



Responsible Official Guidance Document

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

Preface

Revisions: 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:

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Introduction

This document has been prepared to assist a registered entity and its Responsible Official (RO) to plan and develop policies and procedures that comply with federal select agent regulations promulgated under the authority of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The regulatory requirements for a RO are found in Section 9 of the select agent regulations. Each registered entity that possesses, uses, or transfers biological select agents and toxins (i.e., select agents and toxins) is required to designate an individual as their RO and submit that person's name to the Federal Select Agent Program (either the Centers for Disease Control and Prevention (CDC) or the Animal and Plant Health Inspection Service (APHIS)) for approval. While compliance with the select agent regulations is ultimately the responsibility of the registered entity, the RO plays a key role to ensure that his or her entity is in compliance with the select agent regulations and serves as the main point of contact for all select agent registration, reporting, and compliance issues. The latest electronic version of this document can be found at <http://www.selectagents.gov/Resources.html>.

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 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) may 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:

- The RO must have passed 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.
- The RO must be familiar with the select agent regulations to the extent that the RO can ensure that his or her entity is compliant with all of the requirements of the select agent regulations.
- The registered entity must not only assign the RO the responsibility to ensure compliance with the select agent regulations, the entity must also ensure that it delegates to the RO sufficient authority to speak and act on behalf of the entity. A registered entity which fails to vest in its RO sufficient authority to ensure compliance with all of the requirements of the select agent regulations has failed in one of its primary responsibilities.
- The RO must ensure compliance with the select agent regulations.
- The RO must ensure that annual inspections are conducted 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. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.
- The RO must have a physical (and not merely a telephonic or audio/visual) presence at the registered entity 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.

Designation of Responsible Official

The registered entity, as a part of its initial registration with the Federal Select Agent Program, must submit the name of the RO (and any ARO's) using the APHIS/CDC Form 1. The Federal Select Agent Program may also request that a current résumé or curriculum vitae for the RO be submitted as well.

The RO will need to foster open lines of communication with upper management, facility directors, principal investigators, veterinarians, contractors, local authorities and institutional oversight committees in order to manage a successful program compliant with the select agent regulations. The RO should be engaged in and be knowledgeable about the programs and operations of his or her entity. To the extent possible, an entity should avoid designating an owner, controller, or principal investigator as the RO as this arrangement may present conflict-of-interest situations. Nevertheless, the Federal Select Agent Program recognizes there are situations (e.g., small entities with limited personnel), in which this scenario may be unavoidable. Based on our experience with many types of entities, the RO position is a full time endeavor and requires much more time than what a principal investigator or owner can provide. Although it is not a violation of the select agent regulations for an individual serving as an RO to have other responsibilities, the Federal Select Agent Program would not recommend this--especially at institutions with large and/or complex select agent programs.

When there is an anticipated change in an RO assignment, a registered entity must submit the appropriate sections of APHIS/CDC Form 1 as early as possible for approval of the new RO. The approval must occur before the current RO vacates the assignment, as it is a requirement of the select agent regulations for a registered entity to have a RO approved by the Federal Select Agent Program at all times. This is not a lengthy process if the successor has a current security risk assessment. However, the entity should anticipate that for an individual without a current security risk assessment, it may take 45 to 60 days to complete this process, depending upon the results of the criminal database review. For RO positions which would have access to Tier 1 agents and toxins they must also have undergone the suitability assessment process. This process also needs to be considered during RO transitions if the entity finds itself without an RO.

The ARO assumes the position and responsibilities of the RO either permanently or temporarily until a replacement is selected by the entity or the RO assumes full duties. The ARO must be able and willing to assume the full range of responsibilities of the RO. The entity would need only to submit an amendment to the APHIS/CDC Form 1 noting a permanent change.

Any time the Federal Select Agent Program determines the RO has not or is not fulfilling his or her responsibilities to ensure compliance with the requirements of the select agent regulations, the Federal Select Agent Program has authority to suspend, revoke or deny an entity's certificate of registration.

Designation of an Alternate Responsible Official

The regulations in Section 9(b) require that an entity may designate one or more individuals to be an ARO, who may act for the RO in his/her absence. Although it is not a requirement in the select agent regulations for an entity to designate an ARO, situations arise in which the RO is not available to provide appropriate regulatory oversight (e.g., vacation, protracted illness or extended travel). Therefore, it is advisable for the registered entity to designate one or more AROs to be available to act in the absence of the RO on a short-term, temporary basis. These individuals must have the knowledge and authority to ensure compliance with the select agent regulations when acting as the RO and be able to take appropriate action on behalf of the entity. Like the RO, an individual designated to serve as an ARO must be designated as an ARO on APHIS/CDC Form 1, have an SRA conducted by CJIS with a status of “Unrestricted,” and be approved for the role by the Federal Select Agent Program.

