

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

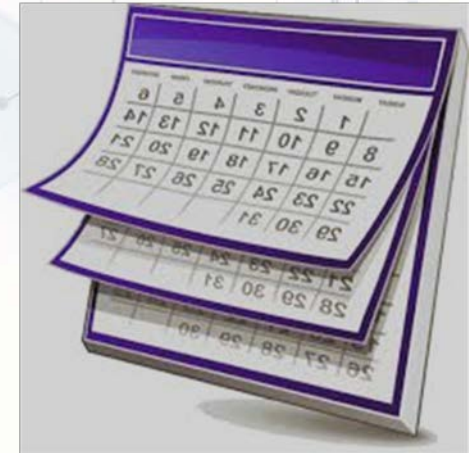


History: Remote Inspection Timeline



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

File Edit View Favorites Tools Help


 Federal Select Agent Program Information System

responsible.official4@dev.odcipsas.com
(responsible.official4)
[Sign Out](#)

Home Form 1 Form 2 Form 3 Form 4 Inspections Admin Center

eFSAP Test Entity

On Contingency Registration

LEAD AGENCY: CDC REGISTRATION STATUS: Approved REGISTRATION EXPIRES: 03/23/2022 

Facility Address: 12345 N. Facility Circle, GA 00300 Registration #: 20200401-103033

Responsible Official Name: Alexander Bell Responsible Official Business #: 444-121-1236 Responsible Official Emergency #: 444-121-1236

Primary FSAP POC: Janet Name Primary POC Office #: 012-345-6789 Primary POC Mobile #: 012-345-6789

Secondary FSAP POC: Manny Name Secondary POC Office #: 123-456-7890 Secondary POC Mobile #: 999-124-7891

Notifications

Filter:

Archive Selected Current Archived Flagged

Select All	From	Type	Date And Time	Notification	
<input type="checkbox"/>					
<input type="checkbox"/>	eFSAP system	Form1 View	6/30/2021 1:00:09 PM	The following person(s) have no role assigned in Form 1 Section 4, please assign them a role: James Watson	Flag
<input type="checkbox"/>	eFSAP system	Form1 View	6/30/2021 5:30:09 AM	The following personnel have no supervising PIs assigned on Form 1 section 4: Murphy Once, Murphy Thrice. Please assign them a supervising PI.	Flag

- Entity home landing page



Uploading Documents

- Scroll down
- Don't upload inspection documents here

The screenshot displays a web application interface. At the top, there is a table with three rows of data. Below the table is a pagination control showing '1 / 10' and '25 items per page'. Below the pagination is a section titled 'Upload an Entity File' with an 'Upload' button. Below the 'Upload' button are two tabs: 'Current Files' and 'Archived Files'. Below the tabs is a 'Send Back to Current' button and a table with columns: 'Select', 'Original Name', 'Unique File Identifier...', 'Uploaded Date', 'Uploaded By', 'File Category', and 'Review Status'. The 'Select' column has a radio button and the text 'All'. An orange arrow points from a callout bubble to the 'Upload' button.

	Original Name	Unique File Identifier...	Uploaded Date	Uploaded By	File Category	Review Status
<input type="checkbox"/>	Section 1 - Change Ent...	00332008	testing read o...	09/09/2020		Pending
<input type="checkbox"/>	Section 6 - Modify Roo...	00332009	test	09/09/2020	09/18/2020	Approved
<input type="checkbox"/>	Section 7AC - Modify...	00331976	update work o...	09/03/2020	09/03/2020	Approved

1 - 25 of 230 items

Upload an Entity File

Upload

Current Files Archived Files

Send Back to Current

Select	Original Name	Unique File Identifier...	Uploaded Date	Uploaded By	File Category	Review Status
All						



Uploading Documents

File Edit View Favorites Tools Help

USDA Federal Select Agent Program Information System

responsible.official4@dev.odcipsas.com (responsible official4) Sign Out

Home Form 1 Form 2 Form 3 Form 4 **Inspections** Admin Center

eFSAP Test Entity

On Contingency Registration

LEAD AGENCY: CDC REGISTRATION STATUS: Approved REGISTRATION EXPIRES: 03/23/2022

Facility Address: 12345 N. Facility Circle, GA 00300 Registration #: 20200401-103033

Responsible Official Name: Alexander Bell Responsible Official Business #: 444-121-1238 Responsible Official Emergency #: 444-121-1238

Primary FSAP POC: Janet Name Primary POC Office #: 012-345-8789 Primary POC Mobile #: 012-345-8789

Secondary FSAP POC: Manny Name Secondary POC Office #: 123-456-7890 Secondary POC Mobile #: 999-124-7891

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Filter: All

Archive Selected Current Archived Flagged

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- Select “Inspections” to move to your list of inspections page



Uploading Documents

The screenshot shows the FSAPIS interface. At the top, there is a navigation bar with the USDA logo and the system name. Below this is a 'Home' button. The main content area is titled 'Inspections' and contains a table with the following data:

