eFSAP and Entity Inspections: What Can We Expect?

Federal Select Agent Program
Thursday, July 25, 2019
Federal Select Agent Program Information System

Entity: RO 2's Entity

LEAD AGENCY: APHIS  
REGISTRATION STATUS: Approved

REGISTRATION EXPIRES: 04/25/2022

Facility Address: 426 Beaver Ruin Rd, Duluth, GA 33333-1234

Responsible Official Name: Allen Smith  
Responsible Official Title: If

Registration #: 20190425-130706  
Application #: cc94af9d-0413-e711-80cd-001dd8003fe2

Responsible Official Address: 22 all, Idl, AL 93938  
Type Status: Commercial - Profit

Notifications

From   Type   Date And Time   Notification

Agency User   Inspections View   5/14/2019 1:21:47...   Inspection #7338 has been scheduled.
Navigating to Inspections

Federal Select Agent Program Information System

Entity: RO 2's Entity
LEAD AGENCY: APHIS
REGISTRATION STATUS: Approved
REGISTRATION EXPIRES: 04/25/2022

Facility Address: 426 Beaver Run Rd, Duluth, GA 30093-1234

Responsible Official Name: Allen Smith
Responsible Official Title: If
Responsible Official Address: 22 all, Idl, Al 93939

Registration #: 20190425.130706
Application #: cc94a9d-0413-e711-80cd-001ed8003fe2
Type Status: Commercial - Profit

Notifications

From: Agency User
Type: Inspection
Date And Time: 03/14/2019 1:21:47
Notification: Inspection #7338 has been scheduled.
### Navigating to Inspections

#### Federal Select Agent Program Information System

<table>
<thead>
<tr>
<th>Inspection #</th>
<th>Inspection Type</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Lead Inspector</th>
<th>Inspection Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>7331</td>
<td>Announced</td>
<td>02/11/2019</td>
<td>03/11/2019</td>
<td></td>
<td>Scheduled</td>
</tr>
<tr>
<td>7331</td>
<td>Announced</td>
<td>05/11/2019</td>
<td>06/11/2019</td>
<td></td>
<td>Scheduled</td>
</tr>
<tr>
<td>7324</td>
<td>Announced</td>
<td>06/04/2019</td>
<td>07/04/2019</td>
<td></td>
<td>Scheduled</td>
</tr>
<tr>
<td>7321</td>
<td>Announced</td>
<td>03/02/2019</td>
<td>04/02/2019</td>
<td></td>
<td>Scheduled</td>
</tr>
<tr>
<td>7321</td>
<td>Announced</td>
<td>06/02/2019</td>
<td>07/02/2019</td>
<td></td>
<td>Scheduled</td>
</tr>
<tr>
<td>7321</td>
<td>Announced</td>
<td>08/02/2019</td>
<td>09/02/2019</td>
<td></td>
<td>Scheduled</td>
</tr>
<tr>
<td>7320</td>
<td>Announced</td>
<td>10/02/2019</td>
<td>11/02/2019</td>
<td></td>
<td>Scheduled</td>
</tr>
<tr>
<td>7320</td>
<td>Announced</td>
<td>12/02/2019</td>
<td>01/02/2020</td>
<td></td>
<td>Scheduled</td>
</tr>
</tbody>
</table>

*Details available for each inspection.*
Navigating to Inspections

- **Inspection List**
- **Inspection Details**

- **Inspection #** 7338
- **Inspection Dates** 07/09/2019 - 07/11/2019
- **Inspection Status** Scheduled

The Lead Inspector and Co-Inspectors listed above are credentialed representatives of the 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).
## Inspection Details

**Inspection number, dates, status and inspectors (including affiliates)**

- **Inspection number**: 7338
- **Inspection dates**: 07/09/2019 - 07/11/2019
- **Inspection status**: Scheduled

The Lead Inspector and Co-Inspectors listed above are credentialled representatives of the 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

- **Current**: 
- **Archived**: 
- **Flagged**: 

<table>
<thead>
<tr>
<th>From</th>
<th>Type</th>
<th>Date And Time</th>
<th>Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency User</td>
<td>Inspections View</td>
<td>5/14/2019 1:21:47...</td>
<td>Inspection #7338 has been scheduled.</td>
</tr>
</tbody>
</table>