However, as noted above, it is not consistent with the select agent regulations for the ARO to fulfill the responsibility and final decision-making of the RO when the RO is available to carry out his or her day-to-day responsibilities. In other words, the RO cannot delegate final decision-making responsibility to an ARO when the RO is physically present at the entity and able to carry out his or her responsibilities.

The RO may delegate authority to an ARO, or others in the program, for a wide range of duties; however, the RO should demonstrate a consistent pattern of constant engagement through effective avenues of communication with which the RO has delegated this authority. The RO must, however, retain final decision-making responsibility over matters concerning overall programmatic compliance with the select agent regulations. In other words, the RO may delegate day-to-day maintenance activities or decisions to an ARO but may not delegate those decisions that affect the nature or complexity of an entity’s select agent program.

Security Risk Assessment

The regulations in Section 9(a) (1) require that the individual designated to be the RO must have a SRA conducted by the CJIS. A SRA renewal is required once every three years. While each RO will be notified by the Federal Select Agent Program to submit the appropriate documents (i.e., a current FD-961) for CJIS review prior the expiration of the security risk assessment, it remains the RO's responsibility to ensure that his or her SRA renewal is submitted in a timely manner.

All individuals that will have access to select agents and toxins are required to obtain a SRA prior to such access and to undergo a renewal of their SRA every three years. Individuals with select agents and toxins access must submit a new completed Form FD-961 to CJIS prior to the three year expiration date. The Federal Select Agent Program assists in this process by providing the RO with the names of individuals due for renewal of their SRA. If CJIS does not receive the required information from these individuals in a timely manner, their access will be terminated and the RO will be notified by the Federal Select Agent Program. If at any point an individual's access to select agents and toxins is terminated by the entity, the RO should immediately report this to the Federal Select Agent Program and provide reasons for the termination of access (See Section 10 (j)). The Federal Select Agent Program recognizes that the termination of access to select agents and toxins, when an entity will begin actions to remove an individual from its registration, is different than when an entity temporarily suspends access due to authorized absences. The entity is not required to report to the Federal Select Agent Program temporary suspensions of access; however, if this removal does become permanent, then Federal Select Agent Program must be notified.

Knowledge of the Select Agent Regulations

The regulations in Section 9(a)(2) require the RO to be familiar with the requirements of the select agent regulations. The select agent regulations also state that the RO is responsible to ensure that the registered entity is in compliance with all the requirements of the select agent regulations (See Section 9(a)(4)) This means that the RO is 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, it is imperative that the RO become familiar with and fully understand the select agent regulations and make him or herself aware of associated Federal Select Agent Program policy and guidance documents that are available to assist in the implementation of a successful program. The RO should have sufficient understanding of the work objectives within their operations in order to make appropriate management decisions regarding security, biocontainment and biosafety, and incident response, which comply with these regulations.

In addition to the select agent regulations, there are Federal Select Agent Program policies and guidance posted on the National Select Agent Registry (NSAR) website located at <http://www.selectagents.gov/>. The Federal Select Agent Program develops guidance documents to help clarify the intent of the regulations and the policies of the Federal Select Agent Program in implementing these requirements. Under most circumstances, the RO will be notified by electronic mail (e-mail) of new developments or documents posted on the website.

A Federal Select Agent Program 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, the Federal Select Agent Program employs security, facility, biosafety, and occupational health personnel who evaluate the applicable components of registered facilities and provide guidance.

Periodically, the Federal Select Agent Program will conduct workshops specifically targeted to the RO. The purpose of these workshops is to keep the RO current about upcoming changes, concerns the program may have, and to listen to concerns ROs may have. The RO will be notified when these workshops are available through e-mails, public notification and <http://www.selectagents.gov/>.

Authority and Responsibility

The regulations in Section 9(a) (3) require that the RO has authority and responsibility to act on behalf of the entity for its select agent program. As noted earlier, the RO (or ARO) must be aware of and certify all the information submitted to the Federal Select Agent Program on APHIS/CDC Forms 1 through 5 is, to the best of his or her knowledge, accurate and truthful. The entity must have delegated to the RO the authority to effectively manage the biosecurity, biocontainment and biosafety, and incident response of select agents and toxins in their facility. This authority must also be delegable to an ARO in the event that the RO is unavailable to exercise this authority. The RO must have the ability to provide direct input to effect changes as needed in operations, personnel, and facilities at the registered entity in order to fulfill his or her responsibilities. The RO position must also 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. Accordingly, the RO must maintain constant engagement with those to whom he or she has delegated duties. For example, while the RO can delegate to an ARO, or other entity official, oversight of the biosafety plan and biosafety issues in the entity's program, the RO must be aware of the overall biosafety concerns of select agents and toxins at the entity and any ongoing issues through regular briefings by the delegate. The select agent regulations require that an ARO have the appropriate knowledge, competence, and authority to execute the full duties of the RO in the RO's absence. The ARO must have the sufficient capability and authority to perform all duties of the RO.

