. The program administrator shall maintain a written copy of the respiratory protection program, a copy of the OSHA standard, copies of training and fit test records, and certain medical records such as the physician's written recommendation regarding each employee's ability to wear a respirator.

D. EHS shall maintain records documenting completion of medical evaluations, OSHA 1910.134 Respiratory Protection Standard training, and fit testing.

VI Respiratory Protection Process Flow Diagram



Respiratory Program Medical Evaluation Process Flow



Appendix G – Integrated Pest Management

Insects and rodents are unwanted visitors in any laboratory setting. Pests can transmit disease pathogens and have the potential to adversely affect research and personnel health. If pests are entering a laboratory space, they can also find their way back into the environment. Therefore, the potential for insects to disseminate biological agents must be evaluated as part of the risk assessment for each laboratory or facility. It is especially important for select agent and toxin laboratories to ensure that there is no breach of containment.

According to the 5th edition of the Biosafety in Microbiological and Biomedical Laboratories, an integrated pest management program is needed for all biosafety level laboratories and facilities. With the exception of the Center for Veterinary Health Sciences (CVHS), OSU has a campus-wide Laboratory Integrated Pest Management Program in place. The Manager of Custodial, Housekeeping, and Apartment Cleaning and Pest Control Personnel Services oversees this program. The goals of the program are to:

- control pests in laboratories and other facilities;
- protect the environment; and
- use treatments that reduce the potential for human health hazards.

Pest control for CVHS facilities is provided by a professional pest control contractor.

A similar program will be used for select agent/toxin labs, with a few modifications instituted in order to adhere to the program's biosecurity policies.

Monitoring

When a PI requests approval of a space for select agents and/or toxin activities the space will be evaluated for inclusion in the integrated pest management program. The BSO will contact the OSU exterminator to review the building and floor plans for that space to determine the required number and placement of sticky traps. The integrated pest management program will commence once work begins and biological agents are present in a given space.

The Office of University Research Compliance will provide the sticky traps and/or live rodent traps to the PIs at no cost. The traps should be monitored frequently to detect insects and rodents.

Reporting

During the initial two months of monitoring in a particular facility, the PI or his/her designee will submit a weekly report to the BSO. Building and room codes have been developed for each space specifically for this program in order to protect sensitive information. The pest report form includes:

- the name of the person monitoring
- the building code
- the room code
- the trap number
- a description of the trap placement (e.g., under the BSC, near the door, near the incubator)
- the date the trap was set
- the date the trap was read

- the number and type of insect caught since the previous report
- the number of rodents caught

Evidence of rodent activity in laboratories or facilities where SATs are used or stored should be reported to the BSO immediately. After the initial two months of monitoring, if the laboratory or facility has not experienced significant pest problems, the PI will only be required to submit a monthly report. A copy of the reports will be sent to the Manager of Custodial, Housekeeping, and Apartment Cleaning.

Treatment

Exterminator personnel will evaluate the reports to determine if any action is required. If there is a significant pest problem, the facilities will be evaluated for structural deficiencies and sanitation. Ways to reduce pest habitats will also be investigated. Limited amounts of pesticides may be used to control the pest problem.

Sticky trap replacement

If traps become full, they should be emptied or replaced. Sticky traps should be changed at least every three months. Contact the BSO for additional traps.

Sticky trap disposal

The traps and their inhabitants should be treated as though they are contaminated with a select agent and/or toxin. The traps should be autoclaved or decontaminated according to lab-specific SOPs. The sticky trap manufacturer has verified that the traps are safe to autoclave.

Appendix H – Biosafety Level 2 (BSL-2) Inspection Checklist

INSPECTION CHECKLIST (revised 10/2015)					
Verbal Inspection		**YES**	**NO**	**N/A**	**Comments**
1.1	Lab access limited/restricted when work with cultures/specimens is in progress				
1.2	Laboratory doors are kept shut at all times and are locked when laboratory personnel are not present.				
1.3	Select agent labs: access is restricted to SRA cleared personnel when lab is hot and when SATs are present; non-SRA cleared personnel are escorted				
1.4	Non lab personnel are escorted				
1.5	Minimum requirements to enter and work in lab are established and enforced.				
1.6	Personnel at risk of acquiring infections or for whom infections may have serious consequences are denied access to lab				
1.7	All personnel are advised of potential hazards prior to entering and working in the lab				
1.8	Lab personnel receive appropriate training on standard operating procedures, potential hazards, precautions to prevent exposures, and exposure evaluation procedures				
1.9	Lab personnel have read and follow biosafety procedures and practices				
1.10	Lab personnel are trained in the opening of packages containing biohazards				
1.11	Personnel are trained on how to contain, decontaminate, and clean spills				
1.12	All lab employees have attended chemical hygiene or hazard communication training				
1.13	Lab personnel receive annual refresher training and/or additional training as necessary				
1.14	Lab personnel have been offered appropriate immunizations for agents and materials handled or potentially present in laboratory (e.g., Hepatitis B vaccine, Influenza vaccine, etc.)				
1.16	Baseline and periodic serum samples are collected/stored as dictated by risk assessment				
1.17	Protective laboratory clothing such as a lab coats, solid-front or wrap-around gown, scrub suits or coveralls is worn when handling recombinant/infectious materials				
1.18	Eye and face protection (e.g., goggles, mask, face shield, or other splatter guard) is used for anticipated splashes or sprays of biohazardous materials				
1.19	Persons who wear contact lenses in the laboratory also wear eye protection				
1.20	Eye and face protection is disposed of as biohazardous waste or decontaminated before reuse				
1.21	Personnel using respirators are enrolled in Respiratory Protection Program				
1.23	Gloves are worn if hands are at risk of contact with infectious materials, infected animals, or contaminated surfaces				
1.24	Gloves are not worn outside of the lab or when touching "clean" surfaces (e.g., telephones, keyboards, elevator buttons, etc.)				

