



RESPONSIBLE OFFICIAL RESOURCE MANUAL

7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73

FEBRUARY 2019



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



**Animal and Plant Health
Inspection Service (APHIS)**
Agricultural Select
Agent Program

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Change/Highlight Section

Revisions: This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from entities registered with the Federal Select Agent Program (FSAP), as well as the general public, are welcomed.

Submit comments directly to FSAP at:

AgSAS: AgSAS@usda.gov

DSAT: LRSAT@cdc.gov

Revision History:

June 2016: Initial posting.

March 2017: Revised due to updates to the select agent regulations.

February 2019: Revised to remove “Three Year Cycle of RO Tasks” section and reference FSAP’s recently issued policy and guidance on entity annual internal inspections.

Fundamental Responsibilities of the Responsible Official

The Responsible Official (RO) is the individual designated by the registered entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the select agent regulations. There can be only one RO at a registered entity at any given time. In the absence of an RO, a previously appointed and approved alternate Responsible Official (ARO) must assume the RO’s responsibility and has the authority to act on behalf of the registered entity. It is FSAP policy that an individual *will not* be approved by the FSAP to be an RO at more than one entity, nor will an individual who has been approved to be an RO at one entity also be approved by the FSAP to be an ARO at another registered entity. It is also the policy of the FSAP that an individual who has been approved by the FSAP to be an ARO at one entity *can* be approved by the FSAP to be an ARO at another registered entity if, when they serve as RO, they can meet the provisions outlined in section 9 of the select agent regulations. The core responsibilities of and criteria to be the RO are listed below:

- Be approved by FSAP following a security risk assessment (SRA) by the Federal Bureau of Investigation (FBI).
- Be familiar with the [select agent regulations](#) to the extent that the RO can ensure the entity is compliant with all requirements.
- Communicate with upper management, facility directors, principal investigators (PIs), veterinarians, scientists, contractors, local authorities, and institutional oversight committees in order to manage a successful program compliant with the select agent regulations.
- Ensure that annual internal inspections are conducted for all registered areas where select agents or toxins are stored or used in order to determine compliance with the requirements of the select agent regulations. Document the results of each inspection, correct any deficiencies identified during inspection, and document the corrections.
- Have a physical, not merely a telephonic or audio/visual, presence within a reasonable distance of all of the entity’s registered areas (the principal duty station) to ensure that the entity is in compliance with the select agent regulations. Be able to respond in a timely manner to on-site

incidents involving select agents and toxins in accordance with the entity's incident response plan.

- Have the authority to speak and act on behalf of the entity.
- Ensure that individuals listed on the entity's select agent registration are provided the contact information for the [HHS OIG Hotline](#) and [USDA OIG Hotline](#) so that they may anonymously report any safety or security concerns related to select agents and toxins.
- Investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material. If the entity is unable to determine the cause as a deviation from a validated inactivation procedure or a viable select agent removal procedure, or receives a report of any inactivation failure after the movement of material to another location, the RO must report the inactivation or viable agent removal procedure failure to FSAP immediately by phone or email.
- Review and approve each of the entity's validated inactivation procedures and viable select agent removal procedures. Conduct and document the review annually or after any change in PI, change in the validated inactivation procedure or viable select agent removal procedure, or failure of the validated inactivation procedure or viable select agent removal procedure. Ensures that training is conducted for those personnel performing the procedures for any changes that occur to the validated inactivation procedure, viable select agent removal procedure, or viability testing protocol.
- For entities registered to possess, store, or use Tier 1 select agents and toxins, the RO must coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information.
- Limit access to select agents and toxins to FSAP-approved personnel only.
- Ensure that current and accurate information related to the entity is provided through eFSAP.
- Conduct site-specific drills or exercises at least annually to validate or test the effectiveness of the security, biosafety, and incident response plans. Document drills and exercises to include how the plans were tested and evaluated, any identified problems and corrective actions taken, and the names of drill or exercise participants.

