



GUIDANCE FOR SELECT AGENT REGULATION TRAINING REQUIREMENTS

7 CFR §331.15, 9 CFR §121.15, and 42 CFR §73.15

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Centers for Disease
Control and Prevention
Division of Select
Agents and Toxins



Animal and Plant Health
Inspection Service (APHIS)
Division of Agricultural
Select Agents and Toxins

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Change/Highlight Section

This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from registered Select Agent entities or the public are welcomed. Submit comments directly to the Federal Select Agent Program (FSAP) at:

CDC: LRSAT@cdc.gov

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Revision History:

October 2012: Initial posting

July 2013: The revisions are primarily corrections to editorial errors from previous version.

March 2017: The revisions are based on changes to select agent regulations.

March 2021: Clarified language and added section on non-FSAP-approved individuals.

Introduction

Section 15 of the select agent regulations ([7 CFR §331.15](#), [9 CFR §121.15](#), and [42 CFR §73.15](#)) requires that individuals that access select agents and toxins must receive information and training concerning biocontainment, biosafety, security (including security awareness), and incident response. Section 15 also requires that each entity visitor accessing areas where select agents and toxins are used and/or stored receive risk-based training. A visitor is an individual not approved for access to select agents and toxins (non-FSAP approved). The training should address biocontainment, biosafety, security (including security awareness), and incident response. The Responsible Official (RO) must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

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:

- FSAP-approved individuals before they enter areas where select agents and toxins 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

Training for FSAP-approved individuals must address the needs of the individual and the risks posed by the

BSAT. Specific training should be based on an individual's access or potential for access to select agents and toxins and the scope of their work. The training program should be designed to ensure that individuals can safely work with BSAT and comply with all entity procedures to mitigate risks to people, to security of the agents and toxins, to the environment or to the public.

The FSAP-approved individuals must complete the initial training within twelve months of the approval or prior to entering areas with BSAT, whichever comes first. The training should be designed to ensure that they can carry out their responsibilities without causing harm to themselves, their fellow co-workers, the public or to the environment.

Refresher Training

Refresher training on this information must be provided at least once every calendar year to all FSAP-approved individuals and whenever significant changes are made to the entity's incident response, biosafety, biocontainment and/or security plans. Examples (not all-inclusive) of significant changes include:

- Renovation of the research building resulting in changes to biosafety, biocontainment, security and incident response policies and procedures
- A principal investigator begins a new project with new select agents and/or new protocols
- Modification of the security system
- A change in regulatory requirements
- Changes to the building which alter emergency access or egress routes

Entities with Tier 1 BSAT must conduct an annual insider threat awareness briefing on how to identify and report suspicious behaviors.

Annual refresher training may consist of a review of information provided during initial training and include any changes in regulatory requirements, entity policies and procedures since the previous training.

Non-FSAP-approved Individuals

Prior to entry into the area where BSAT are used and/or stored, non-FSAP-approved individuals (i.e. escorted visitors) should receive training that addresses the hazards of the area they are entering (e.g., laboratory, growth chamber, animal room, greenhouse, storage area, shipping/receiving area, production facility, etc.). The training should consist of components of biocontainment, biosafety, security (including security awareness, insider threat training as appropriate), and incident response, as it relates to the risks associated with them entering areas where BSAT is used and/or stored.

Training Program

The training program should include a detailed review of any changes in entity policies or procedures. The RO should review the training program whenever a new research project is planned, new facilities or equipment is added, or the entity plans to work with different agents or toxins to confirm training content still meets the entity's needs and the regulatory requirements.

The regulations do not require the RO to personally develop or conduct the training program. The RO may delegate the training responsibilities to other entity staff and ensure training is conducted as required. Resources may be available to the RO to help with the training requirement, but the training provided should be site specific based on the risk of work and hazards of the BSAT.

The regulations are performance based and do not specify what is considered an acceptable training program. Training records should include the means used to verify the employee understood the training. The entity has a wide range of options for how to set up a training program, including:

- PowerPoint presentations
- Requirement that staff read the appropriate standard operating procedures and plans
- On-line self-study training programs
- Entity staff member-led presentations (e.g. security training led by the entity's head of security)
- Community expert-led training (e.g., community's hazardous response team)

An effective BSAT training program should be risk based and include biocontainment, biosafety, security (and security awareness, insider threat training as appropriate), incident response, and specific work-related training components. Each training component is discussed in detail below.

