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Fundamental Responsibilities of the Responsible Official

The 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 Section 9 of the select agent regulations. There can be only one RO at a registered entity at any given time. In the absence of the 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. The core responsibilities of and criteria to be the RO are listed below:

- Pass a security risk assessment (SRA) conducted by the Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) and be approved by the Federal Select Agent Program (FSAP).
- Be familiar with the select agent regulations to the extent that the RO can ensure that the entity is compliant with all of the requirements of the select agent regulations.
- Foster open lines of communication with upper management, facility directors, principal investigators (PIs), veterinarians, contractors, local authorities and institutional oversight committees in order to manage a successful program compliant with the select agent regulations.
- Conduct annual internal inspections for each laboratory and all other 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 (and not merely a telephonic or audio/visual) presence within 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 and be able respond in a timely manner to onsite 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 RO 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 CDC or APHIS immediately by phone or email.
- Review, and revise as necessary, 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. Conduct training if changes 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 SRA approved personnel only. Conduct initial and annual refresher training, and provide performance oversight and disciplinary action for employees engaged in work with select agents and toxins.
Knowledge of the Select Agent Regulations

The select agent regulations state that the RO must be familiar with the requirements of the select agent regulations (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, biocontainment and safe use of select agents and toxins at his or her entity. Since the RO certifies that the information on all APHIS/CDC Forms 1 through 5 is, to the best of his or her knowledge, accurate and truthful, the RO must become familiar with and fully understand the select agent regulations. 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, which comply with these regulations.

The FSAP website at is intended to be a resource to assist ROs maintain compliance at their entity. The website provides current guidance, policies and helpful information.

An FSAP file manager is assigned to each entity to serve as an additional source for information or general inquiry. This file manager handles all registration issues, incoming requests for amendments, inspection information, and compliance issues for their assigned registered entities. In addition, FSAP employs security, facility, biosafety, and occupational health personnel who evaluate the applicable components of registered facilities and provide guidance.

Periodically, FSAP will conduct 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 will be notified when these workshops are available through e-mails, public notification, and the FSAP website.
Authority and Responsibility

Section 9(a)(3) of the regulations requires that the RO have authority and responsibility to act on behalf of the entity for its select agent program. To ensure compliance with select agent regulations, the RO should either supervise or coordinate with certain supervisory or management to supervise functions of employees related to select agent activities at the registered entity. ROs who work and communicate with individuals approved to work with select agents and toxins have a better chance to immediately address noncompliance. Based on our experience, FSAP has observed that actively engaged ROs are more successful in carrying out their responsibilities.

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. The ARO must also have this authority in the event he/she needs to act in the absence of the RO. This authority includes the following:

- The RO must have 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.
- The RO position must be senior enough 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 RO must have 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 his or her responsibilities. For example, the RO should have the ability to either make budget decisions or influence these decisions to ensure that necessary actions are taken 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.
- While the RO can delegate duties to others to achieve efficiencies and efficacy in oversight, 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 safety and security programs can be valuable in ensuring the safety and security of select agents and toxins. Timely notification of security incidents and worker safety issues greatly enhance the ability of the RO to ensure that compliance with entity biosafety and security plans and procedures is in place.
Delegating Responsibility as an RO

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

- Retain his or her overall responsibility for oversight of the delegated functions.
- Maintain control over all aspects of an entity’s program and be aware and responsible for all submissions to FSAP.
- Delegate administrative and maintenance functions of the entity’s select agent program as necessary to ensure the efficiency and timeliness of communications with FSAP but should be fully engaged in his or her duties when on site.

While specific roles (e.g., fulfilling the responsibilities of an absent RO) may be fulfilled only by an approved ARO, other duties may be delegated to other individuals at the entity. 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
- Submitting APHIS/CDC Forms

Despite these delegations of authority, the RO is still responsible for maintaining current knowledge of what is occurring within his or her registered entity and being the final decision-maker who has ultimate responsibility for compliance with the select agent regulations.