Knowledge of the Select Agent Regulations

The select agent regulations state that the RO must be familiar with the regulatory requirements (see section 9(a)(2)) and is responsible for ensuring that the registered entity maintains regulatory compliance (see section 9(a)(4)). The RO is also responsible for the security, containment, and safe use of select agents and toxins at his or her entity. The RO should have sufficient understanding of the work objectives within their operations to make appropriate management decisions regarding security, biocontainment and biosafety, and incident response, to ensure compliance with the regulations.

The [FSAP website](#) is intended to assist ROs in maintaining compliance at their entities. The website provides current guidance, policies, and helpful information, such as frequently asked questions (FAQs).

An FSAP Point of Contact is assigned to each entity to serve as an additional resource for information or general inquiry. In addition, FSAP employs science, security, facility, and biosafety personnel who evaluate the applicable components of registered facilities and provide guidance.

Periodically, FSAP conducts workshops specifically targeted to the RO. The purpose of these workshops is to

keep the RO current about upcoming changes, concerns FSAP may have, and to listen to RO concerns. The RO is notified when these workshops are available through e-mails.

Authority and Responsibility

Section 9(a)(3) of the regulations requires that the RO has the authority and responsibility to act on behalf of the entity for its select agent program.

The entity must delegate to the RO the authority to effectively manage the security, biocontainment and biosafety, and incident response of select agents and toxins at their facility. This authority of the RO includes the following:

- The ability to provide direct input to affect changes as needed in operations, personnel, and facilities at the registered entity in order to fulfill his or her responsibilities.
- Be in an authoritative position in the organization such that employees engaged in select agent and toxin activities at the entity recognize the RO's authority to maintain compliance with the select agent regulations.
- The ability and opportunity to effectively communicate with senior laboratory and management officials within the entity in order to gain support and facilitate actions as needed in carrying out the responsibilities. For example, the RO should have the ability to either make budget decisions or influence these decisions to ensure that the entity takes necessary actions for equipment maintenance, repairs of the biocontainment facilities, and physical security systems used to protect and secure select agents and toxins in compliance with the select agent regulations.
- The ability to engage institutional oversight committees, if needed, charged with review of the entity's select agent program. If created, the RO should be engaged in determining how these oversight committees should facilitate, but not limit, the authority and responsibility of the RO's involvement in these committees.

The RO can delegate duties to others to achieve effective oversight in an efficient manner; however, the RO retains responsibility to ensure that the registered entity is in full compliance with the select agent regulations.

In addition, given the scope of the responsibilities of the RO, communication and coordination with the entity's safety and security programs can be valuable in ensuring the safety and security of select agents and toxins.

Delegating Responsibility as an RO

The entity may designate one or more AROs. Each ARO must have the ability to assume the full authority and undertake all of the responsibilities of the RO as needed in accordance with section 9(b).

While specific roles (e.g., fulfilling the responsibilities of an absent RO) may be fulfilled only by an approved ARO, some duties may be delegated to other individuals. Delegated duties may include:

- Developing risk assessments
- Developing written security, incident response, and biosafety plans
- Training select agent personnel
- Developing and maintaining safety, security, or incident response protocols
- Maintaining records

Although the RO may delegate certain functions to others, including the ARO, the RO:

- Retains his or her overall responsibility for oversight of the delegated functions
- Maintains control over all aspects of an entity's program relevant to the select agent regulations
- Must be aware and responsible for all submissions to FSAP
- Must be fully engaged in his or her duties when on site, to ensure efficient and timely communications with FSAP

While duties may be delegated, the RO is still responsible for maintaining current knowledge of what is occurring within the registered entity and ensuring compliance with the select agent regulations.

