



# Federal Select Agent Program (FSAP)

## An Overview of FSAP Operations During the COVID-19 Pandemic

DSAT and AgSAS Operations Branch/  
Section Chief  
Responsible Official Webinar  
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# FSAP Operations

- ❑ **All staff are currently teleworking**
  - Essential functions are being performed remotely (e.g., access to eFSAP, video conference, email)
  - Unless on leave or deployed for the COVID-19 response, all staff are available to provide assistance or answer questions
  
- ❑ **No travel for inspections until further notice**
  - Exceptions: agricultural/public health threat
  
- ❑ **On-site renewal inspections have been temporarily replaced with virtual inspections**
  - On-site verification inspections have been deferred until further notice
  - Follow-up on-site inspection once travel resumes

# FSAP Operations

- ❑ **Due to the limited operations at FBI/CJIS/BRAG obtaining a SRA might be delayed.**
  
- ❑ **Entity registration renewals**
  - Each entity will be evaluated on a case-by-case basis and dependent compliance and history
  
- ❑ **All requests or questions involving SARS-CoV-2 will be expedited**
  - New registrations
  - General questions
  
- ❑ **Technical amendments**
  - Exception are made based on circumstances
  - Average turnaround time: 4-5 business days

# FSAP Operations

## □ Section 18 Inspections

- *(a) Without prior notification, FSAP shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.*
- *(b) Prior to issuing a certificate of registration to an individual or entity, FSAP may inspect and evaluate the premises and records to ensure compliance with this part.*

# VIRTUAL



# Virtual Inspections

## □ Purpose:

- Continuity of inspection operations
- Verify the entity's ability to work safely and securely with select agents or toxins and adherence to the regulations

## □ Advantages:

- Reduce inspection time for future follow-up on-site inspection
- Shortens document review process for future follow-up on-site inspection
- Provides additional opportunity for FSAP and entity to identify potential compliance issues
- Provides additional opportunity for entity to correct compliance issues and receive guidance from inspectors

# Virtual Inspections

## □ Virtual Inspections

- All entities may not be requested to participate
  - Decision based on entity's availability, current status, or their participation in the COVID-19 response
- Average time for inspection: 2-3 days
- Renewal and verification inspections are conducted virtually

# Virtual Inspections

## □ Provides opportunity for inspectors to:

- Review entity records (e.g., biosafety cabinet certifications, HEPA filter certifications, access records, training)
- Review entity biosafety, security, and incident response plans
- Interview pertinent staff
- Identify compliance issues



# Virtual Inspections – Expectations

- Entities contacted 3-5 weeks ahead of time to assess availability
- Lead inspector will work with entity on developing an agenda and identify reasonable times for virtual meetings
  - Coordination of time with the entity
  - In-brief, interviews, daily out-briefs
  - Skype, Zoom, phone
- Inspections will not routinely require a virtual tour of the registered space
- Uploading documents into eFSAP
  - Entity should work with FSAP Point of Contact
  - Document/file naming is important

# Unchanged Inspection Processes

- ❑ FSAP Issuance of inspection reports
- ❑ Entity's responses to inspection report

# Discussion

[www.selectagents.gov](http://www.selectagents.gov)

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