Verbal Inspection		YES	NO	N/A	Comments
1.25	Lab personnel wash hands after handling biohazardous materials, after removing gloves, and before leaving the lab				
1.26	PPE is changed when contaminated, when the integrity is compromised, or at the completion of work				
1.27	Disposable PPE, including gloves, is not reused and is disposed of as biohazardous waste				
1.28	Protective clothing is either discarded appropriately in the lab or laundered on-site				
1.29	Soiled/used lab clothing is autoclaved or chemically disinfected before laundering				
1.30	All PPE is removed and left in lab before leaving				
1.31	No eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing human food in lab				
1.32	Mechanical pipetting devices are used (i.e., no mouth pipetting)				
1.33	Sharps handling policies and practices in place				
1.34	Plasticware is substituted for glassware whenever possible				
1.35	Broken glassware is only handled by mechanical means				
1.36	Needle/syringe use is kept to absolute minimum.				
1.37	Only needle-locking syringes or syringes with permanently affixed needles are used for injection or aspiration of infectious materials				
1.38	Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated prior to disposal				
1.39	Sharps containers are decontaminated (e.g., autoclaved or appropriate chemical treatment) prior to disposal or reprocessing				
1.40	Lab maintains a needlestick injury log				
1.41	Procedures minimize splashes/aerosols				
1.42	Spills and accidents are immediately reported to the lab director (f spill is outside primary containment and >10ml report to the BSO immediately)				
1.43	Work surfaces including those in the BSC are decontaminated at the completion of work and after any spill or splash of viable material				
1.44	Lab equipment is decontaminated on routine basis and prior to sending it for repair/maintenance or packaging it for shipment				
1.45	A method for decontaminating lab waste (e.g., autoclave) is available in the building				
1.46	Materials decontaminated outside of lab are transported in durable, leak-proof, closed containers (e.g., plastic bags transported in tray or pan with a leakproof bottom)				
1.47	Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations				
1.48	Cultures, stocks, and regulated wastes are decontaminated by an approved method (*e.g*., autoclaving) before disposal				
1.49	Cultures, tissues, specimens, and infectious wastes are kept in covered, leak-proof containers during collection, handling, processing, storage, transport, and shipment.				
1.50	There are written procedures in place for offsite transportation of biohazards				

Verbal Inspection		YES	NO	N/A	Comments
1.51	Written procedures are in place for handling leaking or damaged packages containing biohazards				
1.52	Animals and plants not associated with the work are not permitted in the laboratory				
1.53	An insect and rodent control program is in effect				
1.54	A Class II BSC or equivalent is used for procedures that have the potential to create aerosols or splashes and for work w/ high concentrations (>10^8 cfu/ml) or large volumes (>1 liter) of infectious agent				
Visual Inspection		**YES**	**NO**	**N/A**	**Comments**
2.1	Lab is located away from public areas				
2.2	Lab has lockable doors for access control				
2.3	Biohazard signage including a biohazard symbol, the lab biosafety level, required immunizations, required PPE, required lab exit procedures, and emergency contact information is posted at all lab entrances when infectious agents are present				
2.4	Emergency contact information (including the Biosafety Officer's contact information) is posted near the phone				
2.5	A lab-specific biosafety manual has been developed and is available in the lab				
2.6	MSDSs are available for any biohazards used in the lab				
2.7	Training of personnel is adequately documented				
2.8	Spill clean-up procedures are developed and posted				
2.9	Lab has adequate lighting				
2.10	Lab is designed to be easily cleaned (e.g., no carpets/rugs, spaces between cabinets/equipment/furniture are accessible, etc.)				
2.11	Bench tops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and disinfectants.				
2.12	No fabric upholstered/covered furniture or chairs				
2.13	Lab has a sink for hand washing				
2.14	BSC is tested and certified at least annually				
2.15	BSC is not located near doors, windows that can be opened, or heavy traffic areas				
2.16	The front grill of the BSC not blocked or covered and cabinet is free of clutter				
2.17	Vacuum lines are protected with liquid disinfectant traps or are HEPA filtered.				
2.18	Sharps containers are labeled, conveniently located, and puncture resistant				
2.19	Containers for non-disposable sharps are hard-walled and leak proof				
2.20	Effective disinfectants are available for all agents in use				
2.21	Refrigerators and freezers containing biohazards are labeled with a biohazard symbol				
2.22	All lab equipment that may be contaminated is labeled with a biohazard symbol				
2.23	All containers holding biohazardous materials are labeled with a biohazard symbol				

