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Guidance for Select Agent Regulation Training Requirements

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

(March 2017)

Centers for Disease Control and Prevention (CDC)
Division of Select Agents and Toxins (DSAT)
Animal and Plant Health Inspection Service (APHIS)
Agriculture Select Agent Services (AgSAS)

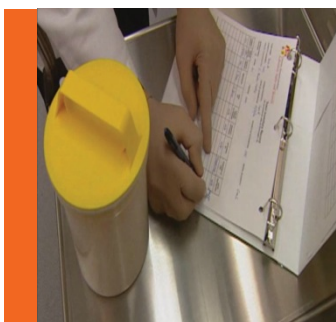


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Change/Highlight Section

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 at:

CDC: LRSAT@cdc.gov

APHIS: AgSAS@aphis.usda.gov

Revision History:

October 12, 2012: Initial posting

July 5, 2013 (Revision 1): The revisions are primarily changes to correct editorial errors from previous version.

March 2017 (Revision 2): The revisions are based on changes to select agent regulations.

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 (an individual not approved for access to select agents and toxins) receive information and training on biocontainment, biosafety, security (including security awareness), and incident response based on the risk associated with that person accessing areas where select agents and toxins are used and/or stored. The Responsible Official (RO) must ensure a record of the training is maintained for each individual with access to select agents and toxins and any individual that enters areas under escort where select agents or toxins are handled or stored. The record must include the name of the individual, the date of the training provided, and the means used to verify that the employee understood the training.

Training Required

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 in biocontainment, biosafety, security (including security awareness) and incident response to:

- Security Risk Assessment (SRA) approved individuals before they are allowed access to select agents and toxins.
- Individuals without access approval (i.e., escorted visitors) before they are allowed to enter areas where select agents and toxins are handled or stored.

The training must address the needs of the individual and the risks posed by the BSATs they will or may come into contact with. Select agent and toxin specific training should be provided based on an individual's access or potential for access to select agents and toxins; and their scope of work with select agents and toxins. The training program should be designed to ensure individuals can carry out their assigned duties without harm to self, other laboratory workers, the environment or the public.

The initial training for SRA approved individuals must be completed within twelve months of the individual's receipt of access approval or prior to him or her entering into areas with BSATs, whichever comes first. The training that each person receives should be designed to ensure that they can carry out their responsibilities without causing harm to themselves, or to their fellow co-workers, the public or the environment.

Prior to entry into the area where BSATs are used and/or stored, individuals without access approval (i.e. 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.).

Refresher training on this information must be provided at least once every calendar year to all SRA approved individuals and whenever substantive changes are made to the entity's incident response, biosafety, biocontainment and/or security plans. Examples (not inclusive) of substantive 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 select agents that have not been used at the entity before and/or new protocols.
- The security system has been modified.
- Regulatory requirements change.
- Changes to the building have altered emergency access or egress routes.

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

Training Program

The training program must include 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. A number of 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 BSATs.

The regulations are performance based and do not specify what is considered an acceptable training program. The entity has a wide range of options for how to set up a training program, including:

- PowerPoint presentations that covers the basics.
- Required staff reading of 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), 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 should 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).
- Procedures for handling spills.
- Proper use of disinfectants and decontamination procedures.
- Risks posed by the select agents or toxins.
- Handwashing procedures.
- Waste handling procedures.

Animal handling, proper use and disposal of sharps.

Biocontainment Training

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

- Recognizing signs of vermin (insects, ectoparasites, mammalian pests)
- Inactivation procedures, viable select agent removal methods, viability testing protocol

- 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.
- Who to notify if select agents or toxins are found missing.
- Inventory control procedures, including control of access and what to do if inventory records are 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.

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 BSATs. 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 particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. An entity must ensure that the training provided is appropriate for the work that the 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 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, SRA approved administrative personnel with access to the areas where BSATs are used and/or stored but no access to BSATs 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. A SRA approved laboratory worker who will handle BSATs as part of his or her job responsibilities would receive the general training described previously but would also receive more detailed and intensive training to be prepared for the risks of his or her work with BSATs 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.

Another option is for the entity to 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.

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.

Tier 1 Biological Select Agents and Toxins Training

There are additional regulatory requirements for those entities that possess Tier 1 BSAT. Employees with access to Tier 1 BSATs must be trained 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 and self 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 possessing Tier 1 BSAT must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors. 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

Individuals with Access

The initial training for SRA approved individuals must be completed within twelve months of the individual's receipt of access approval or prior to him or her entering into 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 SRA approved individuals must receive the required training, regardless of previous experience. Each institution is unique with different floor plans, equipment, protocols and policies. It is important for each new person to become aware of the features that are unique to the entity. Refresher training must be provided annually on this information to all SRA approved individuals, including those in administrative support roles.

For individuals who temporarily "opt out of access" or take an extended leave of absence, training requirements depend on the length of the "opt out" or absence. If the individual had been trained within a year of opting out or 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 "opted out" or taken a leave of absence prior to their annual refresher training, they should receive refresher training upon their return.

In the event the RO delegates select agent program training to another individual, he or she should document preparation and provide entity specific training on biocontainment, biosafety, security and incident response to other SRA approved individuals at that entity.

Unescorted visitors with a valid SRA from another entity must also receive initial training appropriate for their work before being allowed access to BSAT. Because unescorted visitors will have already had some degree of training, they may only be required to receive training critical to the specific work being done at the site they are visiting. The RO should evaluate the level of training needed before the SRA-approved unescorted visitor receives access to BSAT.

Visitors

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 must be escorted into any area where select agents and toxins are used or stored by an SRA-approved person. Prior to entry, they must first receive training appropriate for the risk that the person is likely to encounter in the area. 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.
- Risk associated with accessing the areas where BSAT is stored or used.
- Shower out procedure
- Familiarity with the restrictions in the Personnel Quarantine Policy

Frequency of visitor training must be consistent with the entity's policy. Visitors returning to the entity within a year 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 subsequent to the last visit. Recurring visitors should receive training once per calendar year.

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 SRA-approved 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 when they join the entity 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 individual understood the training.

There are no specific requirements for how or in what format entities maintain their training records. Electronic records are acceptable as long as that record includes all of the information required in Section 15 (Training) and are 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 individual understands the training that 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.

All training records, including those for visitors, must be maintained for three years. The RO must be able to produce a record that individuals who are escorted into laboratories with select agents and toxins have received instructions. Most entities will use a one or two page document listing the name of the individual who enters the area, the information and training they were provided and the signature of the individual verifying that they received the training.

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

The RO must document that training and 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 BSATs.