FSAP approves individuals for access to select agents and toxins but the registered entity retains the authority to make decisions concerning that access. Regardless of whether there is sufficient cause to terminate an employee’s employment at an entity, the RO should have the authority to terminate an individual’s access to select agents and toxins at any point based on knowledge that this individual poses a security or safety risk of any sort, seriousness, or magnitude.
Compliance with the Select Agent Regulations

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

Security, Biosafety, and Incident Response Plans

- Create and maintain 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.
- Create and maintain an agent-specific, site-specific biosafety plan commensurate with the risk of the select agents and toxins, and its use, for which the entity is registered. The plan should contain sufficient information and documentation to describe biosafety and containment procedures.
- Create and maintain 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 names of drill or exercise 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 situation appropriate 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 biosafety and security officials to assess potential personnel security issues for Tier 1 entities.
- Review and maintain the entity’s pre-access and on-going suitability assessments for individuals with access to Tier 1 agents.
- Ensure the entity has an active insider threat awareness training program, required for entities possessing Tier 1 agents.
- Conduct and document annual inspections for each laboratory and storage area (all registered spaces) where select agents and toxins are stored or used. Correct any discrepancies, and document the corrections.
- Ensure that individuals 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 RO 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 CDC or APHIS.
Records

Maintain all records (see Records section for complete list) related to the registration and approval to possess, use, and/or transfer select agents and toxins as required by the select agent regulations for at least 3 years to include:

- An accurate, current inventory for each select agent and toxin held in long term storage.
- Information about all entries into areas containing select agents and toxins.
- A current list of all individuals that have been granted select agents and toxins access approval.

Federal Select Agent Program Notification

- Submit an amendment for any change in circumstances to the certificate of registration, including, but not limited to:
  - Adding or removing individuals.
  - The addition of laboratory or storage area(s) prior to use or storage of select agents and toxins in the area.
  - Any changes to RO or ARO contact information.
  - Changes to registration such as addition or deletion of select agents and toxins and animal species and areas. No work with restricted experiments can be conducted without prior approval from FSAP.
- Request approval (APHIS/CDC Form 2) prior to inter-entity transfer of a select agent and toxin, with exceptions defined in Section 16.
- Upon discovery of a theft or loss of a select agents and toxins, immediately notify FSAP and appropriate Federal, State, or local law enforcement agencies. Submit an APHIS/CDC Form 3 within seven calendar days upon discovery of a theft or loss.
- Upon discovery of a release of a select agent and toxin causing occupational exposure or release of a select agent and toxin outside the primary barriers of its biocontainment area, immediately notify FSAP. Submit an APHIS/CDC Form 3 within seven calendar days upon discovery of a release.
- Immediately report the identification of any Tier 1 select agents and toxins to FSAP and other appropriate authorities when required by Federal, State, or local law.
- Submit APHIS/CDC Form 4 for:
  - The identification and final disposition of a select agent and toxin contained in a specimen within seven calendar days of identification.
  - The final disposition of any select agents and toxins contained in a specimen presented for proficiency testing within 90 calendar days of receipt of the sample.

Report theft, loss or release of a select agent or toxin immediately to FSAP by filling out APHIS/CDC Form 3 within 7 days of the incident. Submit the form to the appropriate organization by facsimile or email and keep a copy for entity documentation records:

**Agriculture Select Agent Services**
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
Tel: 301-851-3300 (Option 3)
Fax: 301-734-3652
Email: AgSAS@aphis.usda.gov

**Centers for Disease Control and Prevention**
**Division of Select Agents and Toxins**
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
Tel: 404-718-2000
Fax: 404-718-2096
Email: form3@cdc.gov
If uncertain about who the entity is registered with, either address is acceptable. Alternatively, send the email to LRSAT@cdc.gov.

Securely maintain records of APHIS/CDC Form 3 for a minimum of 3 years as the RO may be asked to produce these records during onsite FSAP inspection.

**Report the Identification of Select Agents and Toxins**

In compliance with Sections 3, 4, 5, 6, and 9 of the regulations, the RO is responsible for filling out APHIS/CDC Form 4 in the event that the registered entity identifies a select agent or toxin contained within a specimen. Any clinical or diagnostic laboratory, whether registered with FSAP or not, is required to report any confirmed select agents and toxins they identify.

**Note:** While it is not necessary to report an unconfirmed select agent or toxin, it is prudent for the entity to ensure that the agent or toxin is maintained securely until a confirmation test is performed to verify if it is a select agent or toxin.

**Notification Process**

The following select agents and toxins must be reported immediately to APHIS/AgSAS or CDC/DSAT via telephone, fax, or email. Submit the APHIS/CDC Form 4 within 7 days after identification.

