

Select Agent Regulation Training Requirements

Responsible Official Webinar

October 13, 2021



Training Requirements



Training Requirements

- 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

BIOHAZARD



Biosafety Level 2

AUTHORIZED PERSONNEL ONLY



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>
- Training Guidance: <https://www.selectagents.gov/compliance/guidance/training/index.htm>
- Biosafety/Biocontainment Guidance: <https://www.selectagents.gov/compliance/guidance/biosafety/index.htm>
- Incident Response Guidance: <https://www.selectagents.gov/compliance/guidance/incident-response/index.htm>
- Security Guidance: <https://www.selectagents.gov/compliance/guidance/security-plan/index.htm>
- Suitability Assessment Guidance: <https://www.selectagents.gov/compliance/guidance/suitability/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