Visual Inspection		YES	NO	N/A	Comments
2.24	All biohazard waste receptacles are closed/covered when not in use or waste is autoclaved daily				
2.25	Lab windows that open to the outside are fitted with fly screens				
2.26	An eyewash station is readily available				

Appendix I - Biosafety Level 3 (BSL-3) Inspection Checklist

INSPECTION CHECKLIST (revised 11/2015)					
Verbal Inspection		**YES**	**NO**	**N/A**	**Comments**
1.1	Lab doors are locked at all times				
1.2	Lab access limited/restricted when work with cultures/specimens is in progress				
1.3	Select agent labs: access is restricted to SRA cleared personnel when lab is hot and when SATs are present; non-SRA cleared personnel are escorted				
1.4	Non lab personnel are escorted				
1.5	There are written policies on who can enter the lab and these requirements are enforced.				
1.6	Minors are never allowed in the lab				
1.7	Personnel and visitors are advised of potential hazards prior to entering and/or working in the lab				
1.8	Personnel and visitors are advised of conditions and medications that can compromise their immune system				
1.9	Individuals at risk of acquiring infections or for whom infections may have serious consequences are denied access to lab				
1.10	Personnel receive appropriate training on biosafety procedures and practices, standard operating procedures, potential hazards, precautions to prevent exposures, and exposure evaluation procedures				
1.11	Lab personnel are trained to open packages containing biohazards in a BSC				
1.12	Personnel are trained to contain, decontaminate, and clean spills				
1.13	Personnel have been provided with task specific training by the lab supervisor				
1.14	Lab personnel have demonstrated proficiency for all procedures they will perform in the BSL-3 lab				
1.15	All lab employees have attended chemical hygiene or hazard communication training				
1.16	Lab personnel receive annual refresher training and/or additional training as necessary				
1.17	Personnel are enrolled in the OHSP and have their serum banked at UHS				
1.18	Lab personnel have been offered appropriate immunizations for agents and materials handled or potentially present in laboratory (e.g., Hepatitis B vaccine, Anthrax vaccine, etc.)				
1.19	Protective laboratory clothing with a solid front such as a tie-back or wraparound gown or coveralls is worn				
1.20	Eye and face protection (e.g., goggles, mask, face shield, or other splatter guard) is used for anticipated splashes or sprays of biohazardous materials				
1.21	Persons who wear contact lenses in the laboratory also wear eye protection				
1.22	Eye and face protection is disposed of as biohazardous waste or decontaminated before reuse				
1.23	Personnel using respirators are enrolled in Respiratory Protection Program				
1.24	Gloves are worn to protect hands from exposure to hazardous materials				
1.25	Lab personnel wash hands after handling biohazardous materials, after removing gloves, and before leaving the lab				

Verbal Inspection		YES	NO	N/A	Comments
1.26	Hand washing protocols are rigorously followed				
1.27	PPE is changed when contaminated, when the integrity is compromised, and/or at the completion of work				
1.28	Disposable PPE, including gloves, is not reused and is disposed of as biohazardous waste				
1.29	PPE is decontaminated or removed prior to leaving the laboratory				
1.30	Protective clothing is either discarded appropriately or decontaminated and laundered on-site				
1.31	No eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing human food in lab				
1.32	Mechanical pipetting devices are used (i.e., no mouth pipetting)				
1.33	Sharps handling policies and practices in place				
1.34	Plasticware is substituted for glassware whenever possible				
1.35	Broken glassware is only handled by mechanical means				
1.36	Needle/syringe use is kept to absolute minimum.				
1.37	Only needle-locking syringes or syringes with permanently affixed needles are used for injection or aspiration of infectious materials				
1.38	Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated prior to disposal				
1.39	Sharps containers are decontaminated (e.g., autoclaved) prior to disposal or reprocessing				
1.40	Lab maintains a needlestick injury log				
1.41	Procedures minimize splashes/aerosols				
1.42	Spills and accidents are immediately reported to the lab director and the BSO				
1.43	Spills of biohazardous material are decontaminated by trained personnel while wearing HEPA respirators				
1.44	The lab director has prepared an incident/emergency response plan				
1.45	Work surfaces including those in the BSC are decontaminated at the completion of work and after any spill or splash of viable material				
1.46	Lab equipment is decontaminated on routine basis and prior to sending it for repair/maintenance or packaging it for shipment				
1.47	The lab is decontaminated annually, following a biohazardous spill outside of primary containment, and when the space is decommissioned or downgraded to a lower biosafety level				
1.48	An autoclave is available in the facility				
1.49	Materials decontaminated outside of lab are transported in durable, leak-proof, closed containers				
1.50	Materials to be removed from the facility for decontamination are packed in accordance with applicable local, state, and federal regulations				
1.51	Cultures, stocks, and regulated wastes are decontaminated by an approved method (*e.g.*, autoclaving) before disposal				
1.52	Autoclave test strips or biological indicators are used at least monthly to verify decontamination				
1.53	Autoclave records are maintained				

