

Federal Select Agent Program Responsible Official (RO) Webinar Series, 2022

Preparing for a
Successful Inspection Experience

20 July 2022



Preparing for a Federal Select Agent Program (FSAP) Inspection

Responsible Officials (ROs) and Alternate ROs



Depositphotos, Office Mess School Cliparts #3057436

FSAP Inspectors



Depositphotos, Office Mess Cliparts #3065366



Agenda

1. Six Tenets: Preparing For A Successful Inspection.
2. Pre-inspection Process.
3. Documents: Organization and Sharing.
4. Flexibility.
5. Conclusion.



Six Tenets: Preparing For A Successful Inspection

RO and inspector declarations:

1. We will be organized.
2. We will be flexible.
3. We will not be “last minute.”
4. We will communicate.
5. We will communicate.
6. We will communicate!!



Pre-Inspection Process



Pre-Inspection Process: Summary of Scheduling Process

3–6
Months

- Registered entities identified for inspection.
- FSAP coordinates dates.

2–3
Months

- Number of inspectors and number of inspection days determined.
- Lead inspector is notified to initiate pre-inspection with RO.

6–8
Weeks

- Lead inspector coordinates with the RO and the inspection team.

Pre-Inspection Process: RO Timeline

- *3–6 months prior to inspection:*
 - ROs receive an eFSAP message with available inspection dates.
- *4–6 weeks prior to inspection:*
 - Lead inspector contacts RO.
- *3 weeks prior to inspection:*
 - RO/AROs upload records to eFSAP.
- *1–2 weeks prior to onsite inspection:*
 - Remote inspection, if applicable.
- *Onsite inspection.*



Pre-Inspection Process: Touchpoint Meetings with Lead Inspector

- Communication is key.
- Number of meetings is dependent on size, scope and complexity of registered area(s).

Example: Onsite inspection,
May 23–27.

Date	Touchpoint Meeting Topic Discussed
3/7/22	Contact RO; initiate inspection
3/21/22	Organize records and documents
4/21/22	Visitor clearance documents
5/3/22	Daily inspection agenda
5/17/22	Visitor and parking passes



Pre-inspection Process: Inspection Coordination – Planning

- RO ensures that the Form 1 Section 5C- *Entry Requirements for Federal Select Agent Program Inspectors* is current and accurate.
- Lead inspector and RO ensure regular communication.
 - RO plans out escorts in advance with physical space in mind.
 - *Scenario: 1:1 escorts into registered space.*
 - Lead inspector pre-arranges interviews – RO verifies availability and relevance.
 - *Scenario: Interviews with staff who have never accessed select agents or toxins.*



Pre-Inspection Process: Inspection Coordination – Personal Protective Equipment

- Is personal protective equipment (PPE) provided?
 - Section 5C information is reviewed.
- Ensure PPE can accommodate various sizes and features.
 - Tyvek type, dedicated shoe sizes, foot covers.
 - FSAP inspectors can supply their own PPE when needed.
 - *Scenario: Petite lab users vs. tall inspectors.*
- Respiratory protection.
 - Powered Air Purifying Respirator (PAPR) or N95-filtering facepiece.

Pre-Inspection Process: Inspection Coordination – Virtual Platforms

- Confirm virtual platforms to conduct remote portion of hybrid inspections.
 - Microsoft Teams.
 - Zoom.
 - Other.
- *Scenario to Consider: Pre-inspection logistics by Microsoft Teams opening meeting and visitor training completed before being on site.*



Pre-inspection Process: Logistics

- Provide a map and driving directions to facility.
- Coordinate meeting location for entity personnel and the inspection team.
- Parking requirements (parking passes, visitor parking, etc.).
- Lunch options (onsite, nearby locations, bring your lunch, etc.).
- Best route to get to facility (construction, etc.).



Documents: Organization and Sharing



Documents: Organization and Sharing

Examples of effective practices observed by inspectors:

- Collate documents and records into folders.
- Organize as records are generated over the year, or on completion of RO annual inspection.
- When uploading to eFSAP, track documents provided vs. requested using a spreadsheet.