- **Authorization for inspectors to conduct an inspection**
Inspection Details

Inspection # 7338
Inspection Dates 07/09/2019 - 07/11/2019
Inspection Status Scheduled

Assigned Checklists

42 CFR 73: Biosafety: BSL-3
42 CFR 73: Incident Response
42 CFR 73: Records
42 CFR 73: Responsible Official and Theft, Loss, or Release

Form 1 Section 1
Form 1 Section 2
Form 1 Section 3
Form 1 Section 4
Form 1 Section 5A
Form 1 Section 5B
Form 1 Section 5C
Form 1 Section 6
Form 1 Section 7A7C
Form 1 Section 7B
Form 2
Form 3
Form 4

Resources
Amendment History
Inspection Resolution
## Inspections - Checklist

**INSPECTION #:** 7338  
**CHECKLIST:** 42 CFR 73 - Biosafety: BSL-3

<table>
<thead>
<tr>
<th>UID</th>
<th>CFR/Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>42-12-26000</td>
<td>12(b)</td>
<td>Sems, floors, walls, and ceiling surfaces are sealed.</td>
</tr>
<tr>
<td>42-12-25600</td>
<td>12(b)</td>
<td>In addition to meeting BSL-2 requirements, laboratory has two self-closing doors.</td>
</tr>
<tr>
<td>42-12-25900</td>
<td>12(b)</td>
<td>In addition to meeting BSL-2 requirements, laboratory sink is hands-free.</td>
</tr>
<tr>
<td>42-12-26100</td>
<td>12(b)</td>
<td>Laboratory has ducted ventilation system and airflow is inward from clean to potentially contaminated areas.</td>
</tr>
<tr>
<td>42-12-26200</td>
<td>12(b)</td>
<td>In addition to meeting BSL-2 requirements, laboratory airflow does not reverse under failure conditions.</td>
</tr>
<tr>
<td>42-12-26300</td>
<td>12(b)</td>
<td>In addition to meeting BSL-2 requirements, a visual monitoring device is present to allow verification of directional airflow.</td>
</tr>
</tbody>
</table>

[Return to Inspection Details]
AFTER THE INSPECTION
# Notification of Released Findings

## Inspection Details

**Inspection #:** 7338  
**Inspection Dates:** 07/09/2019 - 07/11/2019

*Scheduled*

The Lead Inspector and Co-Inspectors listed above are credentialed representatives of the either the Director of CDO 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

<table>
<thead>
<tr>
<th>From</th>
<th>Type</th>
<th>Date And Time</th>
<th>Notification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agency User</td>
<td>Inspections View</td>
<td>5/14/2019 2:46:42...</td>
<td>Inspection #7338 UID:4-2-19-044899 with Departure Type of Final has been released for entity review.</td>
</tr>
<tr>
<td>Agency User</td>
<td>Inspections View</td>
<td>5/14/2019 2:46:42...</td>
<td>Inspection #7338 UID:42-12-26000 with Departure Type of Final has been released for entity review.</td>
</tr>
<tr>
<td>Agency User</td>
<td>Inspections View</td>
<td>5/14/2019 2:46:42...</td>
<td>Inspection #7338 UID:42-19-00400 with Departure Type of Immediate Action has been released for entity review.</td>
</tr>
<tr>
<td>Agency User</td>
<td>Inspections View</td>
<td>5/14/2019 2:46:42...</td>
<td>Inspection #7338 has been scheduled.</td>
</tr>
<tr>
<td>Agency User</td>
<td>Inspections View</td>
<td>5/14/2019 1:21:47...</td>
<td>Inspection #7338 UID:00301 status changed from Inspection Resolution to Scheduled.</td>
</tr>
</tbody>
</table>

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**Assigned Checklists**
View Released Findings

Inspection Details

**INSPECTION #**: 7338

**INSPECTION DATES**: 07/09/2019 - 07/11/2019

**INSPECTION STATUS**: Scheduled

The Lead Inspector and Co-Inspectors listed above are credentialed representatives of the either the Director of CDO 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**

- Agency User: Inspection View (5/14/2019 2:46:42...)
  - Inspection #7338 UID: 42-14-01802 with the status of Requestor Information has been released for entity review.