Verbal Inspection		YES	NO	N/A	Comments
1.54	Select agent labs: Inventory records are kept for all agents and records are reconciled on a regular basis				
1.55	Cultures, tissues, specimens, and infectious wastes are kept in covered, leak-proof containers during collection, handling, processing, storage, transport, and shipment.				
1.56	There are written procedures in place for offsite transportation of biohazards				
1.57	Animals and plants not associated with the work are not permitted in the laboratory				
1.58	An insect and rodent control program is in effect				
1.59	A Class II or III BSC or other primary containment device is used for all manipulations of infectious materials, necropsies of infected animals, and harvesting of tissues or fluids				
1.60	The lab HVAC system provides 100% make-up air, 100% ducted exhaust, and maintains the lab a negative relative air pressure (i.e., the HVAC system is designed to prevent the lab from becoming positively pressurized)				
1.61	Exhaust air is dispersed away from occupied areas and building air intakes or is HEPA filtered				
1.62	HVAC design allows for leak testing of each HEPA filter and assembly and filters are certified annually				
1.63	The lab is equipped with audible HVAC failure alarms (not required)				
1.64	A system is provided for electronic transfer of information				
1.65	Facilities are commissioned prior to operation and recertified annually				
Visual Inspection		**YES**	**NO**	**N/A**	**Comments**
2.1	Lab is located away from public areas				
2.2	Lab has lockable doors for access control				
2.3	Access to the laboratory is through two self-closing doors				
2.4	SAT labs: A log (manual or electronic) documenting the date/time of each person who enters the lab is maintained				
2.5	Biohazard signage including a biohazard symbol, the laboratory biosafety level, required immunizations, required PPE, required lab entry/exit procedures, and emergency contact information is posted at all lab entrances when infectious agents are present				
2.6	The lab is equipped with a visual device that allows personnel to verify that the lab pressure is negative before entry				
2.7	A lab-specific biosafety, biosecurity, and incident response plans/SOPs have been developed and are available in the lab				
2.8	MSDSs are available for all biohazards used in the lab				
2.9	Emergency contact information for the PI and the BSO is posted near the phone				
2.10	Training of personnel is adequately documented				
2.11	Spill clean-up procedures are developed and posted				
2.12	Emergency exit procedures are posted				
2.13	Lab has adequate lighting				

Visual Inspection		YES	NO	N/A	Comments
2.14	Lab is designed to be easily cleaned and decontaminated (e.g., no carpets or rugs, all surfaces are impervious to liquids and resistant to chemicals)				
2.15	Lab furniture and equipment is capable of supporting anticipated loads and uses				
2.16	No fabric upholstered/covered furniture or chairs				
2.17	Lab has a hands-free sink for hand washing				
2.18	BSC is tested and certified at least annually				
2.19	BSC is located away from possible airflow disruptions (e.g., room air supply and exhaust, doors, etc.)				
2.20	The front grill of the BSC is not blocked or covered and cabinet is free of clutter				
2.21	Vacuum lines are protected with liquid disinfectant traps or are HEPA filtered.				
2.22	Sharps containers are labeled, conveniently located, and puncture resistant				
2.23	Containers for non-disposable sharps are hard-walled and leak proof				
2.24	Effective disinfectants are available for all agents in use				
2.25	Refrigerators and freezers containing biohazards are labeled with a biohazard symbol				
2.26	All lab equipment that may be contaminated is labeled with a biohazard symbol				
2.27	All containers holding biohazardous materials are labeled with a biohazard symbol				
2.28	All biohazard waste receptacles are closed/covered when not in use or waste is autoclaved daily				
2.29	Biological and chemical spill kits are available				
2.30	All windows are sealed				
2.31	An eyewash station is readily available				

