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 and 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)