Federal Select Agent Program (FSAP)

Preparing for a Virtual Inspection
FSAP Operations
Responsible Official Webinar
June 24, 2020

Preparing For A Virtual Inspection

Virtual Inspection: Purpose

Continuity of Inspection operations

Verify the entity's ability to work safely and securely

Ensure compliance with the regulations

Virtual Inspections

❑ **No travel for inspections until further notice**

  ▪ Exceptions: agricultural/public health threat

❑ **Limited Scope**

  ▪ What can be verified through record review and/or confirmed via interviews

Section 17 (c): Records

- The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section.

- The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs.

- All records created under this part must be maintained for 3 years.

Section 18: Inspections

(a) Without prior notification, **Federal Select Agent Program (FSAP) shall be allowed to inspect** any site at which activities regulated by this part are conducted and shall be allowed to inspect **and copy any records** relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, FSAP may inspect and evaluate the premises and records to ensure compliance with this part.

Typical Virtual Inspection Time Line

4-6 Weeks Out
- Scheduling

3-4 Weeks Out
- Document Upload
- Meeting Coordination

Week Of
- Inspection

Post Inspection
- Findings released within 30 business days
- Due dates for responses stipulated in eFSAP

Virtual Inspection Time Line

- ❑ **Scheduling**
    - ▪ Representatives from FSAP will contact the Responsible Official (RO) to determine the availability of entity personnel.
    - ▪ If available, FSAP schedulers will work with the RO to identify the best week for a virtual inspection.
- ❑ **Contact with Lead Inspector**
    - ▪ Lead inspector will contact the entity 2-4 weeks, whenever possible, in advance of the virtual inspection week with the document upload request list.
    - ▪ Lead inspector will work with the entity to establish the inspection agenda, identify personnel that may be interviewed, and assist with any document upload issues.

Document Upload

- Document request list: required records that will assist the inspection team in determining compliance with the select agent regulations.

- **Work with the lead inspector** if the scale of documents requested are not practical or the burden surpasses the resources available.

Documents and Their Sections of the Regulation

- Select agent plans: Sections 11, 12, and 14
- RO inspections: Section 9
- Training records: Section 15
- Access records: Section 17
- Tier 1 associated records: Sections 11, 12, 14, 15 and 17
- Facility and certification records: Section 17
- Inactivation records and validation information: Section 17
- Annual drills and exercises : Sections 11, 12, and 14
- Inventory record and usage logs: Section 17

Additional Record Requests

- ❑ Help us understand laboratory activity or determine compliance with the requirements.

- ❑ These records may be requested to assist the inspection team in understanding entity operations.

- ❑ Examples include:

  - ▪ Laboratory floor plans

  - ▪ Incident reports involving select agents and toxins

  - ▪ Institutional Biosafety Committee (IBC) and Institutional Animal Care and Use Committees (IACUC) meeting minutes involving work objectives with select agents and toxins

Inspection Agenda

- Opening meeting
- Floorplan overview
- Daily touchpoints
- Interviews
- Close-Out meeting

Virtual Inspections
Allow Inspectors to:

❑ Review entity records

  ▪ Biosafety cabinet certifications, HEPA filter certifications, access records, training

❑ Review entity biosafety, security, and incident response plans

❑ Interview pertinent staff

❑ Identify compliance issues

Flexibility

❑ Lead inspector works with entity to develop an agenda and identify times for virtual meetings
- Coordination of time with the entity
- In-brief, interviews, daily out-briefs
- Skype, Zoom, Telephone, Microsoft Teams

❑ Inspections will not routinely require a virtual tour of the registered space.

❑ Review and discussion of laboratory operations with reference to a floor plan is helpful.

Unchanged Inspection Processes

❑ **Issuance of inspection reports**

❑ **Entity's response to inspection report**

Moving Forward/Thinking Ahead…

Once travel safely resumes – hybrid inspections will be considered

- Through 2020, FSAP will prioritize onsite inspections by type, complexity, risk level, compliance issues, etc.

- Renewals <u>and</u> verifications

- **First priority** will be renewals and new entity inspections

- Some verification inspections will be conducted on-site while those of lower risk will be virtual

- FSAP will review and may update Operations/Inspection policies

Moving Forward/Thinking Ahead…

- May reduce inspectors' time on site

- Less disruption for entity (inspectors potentially onsite a fewer number of days)

- Recommend preparing documents for uploading into eFSAP – naming convention, work with file manager/SAPO and LI
  - Think Ahead

- File managers/SAPOs and lead inspectors can help!

Discussion

www.selectagents.gov

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APHIS: AgSAS@usda.gov or

301-851-3300 option 3 (voice only)