Appendix J - Animal Biosafety Level 3 (ABSL-3) Inspection Checklist

INSPECTION CHECKLIST (revised 11/2015)					
Verbal Inspection		**YES**	**NO**	**N/A**	**Comments**
1.1	Facility access is limited to the fewest number of individuals possible				
1.2	Doors to areas where biohazardous materials and/or animals are housed are kept closed and locked when personnel are not present				
1.3	Access to animal/procedure rooms is limited on a per-project basis				
1.4	Select agent spaces: access is restricted to SRA cleared personnel when room is hot and when SATs are present; non-SRA cleared personnel are escorted				
1.5	Non-lab personnel are escorted				
1.6	There are written policies on who can enter the facility and these requirements are enforced.				
1.7	Minors are never allowed in the animal facility				
1.8	Personnel and visitors are advised of potential hazards prior to entering and/or working in the facility				
1.9	Personnel and visitors are advised of conditions and medications that can compromise their immune system				
1.10	Individuals at risk of acquiring infections or for whom infections may have serious consequences are denied access to the facility				
1.11	Personnel receive appropriate training on biosafety procedures and practices, standard operating procedures, animal husbandry, potential hazards, precautions to prevent exposures, and exposure evaluation procedures				
1.12	Personnel are trained to open packages containing biohazards in a BSC				
1.13	Personnel are trained to contain, decontaminate, and clean spills				
1.14	Personnel have been provided with task specific training by the facility supervisor or PI				
1.15	Personnel have demonstrated proficiency for all procedures they will perform in the ABSL-3 lab				
1.16	Personnel have attended chemical hygiene or hazard communication training				
1.17	Training is documented and records are maintained				
1.18	Personnel receive annual refresher training and/or additional training as necessary				
1.19	Personnel are enrolled in the OHSP and have their serum banked at UHS				
1.20	Personnel have been offered appropriate immunizations for agents and materials handled or potentially present in laboratory (e.g., Hepatitis B vaccine, Anthrax vaccine)				
1.21	Protective clothing such as uniforms or scrub suits is worn; additional PPE (e.g., laboratory coats, gowns, or coveralls) is worn over this clothing				
1.22	Appropriate eye, face, and respiratory protection is worn when entering animal/procedure rooms				
1.23	Eye and face protection is disposed of as biohazardous waste or decontaminated before reuse				
1.24	Personnel using respirators are enrolled in Respiratory Protection Program				
1.25	Boots, shoe covers, or other protective footwear and disinfectant foot baths are available and used where indicated				

Verbal Inspection		YES	NO	N/A	Comments
1.26	Gloves are worn to protect hands from exposure to hazardous materials and when handling animals				
1.27	Personnel wash hands after handling biohazardous materials, after removing gloves, and before leaving lab				
1.28	Hand washing protocols are rigorously followed				
1.29	PPE is changed when contaminated, when the integrity is compromised, and/or at the completion of work				
1.30	Disposable PPE, including gloves, is not reused and is disposed of as biohazardous waste				
1.31	PPE is decontaminated or removed prior to leaving the animal/procedure room				
1.32	Protective clothing is either discarded appropriately or decontaminated before laundering				
1.33	No eating, drinking, smoking, handling contact lenses, applying cosmetics, or storing human food in lab				
1.34	Mechanical pipetting devices are used (i.e., no mouth pipetting)				
1.35	Sharps handling policies and practices in place				
1.36	Plasticware is substituted for glassware whenever possible				
1.37	Broken glassware is only handled by mechanical means				
1.38	Needle/syringe use is kept to absolute minimum.				
1.39	Only needle-locking syringes or syringes with permanently affixed needles are used for injection or aspiration of infectious materials				
1.40	Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated prior to disposal				
1.41	Sharps containers are decontaminated (e.g., autoclaved) prior to disposal or reprocessing				
1.42	Procedures minimize splashes/aerosols				
1.43	When possible, restraint devices (physical or chemical) are used to reduce the risk of exposure during animal manipulations				
1.44	Spills and accidents are immediately reported to the facility director, PI, and BSO				
1.45	An accident/injury log is maintained				
1.46	Spills of biohazardous material are contained, decontaminated, and cleaned by trained personnel				
1.47	Work surfaces including those in the BSC are decontaminated at the completion of work and after any spill or splash of viable material				
1.48	Equipment is decontaminated on routine basis and prior to sending it for repair/maintenance or packaging it for shipment				
1.49	Facilities are decontaminated annually, following a biohazardous spill outside of primary containment, and when the space is decommissioned or downgraded to a lower biosafety level				
1.50	An autoclave is available in the facility				
1.51	Materials decontaminated outside of animal/procedure rooms are transported in durable, leak-proof, closed containers				
1.52	All potentially infectious materials (e.g., animal tissues & carcasses, animal waste, bedding, unused feed, etc.) are decontaminated by an approved method (e.g., autoclaving) before disposal				