- *Bacillus anthracis*
- Botulinum neurotoxins
- Botulinum neurotoxin producing species of *Clostridium*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Rinderpest virus
- Variola major virus (Smallpox virus)
- Variola minor virus (Alastrim)
- *Yersinia pestis*

Report all other identified select agents and toxins by submitting APHIS/CDC Form 4A to FSAP within 7 days.

If the select agent or toxin is isolated and identified from proficiency sample, report to FSAP using APHIS/CDC Form 4B within 90 days.
Disposition of Agents Identified in a Specimen

- If the entity is registered for the select agent or toxin it may transfer, retain or destroy the agent or toxin. The entity may retain the select agent or toxin for as long as they are registered for the select agent or toxin.
- If the entity is registered with the FSAP but is not registered for the select agent or toxin that has been identified they must transfer or destroy the select agent or toxin within 7 days of identification.
- If the entity is not registered with the FSAP they must destroy or transfer the select agent or toxin within 7 days of identification.
- A clinical or diagnostic laboratory must report the identification of any select agent toxin regardless of the amount.
- If the entity wishes to transfer the select agent or toxin rather than destroy it because they believe it may have some scientific value contact the FSAP who may be able to assist in identifying the name of entities who can receive the agent or toxin.
- If the entity wishes to transfer the select agent or toxin to an entity that is registered for the select agent and toxin they must first obtain approval to transfer the select agent or toxin by completing APHIS/CDC Form 2 - Request to Transfer of Select Agents or Toxins and sending the request to FSAP.
- If there is any failure of a validated inactivation procedure or failure to remove viable select agents from material, the RO must investigate the cause. If unable to determine the cause as a deviation from validated procedures, the RO must report the failure to CDC or APHIS immediately be 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 CDC or APHIS immediately by telephone or email.
- The RO must review and revise as necessary each of the entity’s validated inactivation procedures or viable select agent removal method, annually or after a change in PI, change in inactivation procedures or viable select agent removal method, or failure of validated inactivation procedures or viable select agent removal methods.

Securely maintain records of APHIS/CDC Form 4 for a minimum of 3 years as the RO may be asked to produce these records during onsite FSAP inspection.

Reporting Requirements Exam
Records

The RO is responsible for the creation and maintenance of all records documenting entity select agent activities. The record requirements in the Select Agent Regulations (42 CFR §73, 9 CFR §121 and 7 CFR §331) are found primarily in Section 17, although other sections of the regulations contain record keeping requirements.

All records must be maintained for a period of at least three years but entity policy may dictate longer retention times. Records and documents can be maintained electronically or hard copy or by both methods. The RO should keep backup copies of any records pertaining to the entity select agent and toxin activities and to store the records in a manner that reduces the risk of loss. The RO should also make copies of any documents submitted to FSAP. The records must be accurate, comprehensive, current, and organized so they can be readily produced if requested by FSAP inspectors. The following records are required by the entity:

- **Application and Amendments** – Maintain file for registration and amendments and retain records for three years. The RO should have a copy of the most recent and previous application at all times. Include all correspondence regarding APHIS/CDC Form 1 records. One of the first things that a new RO should do is to review the current application documents to ensure continuity of compliance.

- **List of Select Agents and Toxins** – Maintain a list of the select agents and toxins that the entity is registered for and ensure that the entity inventory is consistent with the agents the entity is allowed to possess. The inventory should detail what select agents and toxins are at the entity, in what amounts, and where they are located. Refer to Sections 17 (a)(1), (a)(2) and (a)(3) for complete inventory record keeping requirements.

- **Internal Audits** – Conduct and document an internal audit annually to ensure that the entity is meeting all of the regulatory requirements. This audit should include an inspection of the select agent and toxin inventory. The FSAP inspection checklists may be used as a guideline for conducting the internal audit. Document corrective actions taken by the entity to correct any identified deficiencies.

- **Security Risk Assessment** – Maintain a record of all individuals that have a Security Risk Assessment (SRA) including the name, date of the SRA request, date when the individual was approved, when they were allowed access to select agents and toxins, and when the SRA expires. SRAs expire three years after approval.

- **Record of Access** – Ensure that there is a record of access to rooms containing select agents and toxins. Regularly review the record to ensure that only individuals with SRAs or are escorted by someone with an SRA have access to the rooms. It is common for inspectors to check access records against the list of SRA approved individuals.

- **Training** – Maintain a training record for each person who is granted access to select agents and toxins. Include the person’s name, date of each training they received, description of the training, and means used to verify the individual understood the training. Include new and refresher training.