Training

- 2020-2022 Training Curriculum
- 2020-2022 Annual Refresher Training
- 2020-2022 Visitor Training

Inactivations

- Validated Inactivation Procedures
- Viability Testing Protocols
- 2020-2022 Inactivation Certificates

Drills/Exercises

- 2021 Biosafety
- 2020 Security
- 2021 Security
- 2022 Security
- 2020-2022 Incident Response



Documents: Organization and Sharing (cont.)

- Upload Biosafety, Security, and Incident Response plans into eFSAP.
 - Uploading plans following annual review or whenever revisions are made, can be a method to ensure compliance.
- Upload commonly requested files as soon as your inspection number is assigned in eFSAP.

Security	Inventory	Facility Records
<ul style="list-style-type: none">• 2020-2021 Security Plan	<ul style="list-style-type: none">• 2000-2021 Master Inventory	<ul style="list-style-type: none">• 2020-2021 HEPA Certifications
<ul style="list-style-type: none">• 2020-2021 Access Records	<ul style="list-style-type: none">• 2021 Inventory Usage Log	<ul style="list-style-type: none">• 2020-2021 BSC Certifications
<ul style="list-style-type: none">• 2020-2021 Visitor Logs	<ul style="list-style-type: none">• 2020 Inventory Audits by RO or designee	<ul style="list-style-type: none">• 2020-2021 Annual HVAC failure testing records
<ul style="list-style-type: none">• On-going Suitability records		



Documents: Organization and Sharing – Nomenclature

- Be consistent.
 - Standardize the categories and/or replace them with 2- or 3-letter codes.
- Use short but descriptive names.
 - Align it with the category requested.
 - Use common abbreviations, such as Jan for January or Train for Training.
- Avoid special characters (@ /:*).
- Use sequential numbering (01,02,03...instead of 1,2,3).
- Include a version number, if applicable.



Documents: Organization and Sharing – Nomenclature (cont.)



- Insider Threat Training Records 2021.xlsx
- Checklist-RO_02082022.pdf
- Power Failure Test.pdf
- O-ring check documentation_2021.pdf
- Quarantine Policy.docx
- IBC Minutes 2020.pdf
- Appendix 01 BSL3 Facility Diagram.jpg



- Request 56_ExPRO045587_pages 333 thru 390.pdf
- 17.Pdf
- 18A-02, Draft 05-31-18.pdf
- Prod. Form 29-19_Aproved (1).pdf
- 20200727_163944.jpg
- **eFSAP:** > 25MB, Adobe portfolios



Documents: Organization and Sharing - Providing Documents for Inspection

- Documents must be:
 - Uploaded to eFSAP.
 - Under 25MB.
 - Provided immediately upon request.
 - Include any referenced documents that are needed to meet the requirements of the select agent regulations.
- Identify any documents that must be reviewed on-site.
- Discuss options during meetings with the lead inspector.
 - For items with large page quantities, the lead inspector may decide to request a narrower, focused selection of records.
 - Examples: only specific months of entry records, just the last completed experiment, last two inventory access events.



Documents: Organization and Sharing - Providing Documents for Inspection (cont.)

- eFSAP is the official information system for FSAP.
 - Certain documents must be uploaded into eFSAP even if an alternate file sharing software is used.
 - Certain types of documents upload better than others.



Documents: Organization and Sharing - Providing Documents: Challenges

Common issues to consider:

- Last minute upload documents.
 - Name issues.
 - eFSAP issues.
- Large files size upload issues eFSAP.
- Non-targeted uploads/data dumps.



Flexibility

“The green reed which bends in the wind is stronger than the mighty oak which breaks in a storm.” — Confucius



<https://www.gettyimages.com/detail/photo/seascape-with-tall-grass-plants-waving-in-the-wind-royalty-free-image/1270297506?adppopup=true>

- Agendas are made, yet....
 - Donning personal protective equipment (PPE) may take longer.
 - Questions dig deeper.
 - Timelines go out the window!
- Good communication with all parties and regular check-ins on updated schedules as the inspection proceeds will keep it flowing.



Conclusion: Takeaways for a Successful Inspection Experience

- Pre-plan/organize.
- Establish timelines.
- Coordinate/delegate tasks.
- Communicate frequently.
- Prepare to be flexible.



www.selectagents.gov

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