Verbal Inspection		YES	NO	N/A	Comments
1.53	Cages are autoclaved or thoroughly decontaminated before bedding removal and washing				
1.54	Cages are washed manually or in a mechanical cage washer with a final rinse temperature of at least 180°F				
1.55	Autoclave test strips or biological indicators are used at least monthly to verify decontamination				
1.56	Autoclave records are maintained				
1.57	Select agent spaces: Inventory records are kept for all animals infected with a SAT and records are reconciled before carcass disposal				
1.58	Cultures, tissues, specimens, and infectious wastes are kept in covered, leak-proof containers during collection, handling, processing, storage, transport, and shipment.				
1.59	There are written procedures in place for offsite transportation of biohazards				
1.60	Animals and plants not associated with the work are not permitted in the laboratory				
1.61	An insect and rodent control program is in effect				
1.62	A Class II or III BSC or other primary containment device is used for all manipulations of infectious materials, handling of animals, necropsies, and harvesting of tissues or fluids				
1.63	Equipment, cages, and racks are handled in a manner that minimizes contamination of other areas				
1.64	The animal facility HVAC system provides 100% make-up air, 100% ducted exhaust, and maintains animal/procedures rooms at a negative relative air pressure (i.e., the HVAC system is designed to prevent the lab from becoming positively pressurized)				
1.65	Exhaust air is dispersed away from occupied areas and building air intakes or is HEPA filtered				
1.66	HVAC design allows for leak testing of each HEPA filter and assembly and filters are certified annually				
1.67	The lab is equipped with audible HVAC failure alarms (not required)				
1.68	A system is provided for electronic transfer of information				
1.69	Facilities are commissioned prior to operation and recertified annually				
1.70	All genetically engineered neonates are permanently marked with within 72 hours after birth, if their size permits; if their size does not permit marking, their container are marked				
1.71	Transgenic animals contain distinct and biochemically assayable DNA sequences that allow identification of transgenic animals from among non-transgenic animals				
1.72	A double barrier is provided to separate male and female transgenic animals unless reproductive studies are part of the experiment or other measures are taken to avoid reproductive transmission				
Visual Inspection		**YES**	**NO**	**N/A**	**Comments**
2.1	Facility is located away from public areas				
2.2	External facility doors are self-closing and self-locking				
2.3	Doors to areas where infectious materials and/or animals are housed open inward, are self-closing, and have locks for access control				

Visual Inspection		YES	NO	N/A	Comments
2.4	Entry into the containment area is via a double-door entry				
2.5	SAT spaces: A log (manual or electronic) documenting the date/time of each person who enters the facility is maintained				
2.6	Biohazard signage including a biohazard symbol, the laboratory biosafety level, required immunizations, required PPE, required lab entry/exit procedures, and emergency contact information is posted at all animal/procedure room entrances when infectious agents are present				
2.7	Animal/procedure rooms are equipped with a visual device that allows personnel to verify that the lab pressure is negative before entry				
2.8	Facility-specific biosafety, biosecurity, and incident response plans/SOPs have been developed and are available				
2.9	MSDSs are available for all biohazards used in the lab				
2.10	Emergency contact information for the PI and the BSO is posted near the phone				
2.11	Training of personnel is adequately documented				
2.12	Spill clean-up procedures are developed and posted				
2.13	Exit procedures are posted				
2.14	Facility has adequate lighting				
2.15	Facility is designed to be easily cleaned and decontaminated (e.g., no carpets or rugs, all surfaces are sealed, impervious to liquids, and resistant to chemicals)				
2.16	Internal facility light fixtures, air ducts, etc., are arranged to minimize horizontal surface areas to facilitate cleaning and minimize accumulation of debris				
2.17	Furniture and equipment is capable of supporting anticipated loads and uses				
2.18	No fabric upholstered/covered furniture or chairs				
2.19	The animal/procedure room has a hands-free sink for hand washing				
2.20	Sink traps and floor drains are filled with water and/or appropriate disinfectant to prevent the migration of vermin and gasses				
2.21	BSC is tested and certified at least annually				
2.22	BSC is located away from possible airflow disruptions (e.g., room air supply and exhaust, doors, etc.)				
2.23	The front grill of the BSC is not blocked or covered and cabinet is free of clutter				
2.24	Vacuum lines are protected with liquid disinfectant traps or are HEPA filtered.				
2.25	Sharps containers are labeled, conveniently located, and puncture resistant				
2.26	Containers for non-disposable sharps are hard-walled and leak proof				
2.27	Effective disinfectants are available for all agents in use				
2.28	Refrigerators and freezers containing biohazards are labeled with a biohazard symbol				
2.29	All lab equipment that may be contaminated is labeled with a biohazard symbol				

Visual Inspection		YES	NO	N/A	Comments
2.30	All containers holding biohazardous materials are labeled with a biohazard symbol				
2.31	All biohazard waste receptacles are closed/covered when not in use or waste is autoclaved daily				
2.32	Biological and chemical spill kits are available				
2.33	All windows are sealed and resistant to breakage				
2.34	An eyewash station is readily available				

