

Ohio Department of Health Laboratory



Select Agent Training Program Overview

6/2015

SA Rule Training Requirement

- Select Agents and Toxins Rule
 - TITLE 42 -- PUBLIC HEALTH
 - CHAPTER I -- PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES
 - SUBCHAPTER F -- QUARANTINE, INSPECTION, LICENSING
 - PART 73 -- SELECT AGENTS AND TOXINS
- 42 CFR § 73.15 Training – describes training requirements



SA Rule Training Requirement

42 CFR § 73.15 Training

- Applicability: All staff listed on the ODHL Select Agent Registration
- Topics: Biosafety, Security including Security Awareness, Incident Response
- Frequency: Prior to gaining access to select agents, annually, revisions to a plan
- Rule assigns responsibility for training to RO
 - Ensure training is provided
 - Have method to ensure comprehension of training material
 - Document training
- Training
 - Based on select agent registered individual's specific role
 - Addresses the specific work performed
 - Exposure risks posed by select agents or toxins
 - Illnesses associated with select agents



SA Rule Training Requirement

- ODHL Select Agent Program Biosecurity Manual
- Appendix O: ODHL Biosafety, Biosecurity and Incident Response Training Curriculum
 - Defines specific training requirements based on role



SA Rule Training

Role - Support Staff

- No manipulation of select agents
- No entry into the BSL3 Suite while work with infectious disease agents is in progress
- Training:
 - General requirements of the security, safety and incident response plans
 - Security awareness
 - Requirements for BSL3 Suite entry/exit with minimal required Personal Protective Equipment (PPE)
 - Visitor training requirements
 - Exposure risks and recognition of illnesses associated with select agents
- On Call Supervisors; BioWatch; QA Staff



SA Rule Training

Role – Non BT Laboratory Staff

- No manipulation of known select agents though they work with infectious disease agents

- Training:

- General security requirements
- Security awareness
- All aspects of safety and incident response plans
- Exposure risks and recognition of illnesses associated with select agents
- BSL3 safety including entry/exit procedures using the highest level of PPE provided by the ODHL

- Mycobacteriology Laboratory staff



SA Rule Training

Role - BioThreat Laboratory Staff

- Manipulation of select agents
- Training:
 - All aspects of safety, security, incident response plans
 - Transportation Security Plan
 - Work practices specific to BSL3 safety including entry/exit procedures using the highest level of PPE provided by the ODHL
 - Recognition of specific hazards when working with select agents
 - Exposure risks and recognition of illnesses associated with select agents
- BT Rotation Laboratory Staff



SA Rule Training

Responsibility/Accountability

- BT Coordinator to submit quarterly training status reports to the Responsible Official (RO), Alternate Responsible Officials (ARO) and Principal Investigator (PI)
- Based on the reports, the RO may:
 - Direct staff member to complete the assigned training
 - Implement disciplinary action for inconsistent participation in the training program
 - Remove a staff member from participation in the program



SA Rule Training

- Annual Review and Signature of Biosecurity, Biosafety and Incident Response plans
- Applicable to role – Complete specific training assignments
 - Topics presented at quarterly meetings
 - Self-paced review of powerpoint modules
 - Module post-test



SA Rule Training

- Next Assignments
 - Read/acknowledge ODHL Biosafety, Biosecurity and Incident Response Training Curriculum (on MTS website)
 - Read and sign: Biosecurity Plan, Biosafety Plan, Incident Response Plan by August 1, 2016
 - Locations of plans for Annual Review:
 - Sign out from Eric St Germain or Rebekah Carman if Eric is out
 - Announcements for additional training assignment to follow
- Send questions to any of the following staff

Eric St Germain, BT Coordinator

Larry King, PI

Rose Gearhart, RO

Tammy Bannerman, ARO

Steve York, ARO

