

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

The Future of Federal Select
Agent Program Inspections

20 July 2022



On-Site Inspections

A close-up photograph of a person wearing a white lab coat, safety glasses, and a white face mask. They are holding a clipboard and a pen, appearing to be in the middle of an inspection or data collection process. The background is blurred, suggesting an industrial or laboratory setting. The overall color palette is cool, with blues and greys.

On-Site Inspection

- Same as pre-pandemic procedures.
- Transitioning to hybrid inspections with less time spent onsite doing document review.
- At present, all inspections are announced, but unannounced inspections returning soon.
- Provides flexibility for entities who prefer to have staff onsite the entire time of the inspection.



Remote Inspections

A close-up photograph of a person wearing a white lab coat, safety glasses, and a white face mask. They are holding a clipboard and a pen, looking down at the clipboard. The background is a blurred laboratory or office setting. The text 'Remote Inspections' is overlaid on a dark blue oval on the left side of the image.

Remote Inspection

- FSAP considerations for developing:
 - Safety of registered entity and FSAP personnel during the COVID-19 pandemic.
 - Widespread travel restrictions during the pandemic.
 - Increased demand for work involving SARS CoV and SARS-CoV-2 (non-select agent).
 - Entity staff availability while in remote or telework status.
 - A useful tool for review of operations at the registered entities when other options are not feasible or required.



Remote Inspection-Continued

- Began April 2020 in response to the pandemic.
- No onsite component – intensive document review and interviews with staff.
- Developed to ensure continuity of operations and FSAP oversight while under travel restrictions.



Hybrid Inspections

A close-up photograph of a person wearing a white lab coat, safety glasses, and a white face mask. They are holding a dark clipboard and a white pen, looking down at the clipboard. The background is a blurred laboratory or office setting with windows.

Hybrid Inspection

- Usually, a combination of remote documentation and record review with an on-site inspection component to follow.
- Document review, interviews, opening and close-out meetings can be conducted remotely.
- Occur independently or concurrently with the on-site inspection.
- The onsite aspect of the hybrid phase allows us to focus on facility containment, biological select agent and toxin (BSAT) inventory, decontamination systems, and other physical components of the laboratory.



Hybrid Inspection – Continued

- Every hybrid inspection is different, because every entity is unique. However, every entity is not suitable for a hybrid inspection.
- Used to maximize FSAP resources and limit size of inspection teams and on-site presence.
- Geared toward allowing comprehensive review of records remotely and more focused inspection of on-site operations.
- Future of FSAP regulatory oversight.
 - Evolving as we learn more about the process.



FSAP Inspection Statistics (2021)

- 206 total inspections conducted
- By lead agency:
 - 139 by DSAT
 - 21 by DASAT
 - 46 joint DSAT/DASAT
- Type
 - 19 on-site
 - 106 remote
 - 81 hybrid (combination of on-site and remote)

Source: 2022 Annual Report of the Federal Select Agent Program



Five Key Points

- Unannounced inspections are returning – Be prepared.
- Submit documents, plans, and records at least 3–4 weeks before inspection date.
- Hybrid and remote inspections are here to stay.



Five Key Points – Continued

- Work with inspectors to identify the best and most efficient hybrid approach for your entity.
 - All entities are not the same.
 - The remote portion of the hybrid inspection can be the week before, during, or the week after the on-site inspection.
- Inspectors will continue to follow entity-specific COVID protocols and guidance.



A close-up photograph of a scientist in a laboratory. The scientist is wearing a white lab coat over a blue shirt and a dark tie. They are also wearing clear safety glasses and a white surgical mask. The scientist is holding a clipboard and a pen, looking down at the clipboard. The background is a blurred laboratory setting with various pieces of equipment.

Open Discussion

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