ODHL Biosafety, Biosecurity and Incident Response Training Curriculum

Purpose

The purpose of this document is to define the training plan for the Ohio Department of Health Laboratory (ODHL) Select Agent Program (SAP). The curriculum is designed to provide training on the following topics: General Safety and Security; Biosafety; Biosecurity; Incident Response; and Transportation Security.

Principle

The regulatory requirements for training are found in Section 15 of the select agent regulations, 42 CFR Part 73. Individuals that have access to select agents and toxins must know the requirements of their entity's safety, security, and incident response programs if their entity is to be compliant to the select agent regulations. The regulations define the training that must be provided, who must receive the training and how often the training must be provided. The Responsible Official (RO) must ensure that the individuals in their entity who are required to be trained are provided information and trained in the areas specified, that they understand the training, that they are trained at least annually, and that the training is documented. Training is provided to address the needs of the individual based on their specific roles and the risks posed by the select agents or toxins.

1. Roles and Training

1.1. Role - Support Staff:

    1.1.1. Work performed: No manipulation of select agents and no entry into the BSL3 Suite while work with infectious disease agents is in progress.

    1.1.2. Training: Support staff members are provided training on the general requirements of the security, safety and incident response plans, including the requirement for BSL3 Suite entry/exit with minimal required Personal Protective Equipment (PPE). Training also includes exposure risks and recognition of illnesses associated with select agents.

1.2. Role - Laboratory Staff :

    1.2.1. BioThreat Rotation Laboratory Staff:

        1.2.1.1. Work performed: Manipulation of select agents.

  1.2.1.2. Training: These staff members are provided training on all aspects of the safety, security, incident response plans and work practices specific to BSL3 safety including entry/exit procedures using the highest level of PPE provided by the ODHL. Training also includes recognition of specific hazards when working with select agents and illnesses associated with exposure to select agents.

 1.2.2. Non-BioThreat Laboratory Staff:

  1.2.2.1. Work performed: No manipulation of known select agents though they work with infectious disease agents.

  1.2.2.2. Training: These staff members are provided training on the general security procedures and all aspects of safety and incident response plans and practices specific to BSL3 safety including entry/exit procedures using the highest level of PPE provided by the ODHL.

2. General Safety and Security

2.1. Frequency: Initial, annual training, and after changes to the plan

2.2. Manuals: <u>Ohio Department of Health Laboratory Hazard Communication Manual,</u> includes the <u>Chemical Hygiene Plan, Bloodborne Pathogens/Exposure Control Plan</u> and <u>General Biosafety Plan</u>; and the <u>Ohio Department of Health Laboratory Safety and Security Manual</u>

2.3 Tools: Documented annual review of manual and classroom training with post-test.

3. SAP - Biosafety

3.1. Biosafety training consists of how to work with select agents and toxins in a safe manner. Examples of the types of topics that are addressed include: how to use the biosafety cabinet, what kind of personal protective equipment is required and how to use the equipment, what to do if there is a spill, how to prepare and use disinfectants, and the specific hazards of the select agents or toxins the entity uses.

3.2. Frequency: Initial prior to working in the BSL3 suite, annual training, and after changes to the plan

3.3. Manual: <u>Ohio Department of Health, Select Agents and Toxins, Biosafety Plan and General Safety Practices in the Microbiology Section</u>

3.4. Tools: Documented annual review of manual and attendance at quarterly meetings or review of quarterly meeting minutes (if unable to attend). Specific

topics related to biosafety are provided at the quarterly meetings through presentations with post-test (or through self-paced review of presentations with post-test, if unable to attend quarterly meeting). BioThreat Rotation Laboratory Staff and Non-BioThreat Laboratory Staff undergo direct observation of entry/exit procedures [includes donning and doffing PPE].

4. Biosecurity

4.1. Security training consists of information on how to protect select agents from loss and security awareness. Examples include what to do if a staff member loses their key or identification badge, what to do when encountering someone in the laboratory who is not authorized, who to notify if select agents or toxins are found missing, and what to do if a suspicious package is discovered. Examples of security awareness include how to recognize breaches in security and who to notify, what to do if a colleague is displaying unsafe or suspicious behaviors, and what to do if individuals who are not part of your organization are asking specific questions about security procedures.

4.2. Frequency: Initial prior to working in the BSL3 suite, annual training, and after changes to the plan

4.3. Manual: ODHL, Biosecurity Plan

4.4. Tools: Documented annual review of manual and attendance at quarterly meetings or review of quarterly meeting minutes (if unable to attend). Specific topics related to biosecurity are provided at the quarterly meetings through presentations with post-test (or through self-paced review of presentation with post-test, if unable to attend quarterly meetings).

5. Incident Response

5.1. Incident response training consists of information on how to react to emergencies. Examples include the correct response if the fire alarm goes off, how to exit containment in an emergency, what to do if a colleague collapses in containment, where to go if there is a tornado warning and what to do if the air handling system malfunctions.

5.2. Frequency: Initial prior to working in the BSL3 suite, annual training, and after changes to the plan

5.3. Manual: ODHL, Incident Response Plan

5.4. Tools: Documented annual review of manual and attendance at quarterly meetings or review of quarterly meeting minutes (if unable to attend). Specific topics related to incidence response are provided at the quarterly meetings

through presentations with post-test (or through self-paced review of presentation with post-test, if unable to attend quarterly meetings).

6. Transportation Security

6.1. Transportation security training is provided to staff responsible for packaging and shipping select agents and consists of procedures to assure proper packaging, storage and shipping of packages containing select agents.

6.2. Frequency: Initial prior to working in the BSL3 suite, annual training, and after changes to the plan

6.3. Manual: ODHL, Transportation Security Plan for Select Agents

6.4. Tools: Documented annual review of plan and attendance at quarterly meetings or review of quarterly meeting minutes (if unable to attend). Specific topics related to transportation security are provided at the quarterly meetings through presentations with post-test (or through self-paced review of presentation with post-test, if unable to attend quarterly meetings).

7. Documentation

7.1. Attendance rosters for the quarterly meetings and post-test files are maintained by the BT Coordinator for three years.

7.2. Initial training, 6-month follow up training, and annual competency documentation is maintained by the Laboratory Safety Officer for the duration of staff employment plus 3 years.

8. Responsibility/Accountability

8.1. The BT Coordinator will provide quarterly reports to the Responsible Official (RO), Alternate Responsible Officials (ARO) and Principal Investigator (PI) regarding training status of Select Agent registered staff.

8.2. Based on the reports, the RO may provide:

8.2.1. Direct instruction to staff member to complete the assigned training,

8.2.2. Implement disciplinary action for inconsistent participation in the training program, or

8.2.3. Remove a staff member from participation in the program.

9. Training Plan Review and Updates

9.1. The plan will be reviewed annually and when changes to the select agent regulations are announced that affect the plan and training requirements.

Signature Approvals

_____ /   3/4/2015
Originator   Date

_____ /   3/4/2015
Reviewer   Date

_____ /   3/4/2015
Responsible Official   Date

Changes

Version	Effective Date	Superseded / Modified	Significant Change
7/30/2014	7/30/2014	V7/2/2012	Reformat and minor changes to content
3/4/2015	3/4/2015	V7/30/2014	Extensive revision