Select Agent Regulation
Training Requirements

Responsible Official Webinar

October 13, 2021
Training Requirements
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• Section 15(a) of the select agent regulations states that entities registered to possess, use, and transfer biological select agents and toxins (BSAT) must provide site-specific information and training on biocontainment, biosafety, security (including security awareness) and incident response to:

• Federal Select Agent Program (FSAP)-approved individuals before they enter areas where BSAT are handled or stored, or within 12 months of the date the individual was approved

• Non-FSAP-approved individuals (i.e., escorted visitors) before they enter areas where select agents and toxins are handled or stored
FSAP-Approved Individuals

• Must address the needs of the individual and the risks posed
• Based on their access or potential for access to BSAT and the scope of the work and designed to mitigate risks to
  • People
  • Security of the BSAT
  • The environment
  • The public
• To ensure that they can do their jobs without causing harm to themselves, coworkers, the public or the environment
Annual Refresher Training

• For **all** FSAP-approved individuals
• A minimum of once per calendar year and whenever significant changes are made to the entity’s biocontainment, biosafety, incident response, and/or security plans
  • Building renovations or alterations
  • New agents and/or protocols
  • Modification of security system
  • Regulatory changes

* Please see https://www.selectagents.gov/regulations/interpretations/training.htm
Non-FSAP-Approved Individuals

• Prior to entry into an area where BSAT are used and/or stored
• Needs to address risks and hazards of the area and the BSAT
• Should include biocontainment, biosafety, incident response, and security
  • Insider threat and security awareness as appropriate
How to Develop Your Training Program
Training Basics

• Should include any changes to policy or procedure
• Should be reviewed when any major program change occurs
  • New agents, new spaces, new equipment, etc.
• Responsible Official (RO) does NOT need to develop or conduct the training themselves
• Training can be many things
  • Classroom training
  • Online modules
  • Group or individual
  • Reading plans
• Should include the means used to verify the employee understood the training
Biocontainment

- How to ensure that select agents and toxins are safely contained
  - Facility operations
  - Use of select and non-select agents in the same space
  - Identifying signs of pests
  - Staff quarantine
Biosafety

• How to handle and work with select agents and toxins safely
  • Biological risks and hazards
  • Personal Protective Equipment (PPE) usage and handwashing
    • Respirator training
  • Equipment use (biosafety cabinets, etc.)
  • Waste and sharps disposal
  • Animal use
  • Decontamination
  • Spill procedures
Incident Response

• How to react in emergencies and account for the hazards associated with the BSAT
  • Fires or natural disasters
  • Emergency egress
  • Air flow problems
  • First aid or downed coworker
Security

• How to protect BSAT from theft
  • Based on job duties (laboratorian, RO, security personnel, etc.)
  • Inventory control and access
  • Suspicious person or unauthorized person
  • Lost keys or ID badge
  • Information Technology (IT) information
  • Shipping and receiving, suspicious packages
  • Barriers

• Security Awareness
  • Identifying breaches, suspicious or unsafe behaviors
  • Who to contact
  • Insider threat (Tier 1)
Other Important Things to Consider

• Your entity must ensure
  • Training is appropriate for the work personnel are performing
  • Should ensure that personnel can carry out their duties without causing harm to themselves, co-workers, the public or the environment

• There are many ways to accomplish this
  • General training for everyone on biocontainment, biosafety, incident response and security; then specific training for different roles
  • Do it specific to group and the risk those groups face
    • IT vs admin vs laboratorian, etc.
Other Important Things to Consider

• Record of training
  • The name of the individual, the date of training, a description of the training and the means to verify the employee understood
  • Maintained for three years

• Hotline information
  • Staff must be provided with both the HHS Office of Inspector General and USDA Office of Inspector General Hotlines
  • The RO must document it was provided
Tier 1
Tier 1 Additional Requirements

• Provide training on entity policies and procedures for reporting, and training on evaluation and corrective actions concerning the assessment of personnel suitability
  • Ongoing suitability assessments
  • Self-reporting
  • Peer reporting

• Trainings on procedures for
  • Failure of laboratory intrusion detection systems
  • Reporting suspicious activities
  • Occupational health program

• Insider Threat Awareness
  • Annual
  • **All** FSAP-approved personnel at Tier 1 entity
  • **Must** be in training records
Resources

- Select Agents Regulations: https://www.selectagents.gov/regulations/index.htm
www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural Select Agents and Toxins
DASAT@usda.gov
301-851-2070