Compliance with the Select Agent Regulations

The RO is responsible for ensuring the following specific items and duties occur to maintain compliance with the select agent regulations:

- Develop and implement a site-specific [security plan](#) designed according to a site-specific risk assessment that provides graded protection in accordance with the risk of the select agents and toxins for which the entity is registered.
- Develop and implement an agent-specific, site-specific [biosafety plan](#) commensurate with the risk of the select agents and toxins, and the use and disposal of the agents or toxins, for which the entity is registered. The plan should contain sufficient information and documentation to describe biosafety and containment procedures.
- Develop and implement a site-specific [incident response plan](#) commensurate with the hazards of the select agents and toxins for which the entity is registered. Describe the entity's response procedures for the theft, loss, or release of a select agent and toxin, inventory discrepancies, security breaches, natural disasters, and other emergencies.
- Review the security, biosafety, and incident response plans at least annually and revise them as necessary, including after any drill or exercise, and after any incident.
- Conduct site-specific [drills or exercises](#) at least annually to validate or test the effectiveness of the security, biosafety, and incident response plans. Document drills and exercises to include how the plans were tested and evaluated, any identified problems and corrective actions taken, and the list of participants.
- Provide information and [training](#) on incident response, biosafety, and security to each individual with access approval prior to him or her having access to select agents and toxins. Provide refresher training annually. This training must be documented.
- Provide risk-based training to individuals escorted into registered space on incident response, biosafety and security prior to entering into registered space. This training must be documented.

- Ensure coordination and communication with the entity's biosafety and security officials to assess potential personnel security issues for Tier 1 entities.
- Review and maintain the entity's pre-access and ongoing [suitability assessments](#) for individuals with access to Tier 1 agents.
- Ensure the entity has an active insider threat awareness training program if they have Tier 1 agents.
- Ensure that annual inspections are conducted and documented for each laboratory and storage area where select agents and toxins are stored or used. Correct any discrepancies, and document the corrections made.
- Ensure that individuals are provided the contact information for the [HHS OIG Hotline](#) and the [USDA OIG Hotline](#) so that they may anonymously report any safety or security concerns related to select agents and toxins.
- Ensure that an investigation is conducted to determine the reason for any failure of a validated [inactivation procedure](#) or any failure to remove viable select agent from material. If the entity is unable to determine the cause as a deviation from a validated inactivation procedure or a viable select agent removal procedure, or receives a report of any inactivation failure after the movement of material to another location, the RO must report the inactivation or viable agent removal procedure failure to FSAP.

Federal Select Agent Program Notification

The RO submits reports and requests by utilizing [eFSAP](#), FSAP's secure information system. eFSAP is used to submit select agent program information via a two-way portal that is accessible by both FSAP and the regulated community.

Form notification:

Form Title	Form Name	Purpose of Form	eFSAP Instructions
APHIS/CDC Form 1	Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins	<ul style="list-style-type: none"> • Apply to possess, use, or transfer select agents and toxins • Amend registration • Registration renewal 	https://www.selectagents.gov/efsap-tools-form1.html
APHIS/CDC Form 2	Request to Transfer Select Agents and Toxins	<ul style="list-style-type: none"> • Recipient requests prior authorization of a transfer of select agents or toxins • Sender updating transfer request • Completion of transfer 	https://www.selectagents.gov/efsap-tools-form2.html
APHIS/CDC Form 3	Incident Notification and Reporting (Theft, Loss, or Release)	<ul style="list-style-type: none"> • Report a theft, loss, or release of a select agent or toxin • Immediate report a theft, loss or release of Tier 1 select agent or toxin 	https://www.selectagents.gov/efsap-tools-form3.html Immediate reporting: https://www.selectagents.gov/efsap-tools-form3-quickref-in.html

APHIS/CDC Form 4	Reporting the Identification of a Select Agent or Toxin	<ul style="list-style-type: none"> • Identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin • Immediate notification of Tier 1 select agent or toxin 	https://www.selectagents.gov/efsap-tools-form4.html Immediate reporting: https://www.selectagents.gov/efsap-tools-form4-quickref-in.html
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Non-form notification via eFSAP:

- If there is any failure of a validated inactivation procedure or failure to remove a select agent from material, the RO must investigate the cause. If unable to identify the cause as a deviation from a validated procedure, the RO must report the failure to FSAP immediately by telephone or email.
- If the RO receives a report of inactivation failure after material has been transferred to another location, the RO must report the failure to FSAP immediately through eFSAP, telephone, or email.

