


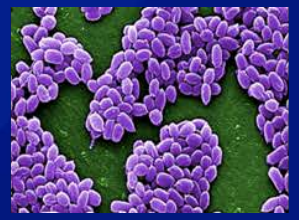

Federal Select Agent Program (FSAP)

RO Workshop
August 15-17, 2018

USDA

CDC

Inspections

Planning and Logistics

Overview

- Types of inspections
- Inspection preparation
  - FSAP
  - Entity
- Inspection logistics
- Availability of entity personnel
- Inspection reports and follow-up responses

Inspection Preparation

- **Types of Inspections**
  - Renewal: Full review of space and records
  - Verification: Full review of space and past corrective actions; limited records review
  - New Space: Focused review of new space and updated plans/procedures
  - Compliance: Focused review of compliance issues and resulting corrective actions
- **Announced versus Unannounced**
  - Announced inspections are coordinated with entity officials ahead of the inspection including Notification of Inspection. These can be coordinated months in advance or on short notice depending on the inspection type.
  - Unannounced inspections are as stated. Entity personnel could receive notification the night before, morning or upon arrival depending on the organization demands of the inspection.

Inspection Preparation

- **FSAP Preparation: What we do before you see us**
  - Review of entity registration (APHIS/CDC Form 1) and APHIS/CDC Forms 2-4
  - Review of plans submitted ahead of inspections
  - Review of previous inspection reports and stated corrective actions
  - Review of past compliance history, if applicable
  - Review of NIH funding sources and relevant publications for more detailed view of PI's work objectives, if applicable
  - NEW*- Review of recent information uploaded into eFSAP by the entity

Inspection Preparation

- **Entity Preparation**
  - Coordination of staff with expertise in select agent operations; these are persons that can provide operational details to inspectors when requested
    - Laboratory staff
    - Safety staff
    - Security personnel
    - Facility personnel
    - Occupation health personnel, if applicable
  - Ensure availability of select agent records
    - Can be electronic or paper
  - Ensure entry requirements are up to date in the APHIS/CDC Form 1 to facilitate inspector entry to the site and laboratory
  - Ensure contact information for Responsible Officials and Alternate Responsible Officials is up to date on the registration

Inspection Logistics

- **Inspections can last from 1 day to 2 weeks depending on the scope and scale of the inspection**
  - Inspection agendas are fluid and can be changed depending on the availability of entity staff or entity operational considerations (work occurring, planned decontaminations, etc.)
  - Inspections typically follow the same logistical schedule regardless of duration, with laboratory tours being first and records reviews toward the end
  - *Inspections should start after the entity's typical start time
  - *Inspections should end before the entity's typical close of business
  - Be sure to inform the inspection team of time limitations for responsible staff at the beginning of the inspection so the agenda can be adjusted accordingly

Inspection Logistics

In General:

- **Part 1: The walking and talking part of the inspection**
  - Laboratory/storage area inspections, including inventory verification
  - Tour HVAC and supporting facilities inspection
  - Security and shipping reviews, as applicable
- **Part 2: The reviewing and talking part of the inspection**
  - Record review and personnel interviews
  - Inspectors have made efforts to speak with staff as available during part 1 of the inspection to limit time demands on entity staff for interview purposes
  - Inspectors can and should interview support staff as needed to answer remaining questions from the physical inspection or records review

Inspection Logistics

Points of Emphasis for Verification Inspections

- Inspection of the laboratory or other registered areas
- Tour of laboratory-related facilities
- Review of security features
- Resolution of previous corrective actions
- Verification inspections are typically shorter and involve less document review

Personnel Availability

- It is in the RO's best interest to be part of the inspection in-briefing and readily available throughout the inspection, if possible.
- ARO involvement is largely determined by the entity but it is also in their best interest to be involved with the inspection for their own knowledge.
- Inspectors request the most knowledgeable staff be present for each specific aspect of the inspection. If this is not possible the next-most knowledgeable person should attend, and so on.
- Entity staff are not required to be with inspectors the entire inspection, except for required escort purposes, but the entity should ensure the availability of knowledgeable persons to facilitate the inspection process.

Inspection Follow-up

- **FSAP issues the inspection report within 30 business days of the conclusion of the inspection**
- **Immediate action or compliance action letters are issued within 10 business days of the inspection**
- **New*- Inspection reports are uploaded into eFSAP for entity viewing**
- **New*- Entities have 30 business days to upload their responses into eFSAP for review**
- **Disputes of inspection observations sent within 14 business days to the FSAP leadership through LRSAT@cdc.gov/AgSAS@aphis.usda.gov**
  - These are handled from the top down for resolution of the dispute(s)
- **Questions or concerns regarding the report or requests can be sent to the lead inspector at any time to assist the entity with the development of their corrective actions**

Inspection Follow-up

- More changes to come as the eFSAP inspection portal development and roll-out continues
- Please reach out to your POC, lead inspector, or LRSAT@cdc.gov/AgSAS@aphis.usda.gov if you have any questions, concerns or problems with the inspection report and response process

Ask an Inspector/POC/File Manager/Forms Personnel

- FSAP staff will be circulating among the tables to answer questions about the program.

Discussion

www.selectagents.gov

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

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