Biosafety Training

Biosafety training should address how to work with select agents and toxins in a safe manner. Some examples of the types of topics that may be addressed include:

- Overview of biological risk assessment(s), including potential laboratory hazards
- Safety equipment used in the entity's laboratory (e.g. safely working in a biosafety cabinet)
- Procedures for donning and doffing Personal Protective Equipment (PPE), including respirator training, if applicable
- Procedures for handling spills
- Proper use of disinfectants and decontamination procedures
- Risks posed by the select agents or toxins
- Handwashing procedures
- Waste handling procedures, including disposal of sharps
- Animal handling and carcass disposal

Biocontainment Training

Biocontainment training should address how to ensure that select agents and toxins are safely contained. Some examples of the types of topics that may be addressed include:

- Recognizing signs of vermin (insects, ectoparasites, mammalian pests)
- Recognizing and understanding that the facility is operating and functioning as intended
- Procedures for the handling of select agents and toxins in the same space with non-select agents and toxins to prevent unintentional contamination
- Shower out procedures
- Familiarity with the restrictions in a Personnel Quarantine Policy

Security Training, Including Security Awareness

Security training should consist of information on how to protect the select agents and toxins from theft and be based on the individual's job duties. 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 to be there
- Who to notify if select agents or toxins are found to be missing
- Inventory control procedures, including control of access and what to do if inventory records are discovered to be altered or compromised
- What to do if a staff member observes suspicious activity or a suspicious package is discovered
- Information security safeguards
- Security of long-term inventory, plants, animals and animal tissues
- Shipping/receiving procedures, including unexpected packages
- Access to areas where select agents and/or toxins are used or stored, including "piggybacking", Tier 1 barriers, after hours and visitors

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
- What to do if individuals who are not part of your organization are asking specific questions about security procedures
- Insider threat awareness training

Incident Response Training

Incident response training should consist of information on how to react to emergencies and take into account the hazards associated with the BSAT. 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
- What to do if the air handling system malfunctions
- What to do if a suspicious package is received

Specific Work-Related Training

Training must be provided to address the needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The entity must ensure the following:

- An entity must ensure that training is appropriate for the work employees are performing.
 - For example, the engineer who maintains the air handling systems would not require the same type of biosafety training as the laboratory worker who conducts animal research with *Bacillus anthracis* using aerosol equipment.
- The training that each employee receives should be designed to ensure that they can carry out their responsibilities without causing harm to themselves, their fellow co-workers, the public or the environment.
 - For example, FSAP-approved administrative personnel with access to areas where BSAT is used and/or stored, but do not have access to BSAT, might receive information and training that includes an overview of regulatory requirements, general entity security and incident response policies and requirements, security awareness training, and information about the specific hazards of BSAT present in the areas. An FSAP-approved laboratory worker who will handle BSAT as part of his or her job responsibilities would receive the general training previously described, but would also receive more detailed and intensive training for the risks specific to the work being conducted at the entity.
- The entity can provide specific work-related training in several different ways. One way is to provide general training in biocontainment, biosafety, security, and incident response which everyone would participate in and then specific training would be provided to individuals depending on the work they perform.
 - For example, the animal technician would be provided the training on the risk presented by infected animals while the engineer would be trained on how to ensure equipment is decontaminated before conducting maintenance.
- The entity can also separate individuals into groups based on the risk posed and provide the appropriate training to each of these groups.

- Some entities may require the principal investigator or the laboratory manager to be responsible for developing and conducting the agent specific training. If this is the approach used, then the RO must ensure the training provided meets the regulatory requirements and is consistent.

Tier 1 Biological Select Agents and Toxins Training

There are additional regulatory requirements for those entities that possess Tier 1 BSAT. Entities with Tier 1 BSAT must provide training on entity policies and procedures for reporting, evaluation and corrective actions concerning the assessment of personnel suitability. The training should include entity policies related to ongoing suitability procedures, self-reporting, and peer reporting of incidents or conditions affecting a person's ability to safely work with BSAT. Individuals with access to Tier 1 BSAT should also receive information and training about response procedures for failure of laboratory intrusion detection systems, procedures to report suspicious activities, and the entity's occupational health program policy. Section 15(b) requires that entities with Tier 1 BSAT must conduct **annual insider threat awareness briefings** on how to identify and report suspicious behaviors. This requirement applies to all FSAP-approved personnel on the entity's registration. The FSAP [Security Guidance](#) and [Suitability Assessment Guidance](#) documents provide information on insider threat awareness briefings and should be consulted. These briefings must be part of the individual's training records.