- **Biosafety, Security, and Incident Response Plans** – Maintain and review biosafety, security, and incident response plans at least annually. Keep a record of the review and any modifications to the plan. FSAP may request updated plans during inspections, upon changes to the entity’s registration, of at the time of the entity’s registration renewal.
- **Entry Requirements** – Document and maintain records for any entity requirements such as baseline sera, respiratory evaluations and fit testing, or health evaluation records. Entities with Tier 1 select agents and toxins are required to have all employees working with those agents enrolled in an occupational health plan prior to accessing Tier 1 agents. Since these records contain sensitive personal information the entity policy may dictate that these records are kept by the entity occupational health service. If so, ensure that those responsible for the records understand that the records must be complete and accurate and provide a means of verifying that individuals have met all of the entity requirements for work in the laboratories.

- **FSAP Inspection Reports** – Maintain previous FSAP inspection reports, including the response to deficiencies and all related follow-up documentation to provide information continuity when there is a change in the entity RO. Ensure that previous inspection deficiencies have been corrected as the entity has stated.

- **Commissioning and Verification Documents** – Maintain original commissioning documentation of high and maximum containment laboratories as well as all subsequent annual verification documentation. Expect to produce these documents during inspection.

- **Equipment Records** – Keep maintenance records of all equipment including but not limited to: Biological Safety Cabinet (BSC), Autoclaves, Digesters, Liquid Decontamination Systems (LDS), Heating, Ventilation and Air Conditioning (HVAC), High-efficiency particulate air (HEPA) filters and housings.

- **Certifications and External Inspections/Audits** – Maintain records of inspections, reviews, certifications or audits by other agencies, or groups. This is not a requirement but may be useful in responding to FSAP inquiries and inspection deficiencies.

- **IBC Minutes** – If there is an Institutional Biosafety Committee (IBC) inspectors may ask to look at the committee minutes. There is no requirement under the Select Agent Regulations that there be an IBC.

- **Transfers** – Maintain all record of transfers of select agents and toxins into and from the entity (APHIS/CDC Form 2), including all shipping invoices and related materials. Also maintain records of transfers within the entity.

- **Reports of Identification of Select Agents and Toxins** – Maintain records of the identification of select agents and toxins using APHIS/CDC Form 4 and copies of the reports to FSAP.

- **Reports of Theft, Loss, and Release** – Maintain records of the theft, loss, or release of select agents and toxins using APHIS/CDC Form 3 and copies of the reports to FSAP.

- **Security** – Ensure that there is a record of who has been assigned codes, keys, combinations, and other access equipment. If this is kept by the entity security officer, regularly check these records to ensure that only SRA approved individuals have been given access to restricted areas. Include access granted and removal dates in order to establish a real time record of individuals who are accessing select agents and toxins at the entity.

- **Requests for Restricted Experiments** – Maintain all documentation related to the entity’s submission of a request to conduct restricted experiments, including the letter to FSAP requesting the review, all supportive documents and all related correspondence. The records must be maintained for a minimum of three years or as long as the research is being conducted.
• **Drills/Exercises** – Maintain records of drills and exercises conducted to test the security, safety, and incident response to help with future planning. Include a list of the participants, the date the drill or exercise was conducted, the outcome and any corrections made as a result.

Required records must be maintained for at least three years and should be kept secure to avoid any loss or alternation. Any documents related to activities at the entity which are related to the possession, use and transfer of select agents and toxins not listed above should also be maintained by the RO. Maintaining an organized record system that involves frequent review and updating can avoid problems during FSAP inspections in verifying that the entity is compliance with the regulations.

[Records Exam](#)
Internal Inspections of Select Agent Registered Areas

Section 9(a)(6) of the regulations require the RO to ensure that internal inspections are conducted annually for each laboratory where select agents and toxins are stored or used (all registered areas) in order to determine compliance with the requirements of the select agent regulations. Establishing an internal annual inspection program with unannounced inspections provides a means for the RO to monitor compliance with the select agent regulations and identify deviations from acceptable laboratory safety, biosafety, or security practices. This can be separate from an overall periodic reconciliation of the entire inventory.

