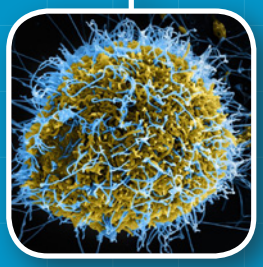

ANNUAL INSPECTION GUIDANCE

AUGUST 2018

Centers for Disease Control and Prevention
Division of Select Agents and Toxins

Animal and Plant Health Inspection Service (APHIS)
Division of Agricultural Select Agents and Toxins

Contents

Change/Highlight Section

Revisions: This is a living document subject to ongoing improvement. Feedback or suggestions for improvement from entities registered with the Federal Select Agent Program, as well as from the general public, are welcome. Submit comments directly to the Federal Select Agent Program at:
DSAT: LRSAT@cdc.gov
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August 2018 - Initial posting

Introduction

This document is intended to provide guidance and assist entities regarding the regulatory requirement that the Responsible Official (RO) ensure that an annual inspection is conducted for each registered space where select agents or toxins are stored or used. See sections 7 C.F.R. §331.9(a)(6), 9 C.F.R. §121.9(a)(6), and 42 C.F.R. §73.9(a)(6)).

Establishing an internal annual inspection program provides a means for the RO to monitor compliance with the select agent regulations and identify deviations from acceptable laboratory safety, containment, or security practices. This action can be separate from an overall periodic reconciliation of the entire select agent and toxin inventory.

Annual Inspection

It is the policy of the Federal Select Agent Program (FSAP) that an annual inspection should address all of the following:

1. The implementation of the entity's biosafety/containment plan.
2. The implementation of the entity's security plan.
3. The entity's incident response plan (e.g. is the appropriate emergency equipment available and functional).
4. Whether each individual with access approval from the HHS Secretary or Administrator has received the appropriate annual training.

The RO may utilize the FSAP checklists to assist with documenting the annual inspection.

Biosafety/Biocontainment Compliance

An annual inspection should include a review of the safeguards in place to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to:

- Engineering controls such as containment equipment including, but not limited to:
    - Biological safety cabinets

    - Animal caging systems
    - Downdraft tables
    - Centrifuge safety containers
    - Decontamination systems (e.g., autoclave, effluent decontamination system)
- Administrative controls contained in the biosafety plan, such as an occupational health program, a post exposure management plan, and any other controls set up by the entity.
- Respirators (i.e., filters and batteries) that are being maintained as outlined in the entity's respiratory protection program.
- For BSL-4 laboratories, suits used in the laboratories should be inspected.

In performing the annual inspection, the RO should address whether:

- The physical space complies with all the provisions of the entity biosafety/biocontainment plan.
- The PPE is appropriate for the work being conducted, is functioning properly, and is being used as described in the entity biosafety plans and procedures.
- The containment level is appropriate for the work being conducted.
- The proper biosafety information is posted.
- The correct biosafety/biocontainment procedures are being followed.

Security Compliance

An annual inspection should include a review of the entity's security plan and procedures in place to safeguard select agents or toxins against unauthorized access, theft, loss, or release and ensure that the security plan and procedures are designed according to a site-specific risk assessment, providing graded protection.

In performing the annual inspection, the entity should address whether:

- Registered space is compliant with all the provisions of the entity security plan.
- Select agents and toxins are protected by the correct number of functioning security barriers.
- Security equipment is operating properly.
- Security procedures are being followed.
- The select agent and toxin inventory is accurate.
- Select agents and toxins are accessed only by approved individuals.
- All access events are being recorded (e.g., no piggy-backing, escorts of visitors).
- Individuals need to be added to or removed from entity registration based on their need to have access to select agents and toxins.
- Non-approved individuals that entered the registered laboratory were appropriately escorted.

Incident Response Compliance

An annual inspection should include a review of the incident response plan and procedures in place to address hazards associated with the select agents and toxins.

In performing the annual inspection, the entity should address whether:

- The incident response plan is coordinated with any entity-wide plans.
- The incident response plan is kept is available to employees for review.
- The incident response plan has an effective communication strategy for local first responders.
- The entity has participated in joint training with first responders.
- The appropriate emergency equipment (e.g., eyewash, drench shower, spill kits, etc.) is available and functional.

Other Areas for Consideration for Annual Review

The RO may utilize the internal inspections to ensure compliance with other parts of the regulations such as to:

- Verify that individuals have received annual training on biocontainment, biosafety, security (including security awareness), and incident response.
- Establish a schedule for recertification and service of laboratory equipment (e.g., biosafety cabinets, autoclaves, HEPA filters) to prevent potential biocontainment lapses.
- Conduct an annual inventory check, which may be all-inclusion or spot checks of the inventory. The inventory check should include a review of the entity's inventory recordkeeping procedures to ensure that individuals with access to inventories follow appropriate procedures for access and recording changes to the inventory.
- Review the biosafety/biocontainment, security, and incident response plans annually to ensure that any changes in facility operations are appropriately captured.
- For entities performing a validated inactivation procedure for removal of viable select agent, review procedures, validation data and certificates.