Training of Individuals

FSAP-approved Individuals

The initial training for FSAP-approved individuals must be completed within twelve months of the individual's receipt of access approval or prior to him or her entering areas with BSAT, whichever comes first. Section 15(a) requires that that training include biocontainment, biosafety, security (including security awareness), and incident response. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.

All FSAP-approved individuals must receive the required training, regardless of previous experience. Each institution is unique with site-specific floor plans, equipment, protocols and policies.

Refresher training must be provided annually to all FSAP approved individuals, including those in administrative support roles.

For individuals on an extended medical or personal leave of absence, training requirements depend on the length of the absence. If the individual had been trained within a year of taking leave and then returns, the original training should be sufficient, provided there were no significant changes to laboratory procedures, biocontainment, biosafety, security, or incident response policies. If the individual has taken a leave of absence prior to their annual refresher training, they should receive refresher training immediately upon their return.

Unescorted visitors with a valid FSAP approval from another entity must also receive site-specific initial training appropriate for their work before being allowed access to BSAT at the host entity. The RO should evaluate the level of training needed before the FSAP-approved unescorted visitor receives access to BSAT.

Non-FSAP-approved Individuals

Section 15(a)(2) requires that individuals not approved for access to select agents and toxins by the HHS Secretary or APHIS Administrator receive information and training on biocontainment, biosafety, security (including security awareness), and incident response before entering areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

Individuals not approved for access entering areas where BSAT is used or stored must be escorted by a FSAP-approved person, unless all BSAT is secured. Prior to entry, they must receive training appropriate for the risk associated with entering areas where BSAT is used or stored. The training that is provided is not expected to be as extensive as it is for those who have access to the select agents and toxins. It may consist of:

- Donning and doffing PPE
- Personal safety precautions while in the laboratory

- Emergency response briefing (e.g. emergency evacuation procedures)
- What to do if the visitor becomes ill after visiting the area
- Shower out procedure
- Familiarity with the restrictions in the Personnel Quarantine Policy
- Signs/symptoms of illnesses caused by used or stored BSAT
- Security provisions

Frequency of visitor training must be consistent with the entity's policy. Visitors returning to the entity within 12 months of their last documented training may not need additional training unless there have been significant changes to the biocontainment, biosafety, security, or incident response plans or changes in entity policies or procedures after the last visit.

Frequency of Training

The select agent regulations require that individuals receive refresher training. Section 15(c) states: "Refresher training must be provided annually for individuals with access approval from the HHS Secretary or APHIS Administrator or at such time as the registered individual or entity significantly amends its security, incident response, biocontainment or biosafety plans."

Training must be provided at least each calendar year to all individuals who have received access approval from either the HHS Secretary or APHIS Administrator.

Refresher training does not necessarily need to be as extensive as the initial training a person receives but should at least consist of an overview of biocontainment, biosafety, security and incident response and include changes to the entity's plans. The RO may consider refresher training as an opportunity to reinforce knowledge of regulatory requirements based on observations of non-compliance. For example, the entity notices a number of laboratory workers consistently "piggybacking" or entering registered areas without presenting credentials by following closely behind a co-worker.

FSAP recommends that the time frame between annual refresher training events should be close to 12 months unless there is a reason for the training to occur sooner, such as a significant alteration to an entity's plan or procedure. The refresher training for biocontainment, biosafety, security and incident response may be incorporated into one training session or divided into different training sessions.

Training Records

Section 15(d) states that the Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., visitors, etc.) is maintained. Section 17 (Records) requires that these records must be maintained for a period of at least three years. The record must contain:

- The name of the individual
- The date they receive training
- A description of the training provided
- The means used to verify that the employee understood the training

There are no specific requirements for how or in what format training records are to be maintained by entities. Electronic records are acceptable as long as that record includes all of the information required in Section 15 (Training) and is maintained in accordance with Section 17 (Records) of the regulations, and the RO is able to provide access to the electronic record upon request.

There must be a means for verifying that the employee understands the training they receive. There is no specific requirement for how the entity verifies that the individual understood the training. Entities may administer a test to determine if individuals understood the material or ask the individual to sign the record that they understood the training.

HHS Office of Inspector General and USDA Office of Inspector General Hotlines

The RO must document that information provided include the contact information of the [HHS Office of Inspector General Hotline](#) and the [USDA Office of Inspector General Hotline](#) so individuals may anonymously report any safety or security concerns related to BSAT. Information should be provided for both HHS and USDA hotlines, regardless of whether the entity possesses HHS-only or USDA-only BSAT.