Federal Select Agent Program (FSAP)

Federal Select Agent Program
Entity Internal Inspection
April, 2019
Overview

- Regulatory requirement
- Revised policy statement
- Conducting internal inspections
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 the requirements of this part.
  - The results of each inspection must be documented and any deficiencies identified during an inspection must be corrected and the corrections documented.
Revised Policy

- Issued on March 22, 2019.
- Replaced the policy dated August 9, 2018.
- The revised policy clarified that the annual inspection must include:
  - Biosafety section
  - Security section
  - Incident response section
  - Training section
Responsible Official Responsibilities

- 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

- Biosafety/biocontainment plan is effectively implemented for that space.
- Security plan is effectively implemented for that space.
- Incident response plan is effectively implemented based on risk assessment.
- Each individual with access approval from the HHS Secretary or Administrator has received the appropriate training.
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 work being conducted and functioning as intended.
  - Containment level is appropriate for work being conducted.
  - Proper safety information is posted.
  - Biosafety procedures are being followed.
  - Any planned exercise was conducted and an after action report (AAR) was developed.
Security Review

- 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.
- Review IT security – for regular maintenance and upgrades.
- Any planned exercise was conducted and an after action report (AAR) was developed.
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 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.
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.
- Any planned exercise was conducted and an after action report (AAR) was developed.
In performing the inspection, the entity should review of employee training records (to know that employees entering the registered space are trained prior to entry).
Best Practices

- May utilize checklists. Checklists are found on [www.selectagents.gov](http://www.selectagents.gov).
- May utilize a written certification statement from the Responsible Official verifying that an annual entity internal inspection had occurred and incorporated the training, security, biosafety/containment and incident response provisions of the select agent regulations.
- Any deficiencies/departures from regulations and corrections needs to be noted either on the checklists or certification statement.
Discussion

www.selectagents.gov

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