Remote Inspections: Best Practices

2021 Federal Select Agent Program Responsible Official Webinar Series

July 14, 2021
A new paradigm
History of Remote Inspections: Purpose

- Continuity of inspection operations
- Verify the entity’s ability to work safely and securely
- Ensure compliance with the regulations
History: Remote Inspections Become Reality

• No travel for inspections until further notice
  • Exceptions: agricultural/public health threat

• Limited in scope
  • What could be verified through plan and record reviews
  • What could be confirmed via interviews
History: Remote Inspection Timeline

- **4 weeks out**
  - Scheduling

- **3-4 weeks out**
  - Document repository
  - Logistics coordination

- **Week of**
  - Inspection

- **Post Inspection**
  - NO CHANGE
History: Inspection Scheduling

- Availability of entity personnel
- Identify the best week for remote inspection
History: Lead Inspector Coordination

- Lead Inspector coordination with the entity began
  - 3-4 weeks prior to inspection
  - Document Request
  - Agenda development
  - Interviews
  - Document uploads
History: Document Upload (eFSAP)

- Document request list: required records for compliance determination with the select agent regulations
- RO worked with the Lead Inspector to overcome document scale burdens
- Reduced document upload burden
Examples of Requested Documents I

• Plans
  • Floor plans
  • Biosafety, security, and incident response
  • Occupational health program medical surveillance, chemical hygiene and allergy prevention

• Entity Annual Internal Inspections
Examples of Requested Documents II

• Training, access and Tier 1 records
• Facility and certification records
• Inactivation records and validation information
• Annual drills and exercises
• Inventory records
Why all the documents?

• Yes, we needed them!

• Understanding laboratory activities and operations

• Determine compliance with the requirements

• Document “Review Complete”
Technology Limitations
One Year Later:
Remote inspections continue and…
The **hybrid approach** will be a combination of remote review and on-site inspection.
Preparing for the Remote Aspect ...

- Communicate with your Lead Inspector
- Do a dry run with the platform
  - Zoom, Teams
  - Internet capabilities vary
- Ask questions – hybrids are evolving
- ROs will receive the meeting invites
Requested Documents

- Use the inspection page for uploading documents
- Refer to the document request list
  - Split large documents into sections if necessary
- Not sure about something? Ask your Lead Inspector
Information and Records Requested for Hybrid or Remote Select Agent Renewal Inspection

Please upload the records indicated into eFSAP over the two weeks prior to the start of your inspection.

Electronic records can be files, documents, scanned images, photographs, or databases converted into a PDF, etc. Please let your lead inspector know if you encounter any issues uploading these documents, as you are unable to convert a file into an electronic document, or do not have access to an electronic copy.

Entry Plans
- Major plans of registerable space
- Current Security, Safety, and Incident Response plans, including any referenced SOPs and documents used to meet the requirements of section 11.12.1 and 1.10
- Evidence of annual plan review and documentation of all revisions
- Occupational Health Program (medical surveillance plan): List of personnel enrolled in occupational health program and enrollment dates
- List of personnel enrolled in respiratory protection program
- Respiratory protection - fit testing training records
- For entities registered to possess select toxins - Chemical Hygiene Plan, specific to select toxins used, risk assessment/health analysis, if the work being performed
- Site specific risk assessment for security and incidents

Access Records
- A selection of electronic and manual access records (including visitor entries) for all points of access to registerable space - “The Li will work with you prior to inspection to determine the extent of the record attack that will be investigated”
- A list of personnel with access to areas containing select agents, electronic access list, key distribution list

Training
- Records of select agent specific training that covers security, biosecurity, and incident response for FSAP-approved individuals as well as laboratory workers, as required under section 11.10 including:
  - Training outlines:
    - Refresher training annually
    - Curriculum and significant plan updates
    - Visitor training curriculum
    - Quarterly training outcomes
  - Metrics used to verify training was understood:
    - Quiz results (if applicable)
  - The Li will work with you prior to inspection to determine the extent of the records which will be requested