It should also be noted that an ARO is not an "assistant" RO and should only conduct functions as the RO while the RO is offsite. The ARO must have the ability to assume the full authority and undertake all of the responsibilities of the RO as needed. While the RO may delegate certain functions to others, including the ARO, the RO must retain his or her overall responsibility for oversight for the delegated functions. The RO must retain oversight of the decisions that would necessitate changes to the registration and submission of documents to the Federal Select Agent Program, but the ARO can sign documents and submit forms and information in support of those decisions. It is important that the RO maintain control over all aspects of an entity's program and be aware and responsible for all submissions to the Federal Select Agent Program. The RO should be fully engaged in his or her duties when on site, but can delegate administrative and

maintenance functions of the entity's select agent program as necessary to ensure the efficiency and timeliness of communications with the Federal Select Agent Program.

The RO, in order to ensure effective compliance with the select agent regulations, should either be in charge of or intimately involved with certain supervisory or management functions of employees related to access to select agents and toxins at the registered entity. The scope of responsibilities includes limiting access to SRA approved personnel, initial and refresher training, and performance oversight and disciplinary action of employees engaged in work with select agents and toxins. Based on our experience since 2003, the Federal Select Agent Program believes that ROs who are knowledgeable about, and interact with, individuals approved to work with select agents and toxins have a better chance of addressing issues of noncompliance and are more successful in carrying out their responsibilities.

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; and 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.

With respect to the granting of access to select agents and toxins, the registered entity retains the authority to make decisions concerning access even if an individual has been approved by the Federal Select Agent Program to have access to select agents and toxins. We note that the first step in granting approval to have access to select agents and toxins is the identification by the entity of an individual that the entity wishes to have access to the select agents and toxins that it possesses. 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 following are specific items and duties which are required and are the responsibility of the RO 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 that contains 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 that fully describes 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 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.
- 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; with refresher training provided 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.
- 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, especially 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.

Records:

- Maintain all records 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, and
 - 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 and
 - 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
- Submit an amendment describing work prior to conducting a restricted experiment as defined in Section 13.
- Ensure personnel who will have access to Tier 1 select agents and toxins are enrolled in a pre-access assessment.
- Ensure ongoing suitability monitoring of personnel with access to Tier 1 select agents and toxins.
- 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 Federal Select Agent Program and appropriate Federal, State, or local law enforcement agencies. An APHIS/CDC Form 3 must be submitted 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 Federal Select Agent Program. An

APHIS/CDC Form 3 must be submitted within seven calendar days upon discovery of a release.

- Immediately report the identification of any Tier 1 select agents and toxins to Federal Select Agent Program 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, and
 - 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.

Internal Inspections of Select Agent Registered Areas

The regulations in Section 9(a) (6) require the RO to ensure that annual inspections are conducted 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 provides a means for the RO to monitor compliance with the select agent regulations and identify deviations from acceptable laboratory safety or security practices. An established schedule for recertification and service of laboratory equipment (e.g., biosafety cabinets, HEPA filters and rendering units) will also help prevent any potential lapses in biocontainment. Internal unannounced inspections of laboratories during ongoing research projects can help identify any deviations from established biosafety standard operating procedures. The annual inspection should encompass every aspect of safety, security, and incident response at the entity, and should also include a review of the entity's inventory procedures to ensure that individuals with access to inventories are following appropriate procedures for access and recording changes to the inventory. This can be separate from an overall periodic reconciliation of the entire inventory (recommended every 3 years). 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. More information on the circumstances that could trigger the need for an inventory audit, and guidance on the thoroughness of that audit, can be found in the Security Guidance document found at <http://www.selectagents.gov/>. Annual reviews of the biosafety plan, security plan, and incident response plans are required and should 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 the Federal Select Agent Program upon request.

Principal Duty Station

The regulations in Section 9(a)(5) require that the RO have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and is able to quickly respond to on-site incidents involving select agents and toxins. Ideally, the RO should be co-located with the entity, or within reasonable distance of all the entity's registered areas, to be able to quickly respond to emergencies and to provide appropriate oversight on a day-to-day basis. The Federal Select Agent Program does not believe effective oversight and control can be properly achieved by an RO located at some distant location. There must be an approved RO or ARO (who becomes the RO) at a registered entity during normal business hours and the RO or ARO must be available for emergencies after normal business hours. There are situations where registered entities have two or more registered laboratory facilities dispersed over a defined geographical location (e.g., a university campus or business complex). The Federal Select Agent Program considers this one general physical location which can be managed as one registration. The intent of the requirement that the RO have a physical presence at the registered entity is not to require that an RO is assigned to each laboratory but to ensure that an RO is physically located on-site. The RO should have the responsibility, as discussed in this document, over the entire registered entity, even if the registered entity contains multiple buildings.