

eFSAP and Entity Inspections: What Can We Expect?

Federal Select Agent Program
Thursday, July 25, 2019



eFSAP Landing Page



[Sign Out](#)

Home

Federal Select Agent Program Information System

Form 1

Form 2

Form 3

Form 4

Inspections

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: lf

Responsible Official Address: 22 all, Idl, AL 93939

Registration #: 20190425-130706


Application #: cc94af9d-0413-e711-80cd-001dd8003fe2

Type Status: Commercial - Profit


Notifications

Current ☒ Archived ☐ Flagged ☐

 Archive Selected

<input checked="" type="checkbox"/>	From	Type	Date And Time	Notification	
<input checked="" type="checkbox"/>	Agency User	Inspections View	5/14/2019 1:21:47...	Inspection #7338 has been scheduled.	 Flag

Navigating to Inspections

Sign Out

Home

Federal Select Agent Program Information System

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From	Type	Date And Time	Notification	
Agency User	Inspections View	3/14/2019 1:21:47...	Inspection #7338 has been scheduled.	<div>Flag</div>

Navigating to Inspections

USDA   [Sign Out](#)

Home

Federal Select Agent Program Information System

Form 1 Form 2 Form 3 Form 4 **Inspections**

Inspections

Inspection #	Inspection Type	Start Date	Stop Date	Lead Inspector	Inspection Status	
		Start Date End Date	Start Date End Date			
7338	Announced	07/09/2019	07/11/2019		Scheduled	Details
7331	Announced	08/08/2019	08/11/2019		Scheduled	Details
7324	Announced	03/24/2019	03/27/2019		Inspection Closeout Activities	Details
7323	Announced	04/01/2019	04/01/2019		Scheduled	Details
7309	Announced	02/21/2019	02/22/2019		Inspection Closeout Activities	Details
7277	Announced	12/16/2018	12/21/2018		Inspection Closeout Activities	Details
7256	Announced	12/05/2018	12/09/2018		Scheduled	Details
7247	Announced	11/15/2018	11/15/2018		Inspection Closeout Activities	Details
7230	Announced	09/20/2018	09/20/2018		Closed	Details
7229	Announced	09/20/2018	09/22/2018		Inspection Closeout Activities	Details
7220	Announced	10/01/2018	10/02/2018		Scheduled	Details
7219	Announced	09/05/2018	09/05/2018		Closed	Details

Navigating to Inspections

Notifications

Current ☒ Archived ☐ Flagged ☐

Archive Selected

✓	From	Type	Date And Time	Notification	
✓	Agency User	Inspection View	5/14/2019 1:21:47...	Inspection #7338 has been scheduled.	Flag

< [Inspection List](#)

Inspection Details

INSPECTION # 7338

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

INSPECTION STATUS

Scheduled

LEAD INSPECTOR

CO-INSPECTORS

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

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Archive Selected

✓	From	Type	Date And Time	Notification	
✓	Agency User	Inspections View	5/14/2019 1:21:47...	Inspection #7338 has been scheduled.	Flag

Inspection Details Page

Inspection Details

INSPECTION #	7338	INSPECTION DATES	07/09/2019 - 07/11/2019		
INSPECTION STATUS	Scheduled	LEAD INSPECTOR	CO-INSPECTORS	OTHER AFFILIATES	

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Notifications

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 Archive Selected

✓	From	Type	Date And Time	Notification	
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
✓	Agency User	Inspections View	5/14/2019 1:21:47...	Inspection #7338 has been scheduled.	Flag

- ❑ Inspection number, dates, status and inspectors (including affiliates)
- ❑ Authorization for inspectors to conduct an inspection

