


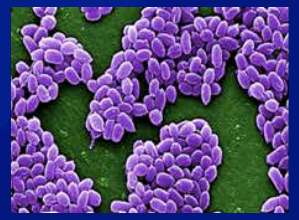

Federal Select Agent Program (FSAP)

RO Workshop
August 15-17, 2018

Entity Internal Inspection

Overview

- Regulatory requirement
- Policy statement
- Conducting internal inspections
- Best practices

Select Agent Regulations

- **Section 9 Responsible Official**
  - 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 Parts 73, 121 and 331.
  - The results of each inspection must be documented and any deficiencies identified during an inspection must be corrected and the corrections documented.

Common Entity Questions

- What if we have not used or stored a select agent or toxin in the registered space in the past year?
- Do the internal inspections have to address every section of the select agent and toxin regulations?

Entity Internal Inspection Policy

- Due the frequency of internal inspection related observations, the FSAP developed a new “Entity Annual Internal Inspections” policy and guidance document.
- Provided to the community for comment 6/12/2018.
- Provided to the community as an official policy 8/9/2018.
- Clarifies what spaces and regulations need to be inspected.

Policy

- **The Responsible Official must develop inspection criteria to demonstrate that an inspection of EACH registered space has been conducted annually.**
  - Because…an entity has the ability to acquire or move select agents/toxins into the space at any time.
- **Document the results of the inspection and the correction of any deficiencies.**
- **Entity will NOT receive a 9(a)(6) departure if the entity does not identify something an inspector does.**

Annual Entity Inspections

- Implementation of the entity's biosafety/biocontainment plan.
- Implementation of the entity's security plan and incident response plan
- Whether each individual with access has received the appropriate training.

Biosafety/Biocontainment Review

- **Review the safeguards in place to protect entity personnel, the public, and the environment**
  - Engineering controls
    - Biological safety cabinets
    - Animal caging systems
    - Downdraft tables
    - Decontamination systems
    - Centrifuge safety cups
  - Administrative controls
    - Review of plans/procedures to ensure they are still valid for work being conducted
    - Personnel vaccination
  - Personal protective equipment (PPE)

Biosafety/Biocontainment Review

- **In performing the inspection, the entity should confirm:**
  - Physical space complies with provisions set forth in biosafety plan.
  - PPE is appropriate for working being conducted and functioning as intended.
  - Containment level is appropriate for work being conducted.
  - Proper safety information is posted.
  - Biosafety procedures are being followed.

Security Compliance

- Review the procedures in place to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.
- Ensure procedures are designed according to a site- specific risk assessment.

Security Review

- **In performing the inspection, the entity should confirm:**
  - Space is compliant with provisions in the security plan.
  - Agent/toxin is secure.
  - Agent/toxin is protected by the correct number of functioning barriers.
  - Security equipment is operating properly.
  - Security procedures are being followed.
  - Agent/toxin inventory is accurate.
  - Agent/toxin only accessed by approved individuals.

Security Review

- **In performing the inspection, the entity should confirm for Tier 1 laboratories:**
  - After hour laboratory access to those only approved by the Responsible Official.
  - Security barriers are sufficient to delay unauthorized access until response force arrives.
  - Intrusion Detection System is operating as intended.
  - Three security barriers limit access to select agents and toxins to only approved individuals.

Security Review

- **In performing the inspection, the entity should confirm when reviewing access records:**
  - All access events are being recorded (no piggy-backing, visitor escorts, etc.).
  - Determine if individuals should be added/removed from registration based on access needs.
  - If non-approved individuals (i.e. cleaning staff, maintenance personnel) entered the space, were they able to access the agent/toxin.

Incident Response Review

- Review the procedures in place to account for the hazards associated with the agents/toxins.
- Plan must outline containment procedures during an incident for all select agents/toxins on the entity's registration.

Incident Response Compliance

- **In performing the inspection, the entity should confirm:**
  - Plan is coordinated with entity-wide plans.
  - Plan is kept in the workplace.
  - Plan has an effective communication strategy for local responders.
  - Entity training has occurred with first responders.
  - Appropriate PPE is available and functional.

Training

- Ensure that each individual with access approval has received training appropriate to the needs of the individual
- Ensure that each person not approved for access (i.e. visitors) have received training based on the risks associated with accessing areas where select agents are used and/or stored.

Other Areas for Consideration

- **The entity may utilize checklists found on www.selectagents.gov.**
- **Ensure compliance with other parts of the regulations:**
  - Establish a schedule for re-certification of laboratory equipment (e.g., BSCs, autoclaves, HEPA filters).
  - Conduct an annual inventory check.
    - May be all inclusive or a spot check
  - Review all plans and referenced SOPs annually.
  - For entities performing a validated inactivation procedure for removal of viable select agent, review procedures, validation data, and certifications.

Discussion

www.selectagents.gov

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APHIS: AgSAS@aphis.usda.gov or
301-851-3300 option 3 (voice only)