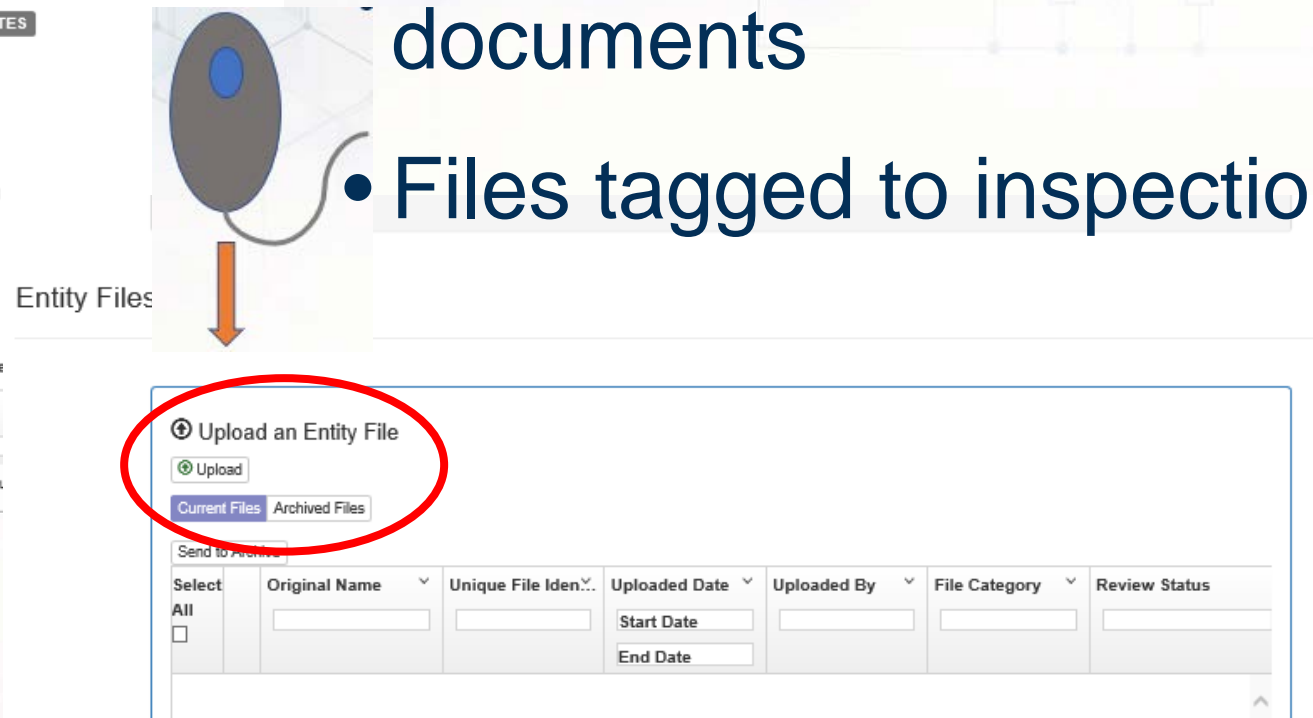
Inspection #	Inspection Type	Start Date	Stop Date	Lead Inspector	Inspection Status		
7709	Announced	07/15/2021	07/17/2021	Jacinta Smith	Scheduled	Details	History
7705	Announced	04/01/2021	04/05/2021		Inspection Closed # Activities	Details	History