- Agency User: Inspections View (5/14/2019 2:46:41...)
  - Inspection #7338 UID: 42-12-26000 with Departure Type of Final has been released for entity review.

- Agency User: Inspections View (5/14/2019 2:46:41...)
  - Inspection #7338 UID: 42-19-00400 with Departure Type of Immediate Action has been released for entity review.

- Agency User: Inspections View (5/14/2019 2:46:41...)
  - Inspection #7338 has been scheduled.

- Agency User: Inspections View (5/14/2019 1:21:47...)
  - Inspection #7338 status changed from Inspection Resolution to Scheduled.

**Assigned Checklists**
Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established regulatory requirements for the possession, use, and transfer of biological agents and toxins that have the potential to pose a serious threat to public health and safety, animal and plant health, and animal and plant products. These requirements can be found at 42 CFR Part 73 (HHS), 7 CFR Part 331 (USDA-PPQ), and 9 CFR Part 121 (USDA-VS).

The Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and the Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS). CDC DSAT inspects entities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 73. APHIS AgSAS inspects entities to evaluate whether they meet the regulatory requirements set forth in 7 CFR Part 331 and 9 CFR Part 121. The above referenced regulations and supporting guidance information may be found at http://www.selectagents.gov.

The Federal Select Agent Program will provide inspection findings through eFSAP. Inspection findings may include departures from regulatory requirements, general concerns, concerns related to amendments, requests for additional information, or issues under review. Inspection departures fall within three categories: immediate actions, preliminary, and final. Descriptions of each type of inspection finding are available here.

You may dispute departures resulting from your inspection. Within 14 calendar days from receipt of a departure, you may email your dispute request to the DSAT Operations Branch Chief (dsat@cdc.gov) or the AgSAS Operations Unit Director (AgSAS@aphis.usda.gov). The request must specify the departures that you are disputing. Upon receipt of your inspection findings, you have 30 calendar days to provide a written statement that clearly states why you consider the disputed departure(s) to be in error. You may include documentation in support of your dispute. The DSAT Operations Branch Chief or the AgSAS Operations Unit Director will attempt to resolve the dispute with you within 30 calendar days of the receipt of the written statement. The resolution of a dispute may include discussions with the entity or additional site visits. If the resolution of a dispute results in a change to an observation or required corrective action, FSAP will update the departure within eFSAP.

Operations Branch Chief
Division of Select Agents and Toxins
Department of Health and Human Services
Center for Disease Control and Prevention

Unit Director
Agriculture Select Agent Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

Go Back

Acknowledge and View Inspection Findings
### Inspection Resolution

The findings below are presented in order of their relative severity — highest to lowest. Repetition of departures, as shown on future inspections, will be considered more serious and may result in compliance actions.

<table>
<thead>
<tr>
<th>Inspection Findings</th>
<th>Departure Type</th>
<th>Departure Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>All (8)</td>
<td>Request For Information (1)</td>
<td>All (4)</td>
</tr>
<tr>
<td>Departure (3)</td>
<td>Amendment Concern (1)</td>
<td>Open (4)</td>
</tr>
<tr>
<td>General Concern (1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Print Capabilities**
- **Toggles:**
  - Inspection Finding
  - Departure Type
  - Departure Status
# Immediate Action Release

<table>
<thead>
<tr>
<th>Departure Type:</th>
<th>Severity:</th>
<th>Initial Response Due:</th>
<th>Repeat Departure:</th>
<th>Status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Action</td>
<td>Serious</td>
<td>08/29/2019</td>
<td>No</td>
<td>Open</td>
</tr>
</tbody>
</table>

**Current Response Due:** 08/29/2019

## CFR/Section

42 CFR 73 - 19(b)(2)

## Requirement

Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biosafety containment area, an individual or entity must immediately notify CDC or APHIS. A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

## Observation

The entity failed to notify FSAP of an incident where the outer door of a pass-through autoclave was opened for repair without first running a sterilization cycle. This incident meets the definition of a release outside the primary barrier of a biosafety containment area.

## Corrective Action:

Submit a Form 3 for this incident. Describe the measures implemented to ensure FSAP is immediately notified of any release of select agent outside the primary barriers of a biosafety containment area. Provide the procedures implemented to ensure the entity submits a completed APHIS/CDC Form 3 within 7 calendar days of any release.

