

Regulatory Guidance for New Responsible Officials (RO)

RO Webinar Series

August 18, 2021



REGULATIONS: Section 9-Responsible Official

- 42 CFR 73.9-Public Health
- 9 CFR 121.9-Animals and Animal Products
- 7 CFR 331.9-Plants and Plant Products



Responsible Official- [9(a)(1)]

- Must be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General



Responsible Official- [9(a)(2)]

- Must be familiar with all the requirements in the regulations
 - This includes security, biosafety, incident response, training, records, etc.



9(a)(2) Inspection Observations- Examples

- The registered entity RO did not conduct/ensure an annual review of inactivation procedures was completed, did not ensure needed updates to the plans and inventory records
- The RO was not familiar with the requirements of the regulations



Responsible Official- [9(a)(3)]

- Must have authority and responsibility to act on behalf of the entity
 - Must be supported by upper management and other key entity leadership personnel to manage a successful select agent program
 - Have knowledge and authority to speak and act on behalf of the entity



9(a)(3) Inspection Observation- Example

- Failure of entity owner/senior leadership to appoint an RO that has been provided authority to act and speak on behalf of the entity resulting in non-compliance with the regulations



Responsible Official- [9(a)(4)]

- Must ensure compliance with the requirements of this part (means 42 CFR Part 73, 9 CFR Part 121, or 7 CFR Part 331 as applicable)



9(a)(4) Inspection Observations- Examples

- Failure to implement procedures and provisions of the biosafety, security, and incident response plans
- Failure to ensure the use of a validated decontamination method (s)
- Failure to adequately train staff on biosafety, security and incident response plans
- Failure to report the release of select agents and toxins (including Tier 1 select agents)
- Failure to maintain current and accurate inventory



Responsible Official- [9(a)(5)]

- 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 to respond in a timely manner to on-site incidents involving select agents and toxins in accordance with the entity's incident response plan



9(a)(5) Inspection Observation- Example

- During interviews, the entity's RO and Alternate Responsible Official (ARO) indicated there were times when both individuals were out of town, leaving neither available to respond in a timely manner to on-site incidents involving select agents



Responsible Official- [9(a)(6)]

- Must ensure that annual inspections are conducted for each registered space where select agents or toxins are stored or used in order to determine compliance with the requirements of the regulation
- Federal Select Agent Program (FSAP) Policy: Inspection must address biosafety, security, incident response and training (*Entity Annual Internal Inspections Policy Statement*)
<https://www.selectagents.gov/regulations/policy/annualinspection.htm>)



9(a)(6) Inspection Observations- Examples

- Annual entity inspections of the registered space not conducted
- Failure to document the results of the inspection
- Deficiencies identified not corrected
- Annual inspection only conducted to evaluate biosafety requirements
- Annual inspection not conducted for all registered spaces



Responsible Official- [9(a)(7)]

- Must ensure that individuals are provided the contact information for HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any biosafety or security concerns related to select agents and toxins



9(a)(7) Inspection Observations- Examples

- No contact information provided to registered staff on HHS Office of Inspector General Hotline or the USDA Office of Inspector General Hotline
- Only one set of OIG information provided



Responsible Official- [9(a)(8)]

- Responsible Official must 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 Responsible Official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately by telephone or email the inactivation or viable agent removal method failure to CDC or APHIS



9(a)(8) Inspection Observations- Examples

- The RO failed to notify the Federal Select Agent Program of an inactivation failure
- The RO did not investigate to determine the reasons for inactivation failures
- RO did not report additional inactivation failures following the movement of material to another non-registered location



Responsible Official- [9(a)(9)]

- Must review and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods
- The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method
- The review must be documented, and training must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol



9(a)(9) Inspection Observations- Examples

- No review and/or documentation of annual review of entity's validated inactivation procedures
- No training provided to staff after procedural changes



Responsible Official- [9(b)]

- An entity may designate one or more individuals to serve as an alternate Responsible Official (ARO), who acts for the Responsible Official in his/her absence
- These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official



9(b) Inspection Observations- Examples

- ARO, while acting for RO, did not have control of the entity's select agent activities in the RO's absence to ensure compliance with the select agent regulations or have authority to act on behalf of the entity
- The ARO was unable to access the current biosafety, security, and incident response plans in the RO's absence or provide required records.