Internal Inspection Best Practices:

- Establish a schedule for recertification and service of laboratory equipment (e.g., biosafety cabinets, HEPA filters and rendering units) to prevent potential biocontainment lapses.
- Create an annual inspection that encompasses every aspect of safety, security, and incident response at the entity. Include a review of the entity’s inventory procedures to ensure that individuals with access to inventories follow appropriate procedures for access and recording changes to the inventory.
- The annual inventory check does not have to be all inclusive; it can be done through spot checks of the inventory to ensure that appropriate procedures are being followed for changes, access, and security of the inventory.
- Check the Select Agents Security Guidance document for more information on the circumstances that could trigger the need for an inventory audit.
- Annually review the biosafety plan, security plan, and incident response plans (required by regulation) to ensure that any changes in the facility operations are appropriately captured. These annual reviews should be appropriately documented, with names, dates, and findings noted for review by FSAP upon request.
- Document the corrective actions taken by the entity to address any identified deficiencies.
**Inspections**

*Section 18 of the select agent regulations* states that:

a) Without prior notification, FSAP is allowed to inspect any regulated site and copy any records.

b) Prior to issuing a certificate of registration to an individual or entity, FSAP is allowed to inspect and evaluate the premises and records to ensure compliance with the Select Agent Regulations.

The entity inspection is the primary means used by the FSAP to verify that the entity is in compliance with the Select Agent Regulations. The inspection provides the entity with both a review of the facilities and the biosafety and biosecurity practices of the entity by outside experts as well as input on improvements.

One or more FSAP inspectors will conduct the inspection, which will typically be at least two days in duration. The number of inspectors and the duration of the inspection depends on the size and complexity of the entity’s select agent program. The purpose of the inspection defines how the inspection is conducted. The various types of FSAP inspection include:

- **New registration or registration renewal inspection** – The most common and most comprehensive type of inspection. Inspections for entities that only have a few laboratories will usually be two days in duration, conducted by two inspectors. Larger institution inspections can be as long as three weeks and involve up to 20 inspectors.

- **Verification/Compliance inspection** – To verify that the entity has resolved deficiencies noted in a previous inspection. It is not uncommon for these inspections to be unannounced. The inspection focuses on specific areas such as security, biosafety, or on previously noted deficiencies. These inspections tend to not be as comprehensive as a renewal inspection. Serious deficiencies can require multiple inspections over a short time.

- **Registration amendment inspection** – For major changes in an entity’s registration, e.g. the addition of new agents, new laboratories, or changes in work objectives. FSAP will most likely conduct an inspection to verify that the changes are in compliance with the requirements of the select agent regulations.

- **Inspection for cause** – Conducted unannounced by FSAP when there has been a loss of select agents or toxins, an exposure requiring treatment or serious uncorrected deficiencies. If FSAP determines that significant violations have occurred, the entity may be referred to the Health and Human Services Office of Inspector General, the USDA Investigative Enforcement Service, or the Federal Bureau of Investigation.

- **Multiple agency inspection** – In all of the above types of inspections, other agencies besides DSAT and AgSAS may be involved. The Department of Defense Office of Inspector General, the Department of Homeland Security, the Department of Transportation and others may participate in an FSAP inspection. Even though these agencies do not have authority under the Select Agent Regulations, the FSAP and other federal agencies have agreed to coordinate inspections when possible to avoid an undue burden on entities.
Inspection Process

Pre-Inspection Phase
The pre-inspection phase is the phase in which the RO is notified of a pending inspection and begins to prepare for the inspection event. The RO should provide any information requested by the FSAP, inquire about the inspection process, notify entity personnel of the pending event, ensure that critical personnel such as biosafety officers, facility and security managers are available and prepare the documentation that will be examined by the inspectors. Inspection checklists, which are used by the inspectors can be helpful for the RO to review in preparation for the inspection.

Inspection Phase
This is the onsite inspection phase where inspectors arrive at the site and begin the inspection. The typical inspection includes the following activities:

- Introductions by inspectors and entity personnel.
- Description of the inspection process by the inspectors and discussion of the inspection schedule. Inspectors will need a secure, lockable room during the duration of the inspection where documents can be examined and interviews conducted.
- Presentation by the PIs or laboratory managers on the select agent and toxin related activities that are conducted at the entity. This is not expected to be a lengthy presentation but just enough to give the inspectors a sense of work being performed with the select agents and toxins at the entity.
- Physical examination of the laboratories and the laboratory supporting areas (HVAC systems, liquid decontamination systems, waste handling systems, physical security systems, engineering controls). Access to the laboratory is required and inspectors should be notified prior to the inspection of any access requirements such as personal protective equipment and immunizations. Examinations include:
  - Spot check or complete inventory.
  - Examination of records and documentation.
  - Review of the current biosafety, security and incident response plans.
  - Review of equipment maintenance records.
  - Review of commissioning or annual facility verification documents, access records, training programs and records, and transfer records.
  - Review of internal audit documents reporting of theft, loss and release, and incident reports.
  - Description of the entity occupational health program and Institutional Biosafety Committee minutes.
- Interviews are conducted throughout the inspection process. This will involve interviews with security and safety personnel, laboratory staff, researchers, and engineers.
- At the conclusion of the inspection, the inspectors will provide a briefing of the primary findings during the inspection. This will not be a complete listing of all observations that will be included in the written report but will provide the RO an idea of the observations that will be included. This is also an opportunity for the RO and other entity staff to ask questions of the inspectors.
Post-inspection Phase
Within 2-3 weeks, a written report of the findings during the inspection will be provided to the RO. The report will list the observations made by the inspectors including descriptions of how any regulatory requirements were not met. The RO generally has 14 calendar days to respond to the report providing detailed responses and documentation to support that the deficiency has been corrected. If the deficiency cannot be corrected within the 14 days, the RO should provide a detailed plan for correction of the deficiency including milestones. If the responses are not adequate, the RO will receive additional requests for information. During this phase, the RO should contact the inspectors or his/her file manager if there are any questions about the observations.

After FSAP has determined that all of the deficiencies have been adequately addressed, the RO will receive a letter stating that the inspection has been closed and no additional information is required.

The inspection described in this chapter is a routine scheduled type of inspection. It should be understood that while the inspection process is as standardized as possible every entity is different and no two inspections are identical.

Please see the informational inspection checklist video on the Inspection Checklist page on the FSAP website.

Inspections Exam
**Three Year Cycle of RO Tasks**

The Three Year Cycle of Events is a listing of the events that can occur over a three year time span from initial registration to registration renewal. It does not include all possible events and there will be variation of events among entities. The intent of the table below is to give the Responsible Official (RO) an overview of the activities that can occur prior to and during registration and then activities after registration during the three year registration cycle. This is hoped to provide the RO with a reminder of checklist of tasks associated with managing their entity select agent program. Please refer to the guidance documentation and the [FSAP website](http://fsap.gov) for additional details. **Note:** The shaded areas are tasks performed by FSAP.