- 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



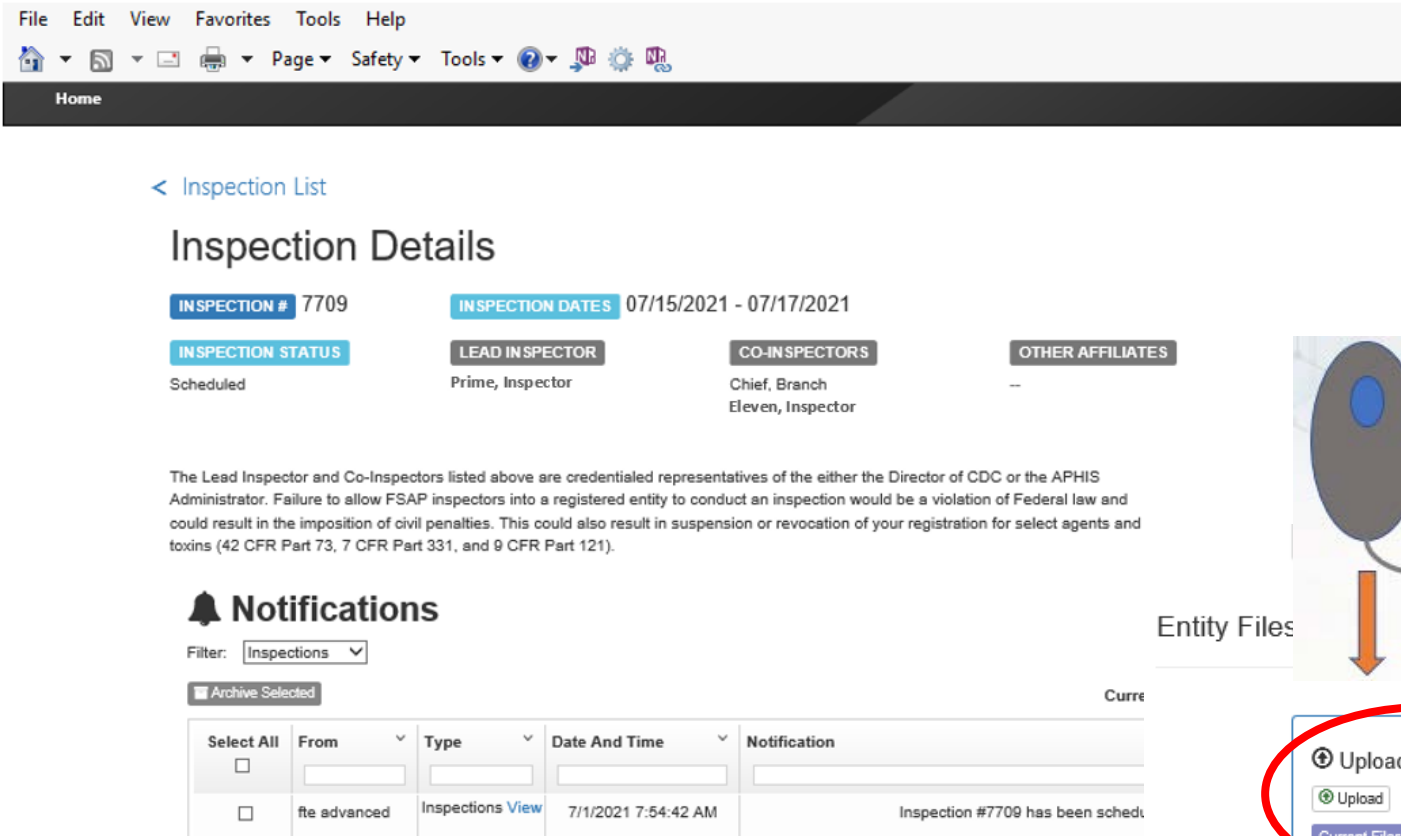
Entity Files

Upload an Entity File

Upload

Current Files Archived Files

Select	Original Name	Unique File Ident...	Uploaded Date	Uploaded By	File Category	Review Status
All			Start Date			
			End Date			



File Edit View Favorites Tools Help

Home

< Inspection List

Inspection Details

INSPECTION # 7709 **INSPECTION DATES** 07/15/2021 - 07/17/2021

INSPECTION STATUS Scheduled **LEAD INSPECTOR** Prime, Inspector **CO-INSPECTORS** Chief, Branch Eleven, Inspector **OTHER AFFILIATES** -

The Lead Inspector and Co-Inspectors listed above are credentialed representatives of either the Director of CDC or the APHIS Administrator. Failure to allow FSAP inspectors into a registered entity to conduct an inspection would be a violation of Federal law and could result in the imposition of civil penalties. This could also result in suspension or revocation of your registration for select agents and toxins (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121).

Notifications

Filter: Inspections

Archive Selected

Select All	From	Type	Date And Time	Notification
<input type="checkbox"/>				
<input type="checkbox"/>	fte advanced	Inspections View	7/1/2021 7:54:42 AM	Inspection #7709 has been sched



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
 - <https://www.selectagents.gov/regulations/policy/BSL3ABSL3.htm>



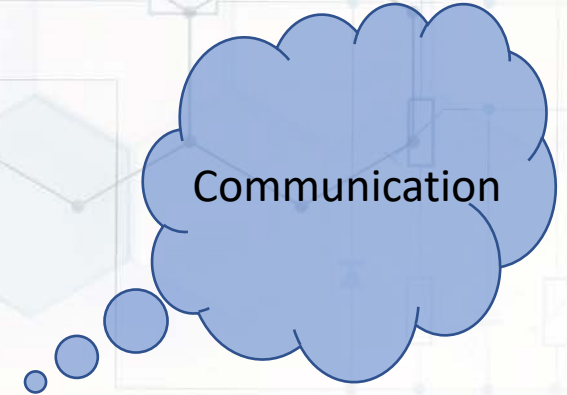
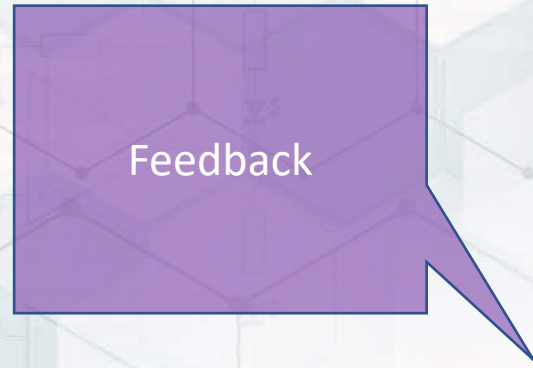
Best Practices

- **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



- 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

CDC Contact Information
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404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
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301- 851-2070