Responsible Official- [9(c)(1) and 9(c)(2)]

- The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail:
 - *Bacillus anthracis*, *Bacillus cereus* Biovar *anthracis*, Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium*, *Burkholderia mallei*, *Burkholderia pseudomallei*, *Francisella tularensis*, Ebola viruses, Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), *Yersinia pestis*, African horse sickness virus, African swine fever virus, Highly pathogenic avian influenza virus, Classical swine fever virus, Foot-and-mouth disease virus, virulent New castle disease virus, Rinderpest virus or Swine vesicular disease virus
- To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within seven calendar days after identification



9(c)(1) and 9(c)(2) Inspection Observations- Examples

- Entity failed to immediately report identification of Botulinum neurotoxin producing species of *Clostridium* from samples, waiting 10 days to notify Federal Select Agent Program by APHIS/CDC Form 4
- The RO failed to submit APHIS/CDC Form 4 to DSAT within 7 days after identifying virulent New castle disease virus
- Entity identified Eastern Equine Encephalitis virus from a mosquito but did not submit an APHIS/CDC Form 4 to report this identification



Responsible Official- [9(d)]

- Must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin

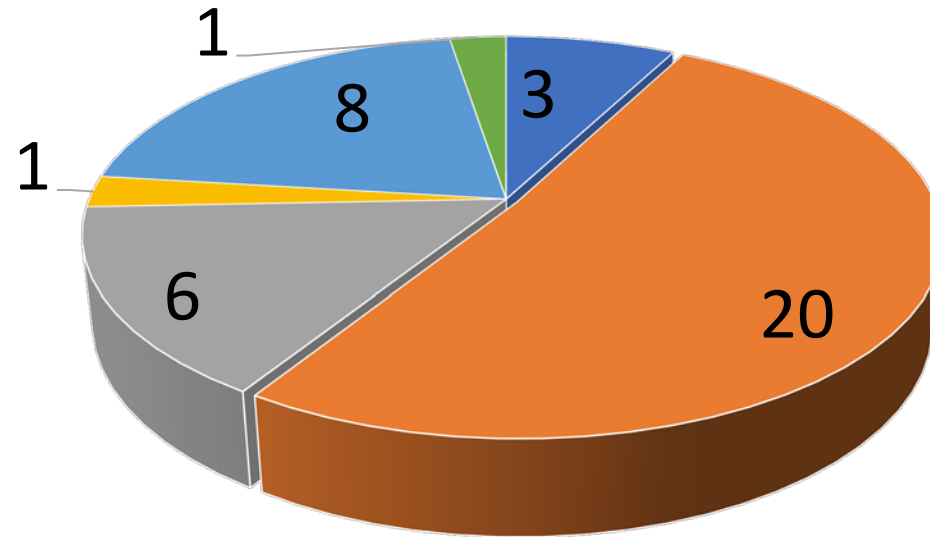


9(d) Inspection Observation- Example

- Entity failed to submit Form 4s for proficiency test



Section 9 Inspection Observations 7/2019 to 5/2020



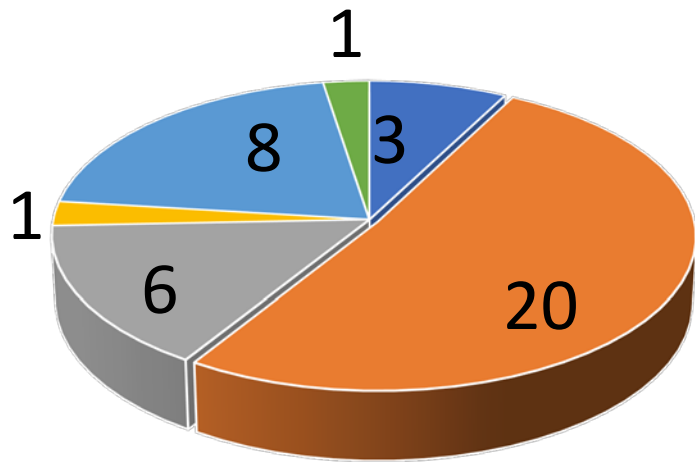
- 20 departures in 9(a)(6)
- 8 departures in 9(a)(9)
- 6 departures in 9(a)(7)

- 3 departures in 9(a)(4)
- 1 departure in 9(a)(8)
- 1 departure in 9(c)(2)

Source: eFSAP Inspection Reports



Section 9: Most Often Cited Observations 7/2019 to 5/2020



- **Section 9(a)(6)**

- Annual inspections not conducted for each registered space where select agents or toxins are stored or used