Inspection Details Page

Inspection Details

INSPECTION # 7338

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

INSPECTION STATUS

Scheduled

LEAD INSPECTOR

CO-INSPECTORS

OTHER AFFILIATES



Resources

Amendment History

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

Assigned Checklists

Inspection Resolution

42 CFR 73 :
Biosafety: BSL-3



42 CFR 73 :
Registration and
Restricted
Experiments



42 CFR 73 : Incident
Response



42 CFR 73 : Records



42 CFR 73 :
Responsible Official
and Theft, Loss, or
Release



Inspection Checklist View

Assigned Checklists

42 CFR 73 :
Biosafety: BSL-3



Inspections - Checklist

INSPECTION #: 7338

CHECKLIST: 42 CFR 73 - Biosafety: BSL-3

UID	CFR/Section	Description
42-12-26000	42 CFR 73 12(b)	Seams, floors, walls, and ceiling surfaces are sealed.
42-12-25800	42 CFR 73 12(b)	In addition to meeting BSL-2 requirements, laboratory has two self-closing doors.
42-12-25900	42 CFR 73 12(b)	In addition to meeting BSL-2 requirements, laboratory sink is hands-free.
42-12-26100	42 CFR 73 12(b)	Laboratory has ducted ventilation system and airflow is inward from clean to potentially contaminated areas.
42-12-26200	42 CFR 73 12(b)	In addition to meeting BSL-2 requirements, laboratory airflow does not reverse under failure conditions.
42-12-26300	42 CFR 73 12(b)	In addition to meeting BSL-2 requirements, a visual monitoring device is present to allow verification of directional airflow.

[Return to
Inspection Details](#)

AFTER THE INSPECTION

Notification of Released Findings

Inspection Details

INSPECTION # 7338

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

INSPECTION STATUS

Scheduled

LEAD INSPECTOR

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Notifications

Current ☒ Archived ☐ Flagged ☐

Archive Selected

From	Type	Date And Time	Notification	
Agency User	Inspections View	5/14/2019 2:46:42...	Inspection #7338 UID:42-11-01000 with Departure Type of Request for Information has been released for entity review.	Flag
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.	Flag
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.	Flag
Agency User	Inspections View	5/14/2019 1:21:47...	Inspection #7338 has been scheduled.	Flag
Agency User	Inspections View	5/14/2019 1:18:30...	Inspection #7331 status changed from Inspection Resolution to Scheduled.	Flag

1 / 13 25 items per page

1 - 25 of 321 items

Resources

Amendment History

[Assigned Checklists](#)

[Inspection Resolution](#)

View Released Findings

Inspection Details

INSPECTION # 7338

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

INSPECTION STATUS

Scheduled

LEAD INSPECTOR

CO-INSPECTORS

OTHER AFFILIATES

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Current ☒ Archived ☐ Flagged ☐

Archive Selected

From	Type	Date And Time	Notification	
Agency User	Inspection View	5/14/2019 2:46:42...	Inspection #7338 UID:42-14-01802 with the status of Request for Information has been released for entity review.	Flag
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.	Flag
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.	Flag
Agency User	Inspections View	5/14/2019 1:21:47...	Inspection #7338 has been scheduled.	Flag
Agency User	Inspections View	5/14/2019 1:18:30...	Inspection #7331 status changed from Inspection Resolution to Scheduled.	Flag

1 / 13 25 items per page

1 - 25 of 321 items

Resources

Amendment History

Assigned Checklists

Inspection Resolution

Inspection Resolution Splash Page



Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, GA

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agriculture Select Agent Services
Riverdale, MD



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 severe 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 (lrsat@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 departures(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
Divisions of Select Agents and Toxins
Department of Health and Human Services
Center of Disease Control and Prevention

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

[Go Back](#)

[Acknowledge and View Inspection Findings](#)

Inspection Resolution

Home

Inspection Resolution

[← Return to Inspection Details Page](#)

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.

 Print Findings

 Print Findings and Responses

Inspection Findings

All (6) ☒

Departure (3) ☐

General Concern (1) ☐

Request For Information (1) ☐

Amendment Concern (1) ☐

Departure Type

All (3) ☒

Immediate Action (1) ☐

Final (2) ☐

Departure Status

All (4) ☒

Open (4) ☐

Print Capabilities

Toggles:

- Inspection Finding
- Departure Type
- Departure Status

Immediate Action Release

Departure UID: 42-19-00400

Departure Type: Immediate Action	Severity: Serious	Initial Response Due: 08/09/2019	Repeat Departure: No	Status: Open
		Current Response Due: 08/09/2019		

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 biocontainment 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 biocontainment 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 biocontainment 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...