Appendix K - Biological Toxin Inspection Checklist

BIOLOGICAL TOXIN INSPECTION CHECKLIST (Revised 11/2013)					
Verbal Inspection		**YES**	**NO**	**N/A**	**Comments**
1.1	Each laboratory worker is trained in the theory and practice of the toxins to be used, with special emphasis on the nature of the practical hazards associated with laboratory operations. This includes how to handle transfers of liquids containing toxin, where to place waste solutions and contaminated materials, or equipment, and how to decontaminate work areas after routine operations, as well as after accidental spills.				
1.2	All laboratory personnel have proven reliability and sufficiently adept at all required manipulations before being provided with the toxin.				
1.3	New laboratory personnel undergo supervised practice runs in which the exact laboratory procedures to be undertaken are rehearsed without active toxin.				
1.4	A chemical hygiene plan specific to the toxin(s) has been developed and all personnel have been trained on it.				
1.5	An inventory control system is in place to account for toxin use and disposal.				
1.6	Toxins stored in the laboratory are stored in sealed, labeled containers and are secured to ensure restricted access; refrigerators and other storage containers are clearly labeled and provide contact information for trained, responsible laboratory staff.				
1.7	Toxin work is done only in designated rooms with controlled access and at pre-determined bench areas.				
1.8	Unrelated and nonessential work is restricted from areas where stock solutions of toxin or organisms producing toxin are used.				
1.9	Visitors/untrained personnel are accompanied at all times.				
1.10	Routine toxin manipulations are performed inside a certified BSC or a chemical fume hood may be used for most protein toxins.				
1.11	All work with toxins is conducted within the operationally effective zone of the hood or BSC, and each user verifies the inward airflow before initiating work.				
1.12	Low molecular weight toxin solutions (T-2 mycotoxin, saxitoxin, tetrodotoxin, brevetoxin, palytoxin, conotoxins, microcystin-LR, etc.), or work involving volatile chemicals or radionucleotides combined with toxin solutions, may require the use of a charcoal-based hood filter in addition to HEPA filtration.				
1.13	While working with the toxin(s) all workers wear appropriate PPE; lab coats, disposable gloves, eye glasses/goggles, etc.				
1.14	Gloves selected for use with toxins that pose percutaneous hazards are impervious to the toxin and the diluents or solvents employed				
1.15	When conducting liquid transfers and other operations that pose a potential splash or droplet hazard in an open-fronted hood or BSC, safety glasses and disposable facemask, or face shield, are worn.				

Verbal Inspection		YES	NO	N/A	Comments
1.16	Toxin solutions are only transported in spill-proof secondary containers				
1.17	The interior of the hood or BSC is decontaminated at the completion of work and after any spill or splash of toxin-containing material				
1.18	Until thoroughly decontaminated, signage indicating the use of toxins remains posted and access remains restricted				
1.19	Procedures minimize toxin aerosol production (e.g., containers are opened inside containment devices, manipulations are carried out inside containment devices, and vacuum lines are protected by HEPA filters)				
1.20	Appropriate respiratory protection is used when the creation of toxin aerosols cannot be avoided				
1.21	Centrifugation of cultures or materials potentially containing toxins are only performed using sealed, thick-walled tubes in safety centrifuge cups or sealed rotors				
1.22	After centrifugation, the rotor assembly is only opened inside a containment device				
1.23	Rotor assembly is decontaminated after use				
1.24	Only workers trained and experienced in handling animals are permitted to conduct operations involving injection of toxin solutions using hollow-bore needles				
1.25	Discarded needles/syringes and other sharps are placed directly into labeled, puncture-resistant containers				
1.26	Sharps containers are decontaminated prior to disposal				
1.27	Plasticware is used with toxins whenever possible				
1.28	Work with dry toxin is minimized				
1.29	When required, work with dry toxin is only undertaken with appropriate respiratory protection and engineering controls				
1.30	At least two knowledgeable individuals are present at all times during high risk operations involving dry toxins				
1.31	Contaminated materials and toxin waste solutions are inactivated by incineration, extensive autoclaving, or by soaking in suitable decontamination solutions before disposal				
1.32	All disposable material used for toxin work is disposed of as biohazardous waste				
1.33	Equipment and protective clothing is decontaminated using suitable chemical methods or autoclaving before removal from the laboratory for disposal, cleaning or repair				
Visual Inspection		**YES**	**NO**	**N/A**	**Comments**
2.1	A “Toxins in Use-Authorized Personnel Only” sign is clearly posted when toxins are in use				
2.2	Chemical Hygiene Plan is available in the lab				
2.3	Toxin solutions are transported in leak/spill-proof secondary containers.				
2.4	Refrigerators and other equipment used for storing toxins are clearly labeled				

Appendix L -Biosafety Spill Procedure

Scope: This procedure should be used by all laboratories and facilities that fall within the IBC's purview.

Purpose: This spill procedure should be used to clean up spills involving biohazardous material, which includes viable infectious, pathogenic, or toxin-producing agents, prions, biologically-derived toxins, recombinant nucleic acids or organisms that have the potential to affect the health of humans, animals, plants, or the environment.

This SOP should be made specific to your laboratory and the agents you work with by filling in the blanks below. Once the SOP is complete, please post this information in the laboratory for all personnel to follow. If this procedure is inadequate for your particular situation, create a lab specific spill SOP and submit to the IBC for review and approval.