<table>
<thead>
<tr>
<th>Event</th>
<th>Description of Event</th>
<th>Comment</th>
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<tbody>
<tr>
<td>1.0</td>
<td>Entity identifies need to register with FSAP.</td>
<td>This decision should involve the key members of the organization and after review of the regulations. Contact FSAP for questions regarding registration and regulations.</td>
</tr>
<tr>
<td>2.0</td>
<td>Entity selects RO. Entity may also designate an alternate RO (ARO).</td>
<td>Consider the RO duties and responsibilities as specified in the regulations. See Fundamental Responsibilities of the Responsible Official</td>
</tr>
<tr>
<td>3.0</td>
<td>Entity reaches out to community in which the registered entity is located.</td>
<td>Depending on the work to be performed and the entity's policies and philosophy it can sometimes be helpful to proactively reach out to local community leaders to address community fears and concerns. This may especially be important if a maximum containment facility is the issue.</td>
</tr>
<tr>
<td>4.0</td>
<td>Entity conducts review of the facilities where BSAT will be stored and used.</td>
<td>Facilities should be appropriate for the agents and work to be performed and operational ready. Refer to the Biosafety in Microbiological and Biomedical Laboratories, 5th Edition and the FSAP for guidance. Please note that the facilities should be ready for operation. All plans should be specific to the BSAT possessed, used, or transferred.</td>
</tr>
<tr>
<td>4.1</td>
<td>Conduct biosafety risk assessment and develop biosafety plan.</td>
<td>The plan should be specific to the select agents and toxins that will be possessed, used or transferred and should complement, not conflict with, any organization wide plans.</td>
</tr>
<tr>
<td>4.2</td>
<td>Conduct security risk assessment and develop security plan.</td>
<td>The security plan should complement and not conflict with any organizational plans. See FSAP website and FBI WMD regional office for assistance with SRA. Create additional security policies if Tier 1 agents are used.</td>
</tr>
<tr>
<td>4.3</td>
<td>Conduct hazard threat assessment and develop incident response plan.</td>
<td>The plan should be consistent with any organization wide plans. Entity should contact and involve local emergency responders.</td>
</tr>
<tr>
<td>4.4</td>
<td>Develop training program and begin staff training.</td>
<td>The plan should be consistent with any organization wide plans. Entity should contact and involve local emergency responders.</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Details</td>
</tr>
<tr>
<td>---</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>5.0</td>
<td>RO prepares application (APHIS/CDC Form 1) and submits to FSAP.</td>
<td>Engage members of the entity in preparation of the application to help build requirements knowledge among the staff and insure that all requirements are covered.</td>
</tr>
<tr>
<td>6.0</td>
<td>FSAP receives application and sends acknowledgement with DOJ numbers for staff identified as needing access.</td>
<td>Approximate time to receive DOJ numbers is 5 – 10 business days.</td>
</tr>
<tr>
<td>6.1</td>
<td>FSAP assigns File Manager to entity.</td>
<td>File Manager is the point of contact and should contact the RO within 5 – 10 business days.</td>
</tr>
<tr>
<td>7.0</td>
<td>Entity personnel submit FD-961, photo and finger prints to Criminal Justice Information Services (CJIS).</td>
<td>To avoid processing delays, provide all information. RO must sign forms before they are sent to CJIS. Processing takes 30-50 calendar days to complete.</td>
</tr>
<tr>
<td>7.1</td>
<td>RO and staff member(s) receive approval or disapproval notification from FSAP based on SRA.</td>
<td>Restricted individuals can appeal decision by following instructions on notification.</td>
</tr>
<tr>
<td>7.2</td>
<td>Entity conducts security, safety, and incident response training with all personnel participating in entity select agent program.</td>
<td>See the Security, Safety, and Incident Response guidance documentation for more information.</td>
</tr>
<tr>
<td>8.0</td>
<td>RO is contacted by FSAP to arrange inspection.</td>
<td>Inspection is generally scheduled 60 – 90 days in advance but may be unannounced.</td>
</tr>
<tr>
<td>9.0</td>
<td>RO prepares for FSAP inspection.</td>
<td>RO can use checklists found on the FSAP website as an aid in evaluating the entity for compliance with the regulations. Please watch the inspection process video on the FSAP website for more information on what to expect during an inspection.</td>
</tr>
<tr>
<td>10.0</td>
<td>FSAP sends RO notice of inspection.</td>
<td>Notice of inspection is typically sent to the entity as least 30-45 days in advance of the inspection.</td>
</tr>
<tr>
<td>10.1</td>
<td>RO provides entry requirements and other required information to the FSAP.</td>
<td>Send Information on security, immunization, and personal protective equipment requirements to FSAP prior to the inspection. Additional documentation may also be required such as biosafety, security and incident response plans.</td>
</tr>
<tr>
<td>11.0</td>
<td>FSAP inspectors arrive to conduct inspection.</td>
<td>Inspections are generally 2-3 days in length and involve 2 -3 inspectors, depending on the size and complexity of the entity.</td>
</tr>
<tr>
<td>12.0</td>
<td>FSAP sends inspection report to RO.</td>
<td>Inspection report typically arrives within 14-28 calendar days after inspection.</td>
</tr>
<tr>
<td>13.0</td>
<td>RO receives report and prepares responses to any noted deficiencies</td>