Save Draft

Send

Moderate Severity Departure

Departure UID: 42-17-01100

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

CFR/Section

42 CFR 73 - 17(a)(2)

Requirement

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).

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...

Save Draft

Send

Change in Response Due Date

Departure UID: 42-17-01100

Departure Type:	Severity:	Initial Response Due:
Final	Moderate	09/06/2019
		Current Response Due:
		09/06/2019

Departure UID: 42-17-01100

Departure Type:	Severity:	Initial Response Due:	Repeat Departure:	Status:
Final	Moderate	09/06/2019	No	Open
		Current Response Due:		
		10/10/2019		

Low Severity Departure

Departure UID: 42-12-26000

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

CFR/Section
42 CFR 73 - 12(b)

Requirement
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).

Observation
Room A has an unsealed wall surface [BMBL: (BSL-3) D3b]

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...

Save Draft

Send

General Concerns

General Concern UID: 42-14-01801

CFR/Section

42 CFR 73 - 14(f)

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 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

Amendment Concern UID: 42-7-00500

CFR/Section

42 CFR 73 - 7(i)(1-3)

Requirement

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.

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)

Request For Information UID: 42-14-01802

Initial Response Due:
09/06/2019

Status:
Open

Current Response Due:
09/06/2019

CFR/Section

42 CFR 73 - 14(f)

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...

Save Draft

Send

- ❑ RFI
- ❑ No Severity
- ❑ Due Date
- ❑ Response

- FSAP will make a final compliance determination upon the entity's submission of data

Note about Released Findings

Note that findings in addition to those listed above may be released until the status of the inspection status is closed.

[← Return to Inspection Details Page](#)

- ❑ **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

📎 Upload an Entity Document

Step 1: Identify Document Data

* = Required

Non-Form *

Inspection # *
32 characters remaining.

Sub-Category *

Post-Inspection Documents *

Description
(Must include Departure UID) *

Other

Dispute of Inspection Finding

Response to Dispute of Inspection Finding

Response to Immediate Action Departure(s)

Response to Final Departures(s)

Response to Request for Information

Step 2: Select the Document

Browse...

Show file naming rules

📤 Upload Close

- ❑ The upload center is located at the bottom of the page
- ❑ Must include the Departure UID in the description

Departure UID: 42-12-26000

Departure Type: Severi

eFSAP Resource Center

<https://www.selectagents.gov/efsap.html>

  **FEDERAL SELECT AGENT PROGRAM** 

[HOME](#) [SELECT AGENTS & TOXINS](#) [COMPLIANCE](#) [REGULATIONS & POLICIES](#) [FORMS](#) [RESOURCES](#) [eFSAP](#)

[Federal Select Agent Program](#) > [Resources](#) > [eFSAP Resource Center](#)

eFSAP RESOURCE CENTER

Contents

- [Overview](#)
- [What is eFSAP?](#)
- [Using eFSAP](#)
 - [Form 1: Registration and Amendments](#)
 - [Form 2: Transfer Requests](#)
 - [Form 3: Report of Theft, Loss, or Release](#)
 - [Form 4: Report of Identification](#)
- [Updates](#)
- [Contact Us](#)
- [Log On](#)

Overview

Welcome to the eFSAP Resource Center! Here you will find everything you need to gain access to and use the new electronic Federal Select Agent Program portal, eFSAP.

Click [here](#) to log on to the system.

[What is eFSAP?](#) describes FSAP's new secure information system, eFSAP, and explains how the system will improve communication between FSAP and regulated entities.

[Using eFSAP](#) provides training materials, reference guides, and answers to frequently asked questions to assist eFSAP users.

[Updates](#) provides the latest information about new features and system roll-out.

[Contact Us](#) if you have any questions or needs regarding eFSAP that are not covered in any of the online resources.

We will be posting regular updates to this page as additional phases of the system, and new materials, are available.

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