Records

The RO has oversight responsibility for the entity's creation and maintenance of all records documenting entity select agent activities. The records should be organized so they can be readily produced if requested by FSAP inspectors. Examples of records kept by the entity:

- **Inventory** – An entity is required to maintain accurate inventory records for each identification number that includes all of the information required in section 17 and an entity is accountable for each vial associated with that number. Refer to [Guidance on the Inventory of Select Agents and Toxins](#) for information regarding the inventory of select agents and toxins for long term storage, including definitions, storage criteria, and record maintenance.
- **Internal Audits** – Ensure that an entity performs annual internal inspections. Refer to Entity Annual Internal Inspections [policy](#) and [guidance](#) for additional information.
- **Record of Access** – Ensure that there is a record of access to rooms containing select agents and toxins and ensure that only FSAP-approved individuals have access to select agents or toxins.
- **Training** – Maintain a training record for each person who is granted access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors). Include the person's name, date of each training they received, description of the training, and means used to verify that the individual understood the training. For each person who is granted access to select agents and toxins, maintain initial and refresher training records. Refer to [Guidance for Select Agent Regulation Training Requirements](#) for meeting the training requirements of the select agent regulations. Topics include what types of training are required, training programs, frequency requirements, and training records.
- **Biosafety, Security, and Incident Response Plans** – Maintain and review biosafety, security, and incident response plans at least annually. Revise as needed.
 - Refer to [Biosafety/Biocontainment Plan Guidance](#) for developing and implementing a biosafety/biocontainment plan in accordance with section 12 of the select agent regulations.
 - Refer to [Incident Response Plan Guidance](#) for developing and implementing an incident

- response plan in accordance with section 14 of the select agent regulations.
- Refer to [Security Plan Guidance](#) for developing and implementing a security plan in compliance with section 11 of the select agent regulations.
- **Drills/Exercises** – Develop, implement, and document drills and exercises in accordance with sections 12, 13, and 14 of the select agent regulations. Refer to [Drills and Exercises Guidance](#) for additional information.

For records not maintained in eFSAP, records must be maintained for at least three years and should be kept secure to avoid any loss or alteration. Entity policy may dictate longer retention times.

Security Risk Assessment

A security risk assessment (SRA) is the electronic records check performed by the Federal Bureau of Investigation (FBI) Criminal Justice Information Services Division (CJIS) to determine whether an entity or an individual who wishes to register to possess, use or transfer a select agent or toxin, or an individual who has been identified by a registered entity as having a legitimate need to access a select agent or toxin meets one of the statutory restrictors which would either prohibit registration or restrict access, respectively.

The results of an SRA will assist FSAP in its determination that the entity may possess, use, or transfer select agents or toxins; or that an individual may have access to select agents and toxins.

For new applicants or applicants who do not have an active SRA on file with CJIS, an FD-961 Form, photo, and two legible fingerprint cards must be completed and mailed (hard copy) as one package to CJIS. The CJIS mailing address is:

Bioterrorism Security Risk Assessment Group E-3
CJIS Division
1000 Custer Hollow Road
Clarksburg, WV 26306-0002

During the application process, the individual's access to select agents and toxins is denied until the decision has been provided by FSAP.

If the applicant already has information on file with CJIS, the FD-961 Form can be completed and emailed to CJIS at FD961@leo.gov or mailed as one package to CJIS at the above address.

The FD-961 form contains instructions on how to complete the form. For questions on the process or form, please email CJIS at FD961@leo.gov or SRA.CDC@leo.gov.

Internal Inspections of Select Agent Registered Areas

Section 9(a)(6) of the regulations require the RO to ensure that the entity's internal inspections are conducted annually for each registered space where select agents and toxins are stored or used in order to determine compliance with the requirements of the select agent regulations. The FSAP has issued a [policy statement](#) and [guidance document](#) to assist entities in meeting this requirement.