



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.**

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 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.**

Incident Response Review

- ❑ **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.

Training Review

- ❑ 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).

Annual Internal Inspection Documentation

- ❑ May utilize checklists. Checklists are found on 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

CDC: Irsat@cdc.gov or 404-718-2000

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

