Remote Inspections: Best Practices

2021 Federal Select Agent Program Responsible Official Webinar Series

July 14, 2021

A new paradigm

History

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
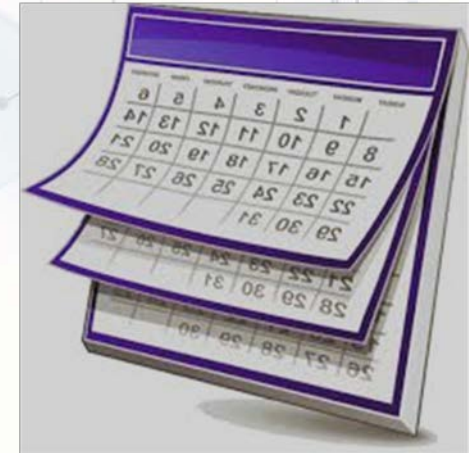 - What could be confirmed via interviews

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

Best Practices

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

How to prepare for a Zoom meeting

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

Example Document Request List

Information and Records Request 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 (LI) know if you encounter any issues uploading these documents, are unable to convert a file into an electronic document, or do not have access to an electronic copy.

Entity plans
- Floor plans of registered space
- Current Biosafety, Security, and Incident Response plans, including any referenced SOP's and documents used to meet the requirements of section 11, 12, and 14
  - Evidence of annual plan review and documentation of drills/exercises
- 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 assessments/hazard analyses of the work being performed
- Site specific risk assessment for security and incidents

Access Records
- A selection of electronic and/or manual access records (including visitor entries) for all points of access to registered space - *The LI will work with you prior to inspection to determine the extent of the record which will be requested
- A list of personnel with access to areas containing select agents/toxins (e.g. card access roster, key distribution list)

Training
- Records of select agent specific training that covers security, biosafety, and incident response for FSAP-approved individuals as well as laboratory visitors (as required under section 15) including
  - Training curriculums
    - Refresher training annually
    - Curriculum after significant plan updates
    - Visitor training curriculum
    - Initial training curriculum
  - Means used to verify training was understood
    - Quizzes/tests (if applicable) - *The LI will work with you prior to inspection to determine the extent of the record which will be requested
    - Sign in sheets
  - Record of annual insider threat awareness briefing for all FSAP approved individuals at Tier 1 entities

Facility Records
- Annual Biological Safety Cabinet certification records
- Annual HEPA filter certification records (lab exhaust air, ventilated caging systems, Biobubble, etc.)
- Annual BSL-3/ABSL-3 facility re-verification records (https://www.selectagents.gov/regBSL3ABSL3policy.html)
- Annual verification for BSL3-Ag facilities (https://www.selectagents.gov/resources/Checklist-BSL3ag.pdf)
- 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 RO review of validated inactivation procedures and any investigations performed following inactivation failures
- Internal incident reports related to select agent/toxin 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/plants/arthropods used to meet the requirements of 17(a)(2)

