

Responsible Official/ Alternate Responsible Official Roles and Responsibilities

July 27, 2023



Outline

- Audience Poll Questions
- Overview of Responsible Official (RO)/Alternate Responsible Official (ARO) Responsibilities
 - Fundamental Responsibilities
 - Knowledge of Select Agent Regulations
 - Authority and Responsibility
 - Delegating Responsibility
 - Compliance with Select Agent Regulations
 - Notifications to Federal Select Agent Program (FSAP)
 - Records
 - Security Risk Assessments (SRAs)
 - Inspections
 - Inactivation Procedures
 - FSAP Notifications
 - Records



Audience Poll Question 1 - Zoom

Question 1: What responsibility do you find the most challenging?

- a. Meeting annual requirements such as training, annual inspections, review of documents
- b. Conducting unique drills and exercises
- c. Maintaining a physical presence
- d. Maintaining a current registration in eFSAP



Audience Poll Question 2 - Zoom

Question 2: Do you have the authority to act on behalf of the entity?

- a. Yes
- b. No



Audience Poll Question 3 - Zoom

Question 3: Do you have support from entity staff to ensure compliance with the select agent regulations?

- a. Yes
- b. No



Audience Poll Question 4 - Zoom

Question 4: What responsibilities are most often delegated to the ARO or others?

- a. Developing plans
- b. Training
- c. Record maintenance
- d. Annual inspections



Responsibilities



Responsibilities of the Responsible Official (1/9)

- FSAP approved by HHS Secretary or APHIS Administrator following SRA
- Serve as RO at only one entity
 - May not serve as RO or ARO at more than one entity
 - However, the ARO may serve as ARO at multiple entities



Responsibilities of the Responsible Official (2/9)

- Communicate with:
 - Upper Management
 - Principal Investigators (PIs)
 - Veterinarians
 - Scientists
 - Contractors
 - Local Authorities
 - Oversight Committees
 - Biosafety Officers (BSOs)
 - Security Officers



Responsibilities of the Responsible Official (3/9)

- Have a physical presence and be able to respond in a timely manner to on-site incidents
- Ensure HHS Office of Inspector General (OIG) and USDA OIG Hotlines are available for staff to anonymously report biosafety/security concerns
- Investigate to determine reason for any failure of a validated inactivation procedure
- Limit access to select agents to only FSAP-approved individuals
- Ensure a current and accurate registration



Responsibilities of the Responsible Official (4/9)

- Immediately report the identification and final disposition of any select agent/toxin contained in a specimen for diagnosis or verification
 - Agricultural Select Agents(7 CFR 331.9(c)(1))
 - *Coniothyrium glycines* (formerly *Phoma glycinicola*, *Pyrenochaeta glycines*)
 - *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
 - *Ralstonia solanacearum*
 - *Rathayibacter toxicus*
 - *Sclerophthora rayssiae*
 - *Synchytrium endobioticum*
 - *Xanthomonas oryzae*



Responsibilities of the Responsible Official (5/9)

○ Animal and Animal Product Select Agents (9 CFR 121.9(c)(1))

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (highly pathogenic)
- *Bacillus anthracis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Classical swine fever virus
- Foot-and-mouth disease virus
- Virulent Newcastle disease virus
- Rinderpest virus
- Swine vesicular disease virus



Responsibilities of the Responsible Official (6/9)

- Public Health Select Agents (42 CFR 73.9(c)(1))
 - *Bacillus anthracis*
 - *Bacillus cereus* Biovar *anthracis*
 - Botulinum neurotoxin producing species of *Clostridium*
 - Botulinum neurotoxin
 - *Burkholderia mallei*
 - *Burkholderia pseudomallei*
 - *Francisella tularensis*
 - Ebola virus
 - Marburg virus
 - Variola major and minor
 - *Yersinia pestis*



Responsibilities of the Responsible Official (7/9)

- Annually
 - Ensure annual inspections are completed for all registered areas where select agent/toxin is used or stored
 - Results must be documented
 - Deficiencies identified must be corrected
 - Review each of the entity's inactivation or viable select agent removal procedures
 - Conduct site-specific drills or exercises
 - Conduct training
 - Biosafety
 - Security
 - Incident Response



Responsibilities of the Responsible Official (8/9)

- Training

- Ensure a record of training is maintained for each individual with access to select agents and toxins
 - Training must occur prior to unescorted access, or
 - Within 1 year of FSAP approval
- Ensure a record of training for each individual include:
 - The name of the individual
 - A description of the training
 - The date the training was provided, and
 - The means used to verify the individual understands the training