The following is a summary of the steps to take when cleaning up a spill:

The ABC's of Cleaning up a Spill

Alert others

Body protection is required, wear appropriate PPE

Contain spill to prevent spread of contamination

Decontaminate spill and equipment with appropriate disinfectant and contact time

Eliminate contaminated items (i.e. paper towels, PPE) and treat as biohazardous waste

Freshen up by washing hands and any exposed areas

Go to PI immediately to report spill if ≥10 mLs outside BSC or if it is a select agent or toxin (any amount)

Spills inside of a Biological Safety Cabinet (BSC) or other primary containment devices:

- Alert people in immediate area of spill.
- Protect your body by wearing gloves and a lab coat during the decontamination procedure, at a minimum. Based on risk assessment, the following PPE is also required:
- Contain the spill by placing absorbent material at the spill's perimeter to prevent the spread of contamination.
- Decontaminate the spill using _____.
  (list appropriate disinfectant)
  - Place paper towels soaked with the disinfectant directly on the spill or pour the disinfectant around the spill and allow this solution to flow into the spill.
  - Do not pour disinfectant directly on the spill to avoid creating aerosols.
- Decontaminate for _____ minutes.
  (list appropriate contact time)
- Use paper towels to wipe up the spill, working from the edges into the center. Dispose of as biohazardous waste.
- Decontaminate all equipment and utensils inside the BSC. Items that are not readily or easily surface decontaminated should be carefully placed into autoclave bags and removed for further treatment.
- If the spill entered grilles of the BSC, apply disinfectant to the grills, allow for appropriate contact time, and empty the drain pan through a tube into a collection vessel containing disinfectant. Flush the drain pan with water and reattach the drain cap.
- Remove PPE and any contaminated clothing and decontaminate by autoclaving or soaking in disinfectant.
- Wash your hands and any other exposed areas with soap and water before exiting the laboratory.

Spills outside of a Biological Safety Cabinet (BSC) or other primary containment devices:

- Alert people in immediate area of spill.
- Protect your body by wearing gloves and a lab coat during the decontamination procedure, at a minimum. Based on risk assessment, the following PPE is also required:_____.
  (list additional PPE)
- If risk assessment dictates that you should wear respiratory protection and you are not wearing respiratory protection at the time of the spill, follow proper exit procedures and evacuate the laboratory. Make sure to remove all PPE and any contaminated clothing prior to exiting. Wait 30 minutes to allow aerosols to dissipate before reentry.
- Ensure that laboratory doors are closed and post warning signs to prevent others from entering the laboratory.
- While wearing the appropriate PPE, contain the spill by placing absorbent material at the spill's perimeter to prevent the spread of contamination.
- Decontaminate the spill using _____.
  (list appropriate disinfectant)
  - Place paper towels soaked with the disinfectant directly on the spill or pour the disinfectant around the spill and allow this solution to flow into the spill.
  - Do not pour disinfectant directly on the spill to avoid creating aerosols.
- Decontaminate for _____ minutes.
  (list appropriate contact time)
- Use paper towels to wipe up the spill, working from the edges into the center. Dispose of as biohazardous waste.
- Horizontal surfaces should also be decontaminated due to dispersal of aerosols.
- Remove PPE and any contaminated clothing and decontaminate by autoclaving or soaking in disinfectant.
- Wash your hands and any other exposed areas with soap before exiting the laboratory.
- Report the spill to the PI if the spill occurred outside the BSC and is greater than 10 mLs.
  - Report the incident to the BSO 4-3203 immediately
  - Send a Laboratory Incident Report form (http://compliance.okstate.edu/ibc/forms) to BSO at 223 Scott Hall within 7 days

Personnel Exposure

In the event that a substance enters the mouth, eyes, lungs, or penetrates/comes in contact with skin, follow the instructions below and seek immediate medical attention.

- Alert others in the laboratory.
- Remove all contaminated PPE and clothing.
- Treat the exposed area by washing with soap and water or flushing with water.
- Post warning sign on the laboratory door.
- Report the incident to the PI.
- Seek medical attention.

On-site emergency assistance can be obtained by dialing 911. Bring the appropriate MSDS to the provider to aid in medical treatment.

Acronyms

ABSL	Animal Biosafety Containment Level
ABSO	Assistant Biological Safety Officer
ACL	Arthropod Containment Level
APHIS	Animal and Plant Health Inspection Service
ARO	Alternate Responsible Official
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSC	Biological Safety Cabinet
BSL	Biosafety Containment Level
BSL-P	Plant Biosafety Containment Level
BSO	Biological Safety Officer
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CVHS	Center for Veterinary Health Sciences
DOJ	Department of Justice
DOT	Department of Transportation
EHS	Environmental Health and Safety
HEPA	High-Efficiency Particulate Air
HHS	Department of Health and Human Services
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
LAI	Laboratory Acquired Infection
NIH	National Institutes of Health
OADDL	Oklahoma Animal Disease and Diagnostic Laboratory
OBA	Office of Biotechnology Activities
OHSP	Occupational Health and Safety Program
PDIDL	Plant Disease and Insect Diagnostic Laboratory
PI	Principal Investigator
PPE	Personal Protective Equipment
PPQ	Plant Protection and Quarantine
rDNA	Recombinant Deoxyribonucleic Acid
RG	Risk Group
RM	Risk Management
RO	Responsible Official
SAT	Select Agent and Toxin

URC	University Research Compliance
USA PATRIOT ACT	Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (**Public Law 107-56**).
USDA	United States Department of Agriculture
UV	Ultraviolet
VHP	Vaporized Hydrogen Peroxide
VTH	Veterinary Teaching Hospital