- Results and/or corrections resulting from annual inspections were not documented

- **Section 9(a)(9)**

- Validated inactivation procedures or viable select agent removal methods
- Not reviewed annually or after any change in Principal Investigator, change in procedure, or failure
- Not documented or training not conducted if there are any changes to the procedure



Summary

- The RO must be familiar with the regulatory requirements and ensure the entity maintains regulatory compliance including:
 - Developing, implementing, reviewing and revising annually the security, biosafety, and incident response plans
 - Conducting site-specific drills or exercises annually to validate the effectiveness of the plans
 - Conducting and documenting annual inspections for each registered storage or laboratory
 - Ensuring the ARO can assume the full authority and undertake all the responsibilities of the RO



Summary

Inactivation

- Conduct investigation to determine reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material
- Report to FSAP if unable to determine the cause of failure or viable select agent removal procedure

Training

- Provide initial and annual refresher training to staff
 - Training must be documented including annual insider threat awareness
- Provide risk-based training on biosafety, security and incident response to individuals escorted to registered space
- Provide contact information for the HHS and USDA OIG Hotlines



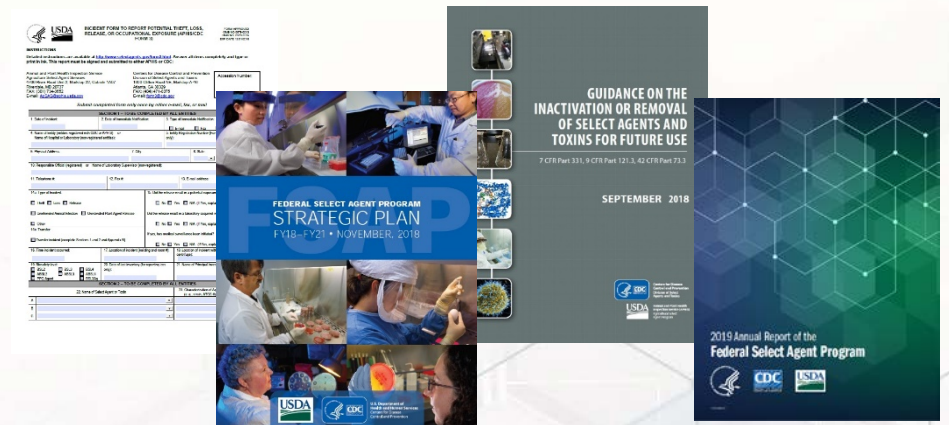
RO Resources

- Federal Select Agent Program staff designated for the entity
- Select Agent (SA) Grams
- Regulatory Interpretations
- RO Webinar Presentations
- eFSAP Resource Center
- FSAP website - www.selectagents.gov



FSAP Website – www.selectagents.gov

- Includes a variety of program information and resources, including:
 - Regulations
 - Frequently asked questions
 - Policies
 - Guidance documents
 - Forms
 - Publications
 - Reports



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301- 851-2070