<td>The RO has 14 calendar days to respond to the inspection report. If inadequate responses are provided additional requests from FSAP for information will be requested.</td>
</tr>
<tr>
<td>14.0</td>
<td>FSAP sends notice that all deficiencies have been addressed.</td>
<td>The resolution of inspection deficiencies is not approval to possess select agents and toxins.</td>
</tr>
<tr>
<td>15.0</td>
<td>FSAP sends certificate of registration to the RO.</td>
<td>The certificate is valid for 3 years and conveys approval to possess select agents and toxins.</td>
</tr>
<tr>
<td>Event</td>
<td>Description</td>
<td></td>
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<tr>
<td>-------</td>
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</tr>
<tr>
<td>16.0</td>
<td>Entity acquires BSAT they are registered for using the APHIS/CDC Form 2. All transfers of select agents and toxins at registered levels must be approved prior to shipment.</td>
<td></td>
</tr>
<tr>
<td>16.1</td>
<td>RO submits amendments to registration anytime there are changes to the application.</td>
<td></td>
</tr>
<tr>
<td>16.2</td>
<td>RO submits APHIS/CDC Form 3 anytime there is a theft, loss or release of a select agent or toxin. See FSAP web site for forms.</td>
<td></td>
</tr>
<tr>
<td>16.3</td>
<td>RO ensures that annual refresher training is conducted for SRA approved staff. Training is in biosafety, security and incident response. Also threat awareness briefings are required if entity possesses Tier 1 agents.</td>
<td></td>
</tr>
<tr>
<td>16.4</td>
<td>RO submits APHIS/CDC Form 4 if select agents or toxins are identified. Select agents and toxins for which the entity is not registered must be transferred or destroyed.</td>
<td></td>
</tr>
<tr>
<td>16.5</td>
<td>RO conducts annual inspections. This includes inventory audits to ensure that the inventory is current and accurate. Inspection checklists provided in Appendix M can be used to develop the internal inspection process.</td>
<td></td>
</tr>
<tr>
<td>16.6</td>
<td>RO ensures that plans (biosafety, security and incident response) are reviewed annually and revised as necessary, including after annual drills and exercises. Retrain staff if plans change significantly. Inspection checklists provided on the FSAP website can be used to develop the internal inspection process.</td>
<td></td>
</tr>
<tr>
<td>16.7</td>
<td>RO reviews access records and ensures select agent inventory records are current and accurate. Access records should be compared with the current list of SRA cleared individuals.</td>
<td></td>
</tr>
<tr>
<td>16.8</td>
<td>RO ensure training is provided to escorted individuals with access to registered areas. Training must be documented and provided to any individuals not SRA cleared who enter registered areas.</td>
<td></td>
</tr>
<tr>
<td>16.9</td>
<td>RO ensures facilities and equipment receive annual maintenance, certification, etc. Maintain records for a minimum of three years.</td>
<td></td>
</tr>
<tr>
<td>17.0</td>
<td>Year 2: Repeat Events 16.0-16.9. Announced or unannounced inspections may occur at any time.</td>
<td></td>
</tr>
<tr>
<td>18.0</td>
<td>Year 3: Repeat Events 16.0-16.9. Announced or unannounced inspections may occur at any time.</td>
<td></td>
</tr>
<tr>
<td>19.0</td>
<td>RO reviews list of staff with SRA. The SRA expires after three years the RO should identify those individuals with expiring SRA at least 90 days prior to expiration and submit FD-961 to FBI. Fingerprints are not normally required for renewal of SRA.</td>
<td></td>
</tr>
<tr>
<td>20.0</td>
<td>FSAP contacts RO to schedule renewal inspection. The RO will be contacted approximately 5-6 months before the registration expires to schedule an inspection 3-4 months in advance.</td>
<td></td>
</tr>
<tr>
<td>20.1</td>
<td>FSAP sends notice of renewal inspection approximately 45 days in advance of the inspection. RO may be requested to provide updated biosafety, security and incident response plans (occupational health plan for Tier 1 agents).</td>
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</tr>
<tr>
<td><strong>20.2</strong></td>
<td>RO ensures that all records are complete and up to date.</td>
<td>Ensure all records, plans and other associated documents ready for inspectors for the inspection process.</td>
</tr>
<tr>
<td><strong>20.3</strong></td>
<td>FSAP conducts inspection of entity.</td>
<td></td>
</tr>
<tr>
<td><strong>20.4</strong></td>
<td>RO receives report of inspection with list of any deficiencies.</td>
<td>Entity has 14 calendar days to respond. If deficiency will take longer than 14 days to resolve RO should ensure that the response provides plans to resolve deficiency along with timelines.</td>
</tr>
<tr>
<td><strong>20.5</strong></td>
<td>RO receives renewal certification.</td>
<td>Renewal is valid for another three years.</td>
</tr>
</tbody>
</table>
RO Knowledge Check

For training and review, click on the following links to access exam material that covers all of the knowledge responsibilities of the RO. Both the RO and the ARO should be able to sufficiently familiar with each of the following topics to pass the short self-exams.

- The Federal Select Agent Program
- Responsibilities of the RO
- Registration with FSAP
- Reporting Requirements
- Transfers of Select Agents and Toxins
- Biosafety and Biosafety Plan
- Security and Security Plan
- Incident Response Plan
- Restricted Experiments, Exemptions, and Exclusions
- Records
- Training
- Drills and Exercises
- Inspections
- Facilities: Commissioning and Verification