Other
- Written explanation of discrepancies noted in the required records
- IBC applications/minutes/approvals
- IACUC applications/minutes/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
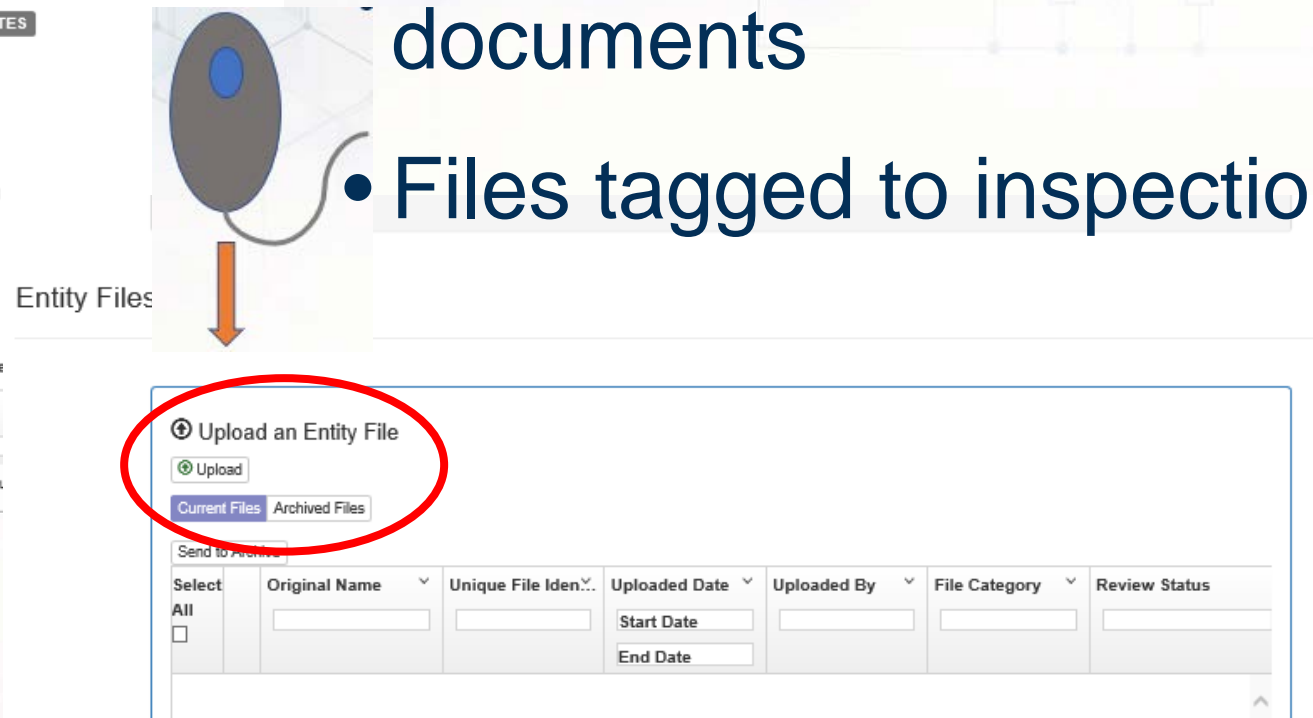
- Select "Details" for the upcoming inspection to move to the inspection landing page
  - Use the inspection number as a reference