Facility Records
- Annual Biological Safety Cabinet certification records
- Annual HEPA filter certification records (ex. exhaust air, ventilated caging systems, BSL2, etc.)
- Annual BSL 3A/3B-I facility re-verification records
- Additional BSL 3A/3B-I facility re-verification records
- Annual verification for BSL-3 facilities
- Effluent Decontamination system validation

Inspection Records
- Annual internal inspection records ensuring compliance with the safety, security, incident response, and training requirements of the records
- Inactivation certificates
- Annual IR review of validated inactivation procedures and any investigations performed following inactivation failures
- Internal incident reports related to select agent/FO program

Li will work with you prior to inspection to determine the number of requested records in the categories below.

Inventory Records
- Inventory records for all select agents/toxins possessed to meet the requirements of section 17(a)(1) and 17(a)(3)
- Accounting of any exposed animals/plant/archetypes used to meet the requirements of 17(a)(2)

Other
- Written explanation of discrepancies noted in the required records
- BAC applications/interim approvals
- LAUC applications/interim approvals
- Personnel quarantine policy records
- Allergy Prevention program (if animal work is being conducted)
Uploading Documents

- Entity home landing page
Uploading Documents

- Scroll down
- Don’t upload inspection documents here
Uploading Documents

• Select “Inspections” to move to your list of inspections page
Uploading Documents

• Select “Details” for the upcoming inspection to move to the inspection landing page

• Use the inspection number as a reference
Uploading Documents

- From the inspection landing page, “upload” documents
- Files tagged to inspection
Uploading 101

• Keep file names short and descriptive

• Remove punctuation from document names
  • Periods, hashtags, commas, etc.
Uploading 101 (continued)

• Combine like documents into 1 PDF
  • Validation certificates, quizzes, training, BSC certificates, etc.

• File size – **20 MB or smaller recommended**

• Ask your File Manager/Point of Contact or Lead Inspector for help

• You may be asked for additional documents during inspection

• Contact IT if you still have issues uploading documents
  • eFSAPSupport@cdc.gov
Do

- Plan for uploading documents kept in the laboratory
  - Documents may be reviewed on site
- Be available during the inspection
  - Don’t need to be always present
- Coordination for interviews and touchpoints
Do

- Include referenced SOP’s and Appendices with plans
  - Review annually with plans
- Be patient when preparing for a hybrid inspection
  - The hybrid is a work in progress
  - Lead Inspector, Point of Contact and File Manager are here to help
Do

• Include documentation for your annual inspections
  • Document, document, document
  • Any deficiencies found, when and how they were addressed

• Documentation for your annual reverification of the BSL-3/ABSL-3 facilities
  • Initial verification and reverification after major changes
  • 1-11 requirements for minimum annual facility verification items
Best Practices

- Constant communication
  - Have a telephone backup plan for meetings

- We will attempt to have same team on both phases

- Use a platform that works for the inspection (MS Teams or Zoom)

- Strive to be flexible and collaborative
• Most entities experienced a remote inspection that was rated as good or improved from the regular inspection (pre-COVID)

• Entities were satisfied with their Opening and Closeout meetings

• Overall inspection experience tipped to the improved side
Wrapping Things Up

• Remote and Hybrid Inspections are here to stay

• Fine tuning inspection methods – Flexibility and consideration

• Remote document reviews
  • Facilitate a more focused approach to onsite inspection
  • May reduce the time inspectors spend onsite (fewer days)

• FSAP plans for the future of inspection – Topic of another webinar
Some Parting Recommendations

• If your PPE for working in the lab has changed due to COVID, please update your biosafety plan to reflect the changes

• Review your entity abstracts on your Form 1

• Update your Section 5c – If your inspector entrance requirements have changed
CDC Contact Information
Division of Select Agents and Toxins
lrsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural Select Agents and Toxins
DASAT@usda.gov
301- 851-2070

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