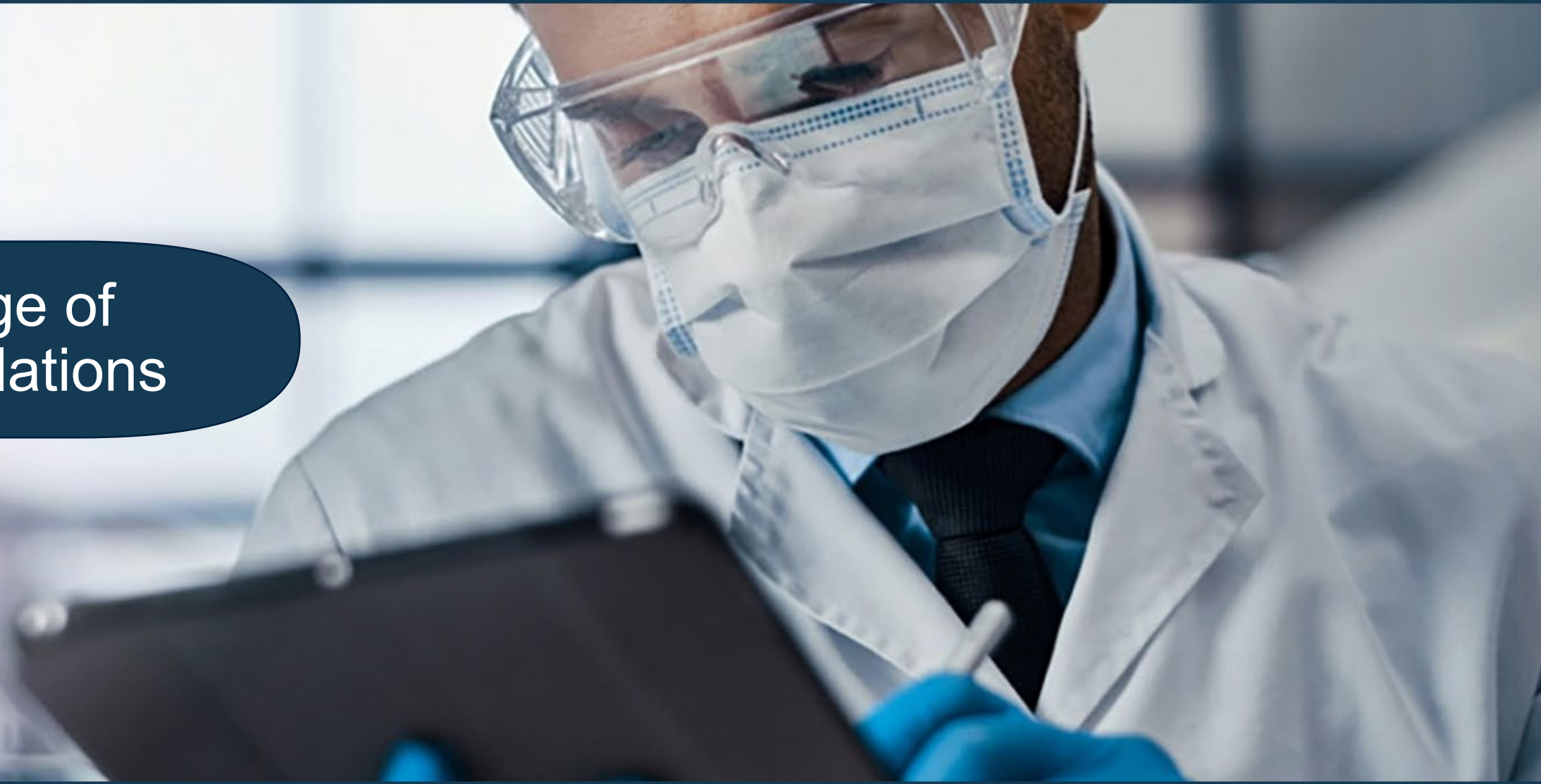
Responsibilities of the Responsible Official (7/7)

- Tier 1 registered entities

- Ensure insider threat awareness briefing is conducted for all FSAP-approved individuals annually
- Coordinate with entity safety and security professionals



Knowledge of the Regulations



Knowledge of the Select Agent Regulations

- Be familiar with the select agent regulations
 - Utilize your FSAP Point of Contact
 - Attend webinars/workshops
 - Reach out to others in the regulated community
 - Utilize FSAP's reference materials
 - Guidance Documents
 - FAQs
 - Policy Statements
 - www.selectagents.gov
 - Learn from your mistakes
 - Inspection observations
 - Incidents
 - Reference the Regulations and Biosafety in Microbiological and Biomedical Laboratories (BMBL)



A close-up photograph of a male scientist in a laboratory. He is wearing a white lab coat over a blue dress shirt and a dark tie. He is also wearing clear safety goggles and a white surgical mask. He is holding a clipboard and a pen, looking down at the clipboard. The background is a blurred laboratory setting with various pieces of equipment.