Uploading Documents

- From the inspection landing page, "upload" documents
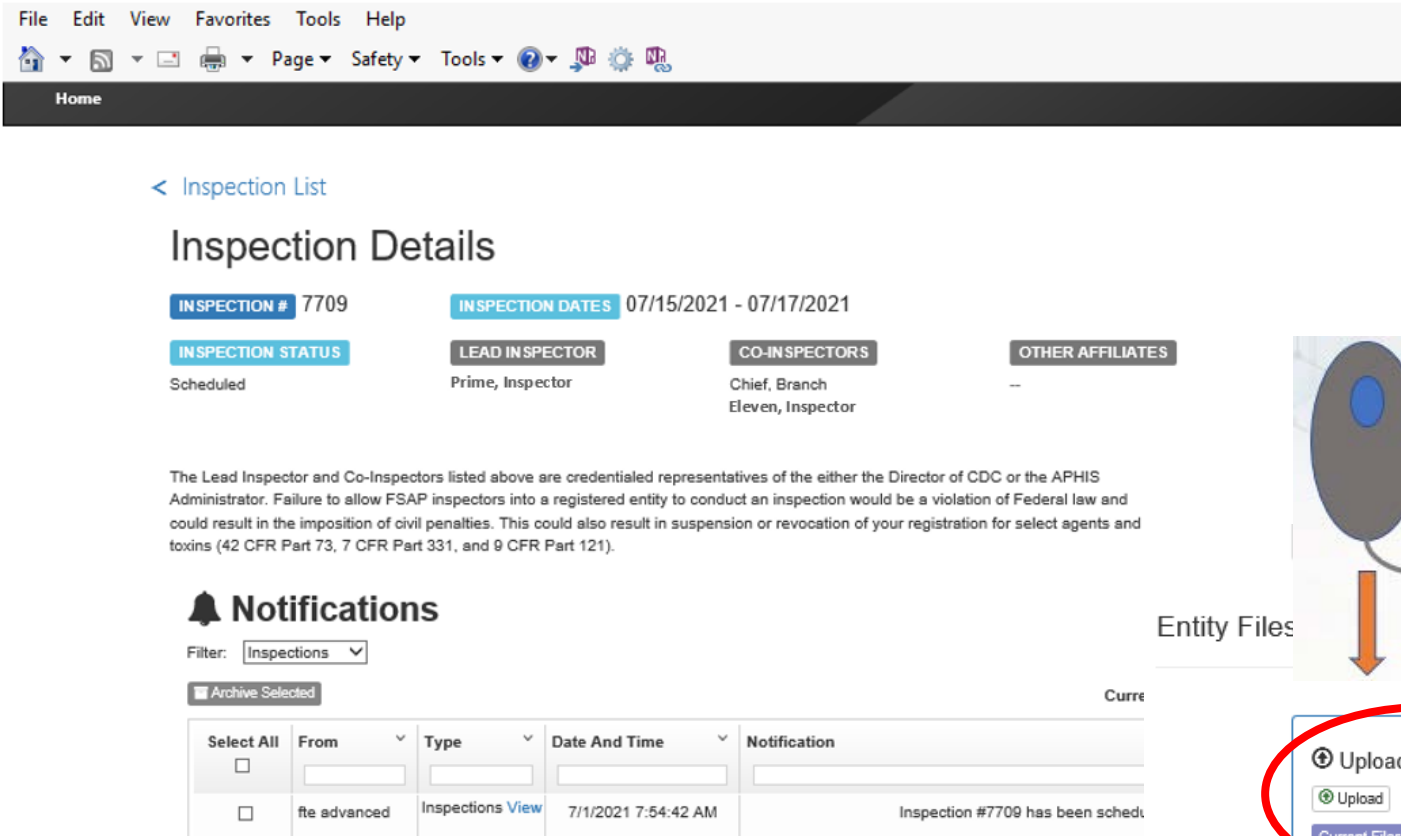
- Files tagged to inspection

Uploading 101

- Keep file names short and descriptive

- Remove punctuation from document names
  - Periods, hashtags, commas, etc.

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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 <u>minimum</u> annual facility verification items
  - https://www.selectagents.gov/regulations/policy/BSL3ABSL3.htm

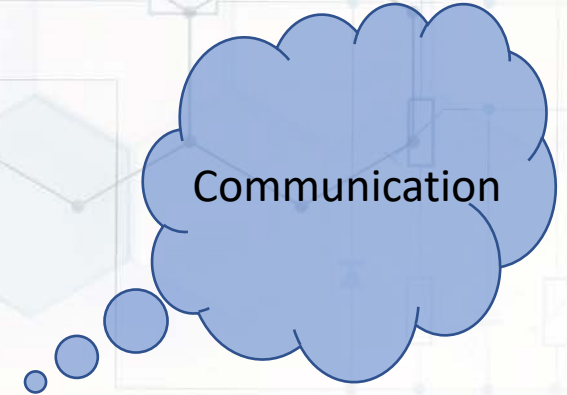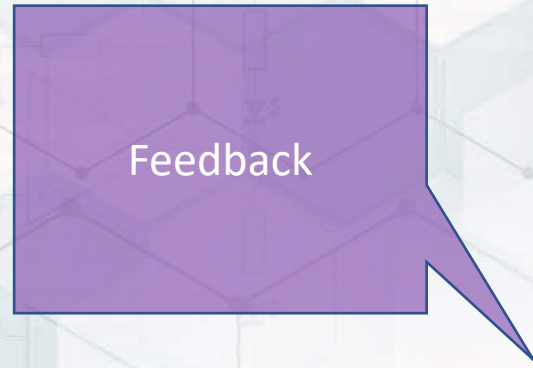# Best Practices

- 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

Looking at Post-Remote Inspection Survey Data

Surveys

Feedback

Ideas

Communication

- 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

www.selectagents.gov

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