## Entity Response

Type your response here...
## Moderate Severity Departure

**Departure Type:** Final  
**Severity:** Moderate  
**Initial Response Due:** 06/06/2019  
**Report Departure:** No  
**Current Response Due:** 06/06/2019  
**Status:** Open

<table>
<thead>
<tr>
<th>CFR/Section</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 CFR 73 - 17(a)(2)</td>
<td>An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: An accurate, current accounting of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition).</td>
</tr>
</tbody>
</table>

**Observation**

In isolated cases, the entity has not maintained an accurate, current accounting of all animals exposed to or infected with a select agent.

**Corrective Action:**

Provide the procedures implemented to ensure that the entity maintains an accurate, current accounting of any animals exposed to or infected with a select agent (including number and species, location, and appropriate disposition).

**Entity Response**

Type your response here...
### Change in Response Due Date

<table>
<thead>
<tr>
<th>Departure Type</th>
<th>Severity</th>
<th>Initial Response Due</th>
<th>Current Response Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final</td>
<td>Moderate</td>
<td>06/06/2019</td>
<td>09/06/2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10/10/2019</td>
</tr>
</tbody>
</table>

**New Response Due Date:** 10/10/2019
# Low Severity Departure

**Departure Type:** Final  
**Severity:** Low  
**Initial Response Due:** 09/06/2019  
**Repeat Departure:** No  
**Current Response Due:** 09/06/2019  
**Status:** Open

<table>
<thead>
<tr>
<th>CFR/Section</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 CFR 73 - 12(b)</td>
<td>The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).</td>
</tr>
</tbody>
</table>

**Observation:**  
Room A has an unsealed wall surface. [BSL-3 EMBL]

**Corrective Action:**  
Provide confirmation that the wall surface in Room A has been repaired to produce a sealed smooth finish that can be easily cleaned and decontaminated.

**Entity Response**  
Type your response here...
# General Concerns

<table>
<thead>
<tr>
<th>CFR/Section</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 CFR 73 - 14(f)</td>
<td>The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.</td>
</tr>
</tbody>
</table>

| Observation       | The incident response plan references several SOPs. The entity does not document the review and revision of the SOPs. Consider documenting the review and revision of referenced SOPs.                               |

- **No Due Date**
- **Observation Only**  
  - Usually includes a consideration
- **No Response**
### Amendment Concerns

**CFR/Section**

<table>
<thead>
<tr>
<th>CFR/Section</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 CFR 73 - 7(0)(1-3)</td>
<td>A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins) (1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. (2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part. (3) No change may be made without such approval.</td>
</tr>
</tbody>
</table>

**Observation**

The entity submitted an amendment to add Room B to WO 3001.001. This work objective is for work and storage of select agent. During the inspection, staff stated that Room B would be used only for storage of select agent.

**Corrective Action:**

Submit an amendment to add a storage-only work objective to Room B.

- **Not considered part of the inspection**
  - No response required in the inspection module
- **Corrective action is addressed within the pending amendment**
Request For Information (RFI)

- RFI
- No Severity
- Due Date
- Response
  - FSAP will make a final compliance determination upon the entity’s submission of data

Initial Response Due: 09/06/2019
Status: Open

Current Response Due: 09/06/2019

CFR/Section
42 CFR 73 - 14(i)

Requirement
The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

Observation
The entity conducted a drill of the incident response plan the Monday prior to the inspection start date. Provide the finalized documentation of the drill.

Entity Response
Type your response here...
Note about Released Findings

- Findings may be released at various times depending upon the type
  - Example: Immediate action items are released prior to other severities
  - Example: Response to an RFI could lead to a new compliance determination
- Check the notification board for any additional items
- Items will not be released after the inspection status is closed
Uploading Responses

- The upload center is located at the bottom of the page.
- Must include the Departure UID in the description.
Please note: As with every eFSAP system update, users must clear their internet browser cache in order for the system to function properly. Instructions can be found on the eFSAP Resource Center page.
Discussion

www.selectagents.gov

CDC: Irsat@cdc.gov or 404-718-2000

APHIS: AgSAS@aphis.usda.gov or 301-851-3300 option 3 (voice only)