Delegating Responsibility

Delegating Responsibility

- AROs must have the ability to assume the full authority and undertake all the responsibilities of the RO, as needed.
- Delegated duties may include:
 - Developing risk assessments
 - Developing plans
 - Training personnel
 - Maintaining records



Delegating Responsibility

- The RO still:
 - Retains overall responsibility for the oversight of delegated functions
 - Must ensure compliance with the select agent regulations
 - Must be aware and responsible for all FSAP submissions



Compliance



Compliance: Security Risk Assessment

- RO is responsible for assisting entity personnel in completing the FD-961 and ensuring all individuals with access to select agents have a valid SRA
- SRA is the electronic records check performed by the Federal Bureau of Investigation's Bioterrorism Risk Assessment Group (BRAG)
- For new applicants, mail to BRAG:
 - FD-961 Form
 - Photo ID
 - Legible fingerprint cards
- Individual's access is denied until decision by FSAP has been provided



Compliance with Select Agent Regulations

- Three plans need to be developed and implemented:
 - Biosafety
 - Commensurate with the risk of the select agents and toxins
 - Security
 - Site-specific risk assessment that provides graded protection in accordance with the risk of the select agents and toxins
 - Incident response
 - Commensurate with the hazards of the select agents and toxins for which the entity is registered



Compliance: Drills and Exercises

- Entities required to conduct a drill or exercise
 - Annually
 - To evaluate the security, biosafety, and incident response plan
 - To detect flaws in plans



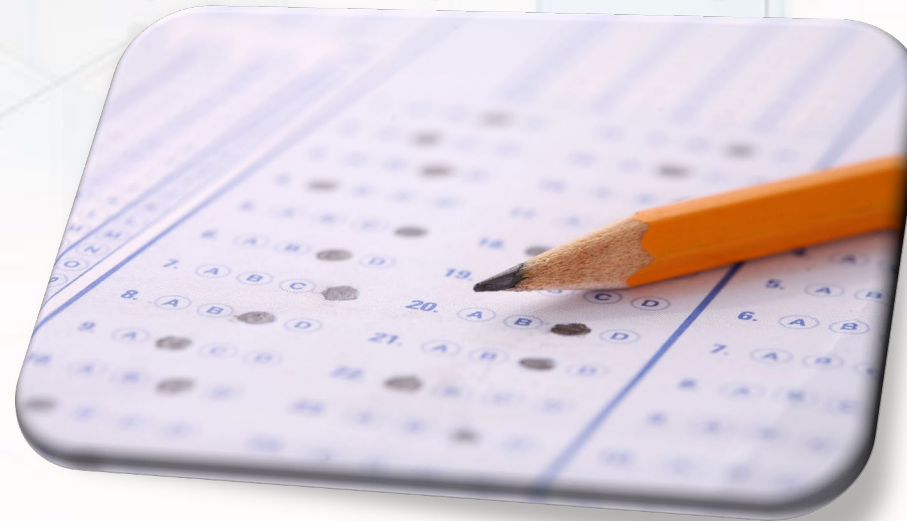
Compliance: Tier 1 Select Agents and Toxins

- RO must:
 - Coordinate and communicate with biosafety and security officials to assess personnel security issues
 - Ensures the entity maintains pre-access and ongoing suitability assessment
 - Ensures the entity maintains an active insider threat awareness training program



Training

- Annual training on all three plans
 - Biosafety/Biocontainment
 - Incident Response
 - Biosecurity
- Agent-specific training
- Risk-based training for visitors
 - All training must be documented
 - Documentation of understanding



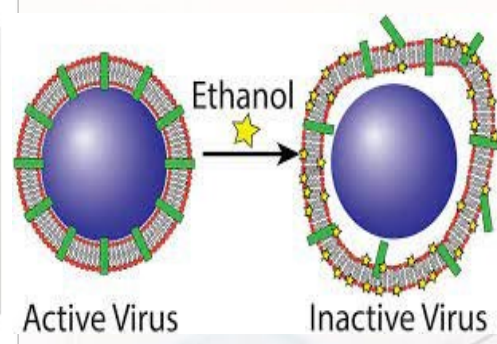
Annual Inspections

- Include the following four sections:
biosafety/biocontainment, security, incident response, and training
- Ensure annual inspections are conducted and documented for each
 - Laboratory
 - Storage area
 - Other i.e., greenhouses, growth chambers,
- Correct and document any discrepancies
- Ensure individuals are provided the HHS OIG Hotline and USDA OIG Hotline



Inactivation Procedures

- RO is responsible for investigating any inactivation failure from
 - Validated inactivation procedure
 - Removal of viable select agent from material
- RO must report the inactivation failures to FSAP



Form Notification

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/using/form1/index.htm
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/using/form2/index.htm
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/using/form3/index.htm Immediate reporting: https://www.selectagents.gov/efsap/using/form3/quickref-in.htm
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 	https://www.selectagents.gov/efsap-tools-form4.html



Records

- Inventory
- Internal Audits
- Record of Access
- Training
- Biosafety, Security, and Incident Response Plans
- Drills/Exercise
- Inactivation



Conclusion

- The Federal Select Agent Program (FSAP) website, www.selectagents.gov, is intended to assist ROs in maintaining compliance.
 - Guidance Documents
 - Policies
 - Frequently Asked Questions (FAQs)
 - eFSAP Resource Center



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
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404-718-2000

APHIS Contact Information
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Animal and Plant Health Inspection Service.

