



# Electronic Federal Select Agent Portal (eFSAP) Inspections Module

**Federal Select Agent  
Program Training**





# Inspections

To access the Inspections Module, click **Inspections** on the home page.

**Federal Select Agent Program Portal**

Entity: eFSAP Test Entity

**LEAD AGENCY:** CDC      **REGISTRATION STATUS:** Approved      **REGISTRATION EXPIRES:** 10/09/2019

**Facility Address:** 1020 Valley Drive, Atlanta, GA 30329-1234

**Responsible Official Name:** Steve Stevenson      **Responsible Official Title:** Director of Science      **Responsible Official Address:** 1020 Valley Drive, Atlanta, GA 30329

**Registration #:** 20161010-1852      **Application #:** c0c7e336-f01e-e711-80cf-001dd8003fe2      **Type Status:** Commercial - Profit

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



# Inspections Table

The Inspections Table includes current and past inspections. As inspections are scheduled, data will display. This table will remain blank until an inspection is scheduled in eFSAP.

Inspections

Inspection #	Inspection Type	Start Date	Stop Date	Inspection Status	
<input type="text"/>	<input type="text"/>	<input type="text"/> Start Date <input type="text"/> End Date	<input type="text"/> Start Date <input type="text"/> End Date	<input type="text"/>	
7280	Announced	12/17/2018	01/20/2019	In Progress	<a href="#">Details</a>
7271	Announced	12/11/2018	12/13/2018	Inspection Closeout Activities	<a href="#">Details</a>
7268	Announced	12/11/2018	12/12/2018	Inspection Resolution	<a href="#">Details</a>
7267	Announced	12/07/2018	12/07/2018	Inspection Resolution	<a href="#">Details</a>
7264	Announced	12/06/2018	12/06/2018	Inspection Resolution	<a href="#">Details</a>

The table includes: inspection number, inspection type, start date, stop date, lead inspector and inspection status.



## Inspection Details Page

The Inspection Details Page provides the inspection number, dates and status as well as the inspectors and other affiliates. The inspectors include both Agriculture Select Agent Services (AgSAS) and Division of Select Agents and Toxins (DSAT) inspectors.



# Resources

The resources section provides quick access to entity forms and amendment history.

<b>Resources</b>	Assigned Checklists
Amendment History	
Form 1 Section 1	<b>42 CFR 73 : Training</b>
Form 1 Section 2	
Form 1 Section 3	<b>42 CFR 73 : Responsible Official and Theft, Loss, or Release</b>
Form 1 Section 4	
Form 1 Section 5A	
Form 1 Section 5B	<a href="#">Inspection Resolution</a>
Form 1 Section 5C	
Form 1 Section 6	
Form 1 Section 7A7C	
Form 1 Section 7B	
Form 2	
Form 3	
Form 4	



# Checklists

Inspection checklists are listed on the Inspection Details page. Only checklists applicable to a scheduled inspection will display.

Assigned Checklists

- 9 CFR 121 : Records 
- 9 CFR 121 : Security 
- 9 CFR 121 : Training 
- 42 CFR 73 : Training 

Inspection Resolution



# Checklist Details

A description for each checklist item will display allowing entities to see what items will be assessed. This is one way FSAP is increasing transparency.

## Inspections - Checklist

**INSPECTION #:** 7142

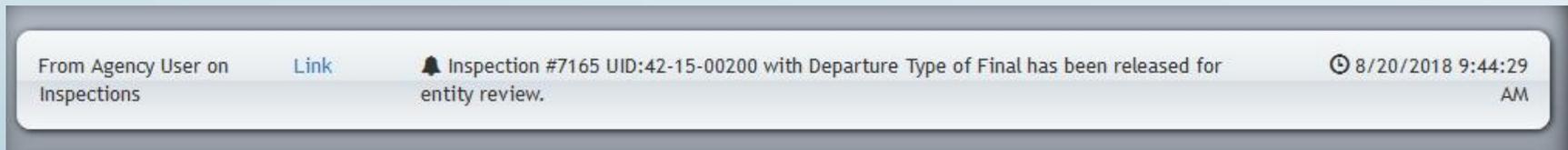
**CHECKLIST:** 9 CFR 121 - Training

UID	CFR/Section	Description
09-15-00100	9 CFR 121 15(a)(1)	An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to each individual with access approval from the Administrator or HHS Secretary. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the Administrator or the HHS Secretary for access, whichever is earlier.
09-15-00200	9 CFR 121 15(a)(2)	An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to each individual not approved for access to select agents and toxins by the Administrator or HHS Secretary before that individual enters areas under escort where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).



# Notifications

As inspection findings are released and additional information is requested, a notification will display on the Inspection Detail Page and the entity Home Page.



eFSAP has the ability to share compliance information faster. With eFSAP, departures can be released as soon as they are finalized, and entities can get the information that they need to be compliant quicker.

For example, instead of waiting for 10 departures to make it through the review process, the FSAP can send departures one at a time or in groups as soon as they're ready to share.



# Inspection Resolution

The Inspection Resolution page details inspection findings.

Assigned Checklists

- 42 CFR 73 : Records 
- 42 CFR 73 : Training 
- 42 CFR 73 : Responsible Official and Theft, Loss, or Release 
- 42 CFR 73 : Incident Response 
- 42 CFR 73 : Security 

[Inspection Resolution](#)

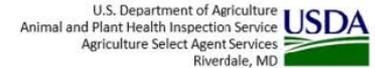


# Inspection Resolution

When you navigate to inspection resolution, you will see a splash page. To view inspection findings click “Acknowledge and View Inspection Findings”.



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 USAI 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 ([irsat@cdc.gov](mailto:irsat@cdc.gov)) or the AgSAS Operations Unit Director ([AgSAS@aphis.usda.gov](mailto: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 USAI Operations Branch Chief or the AgSAS Operations Unit Director will review your dispute. The resolution of a dispute results in an update to the departure within eFSAP.

## Acknowledge and View Inspection Findings

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

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

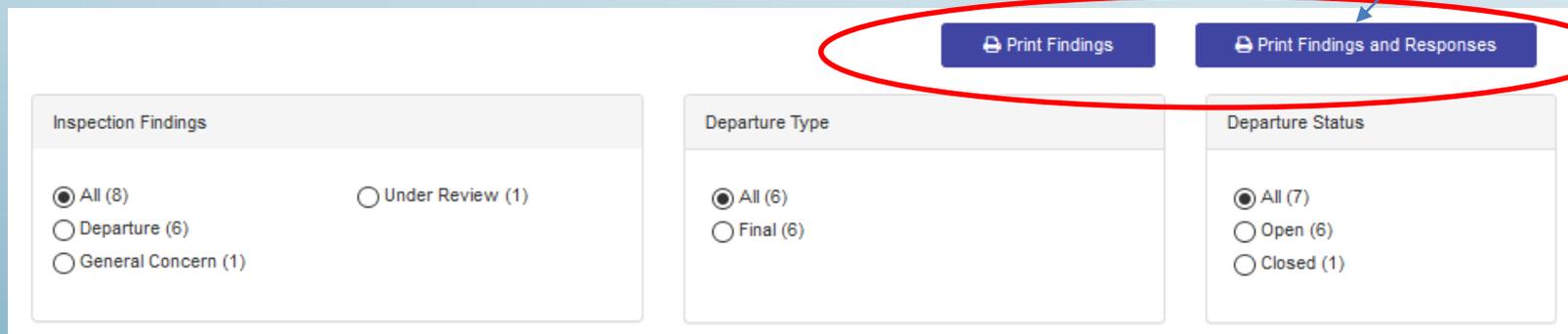
Go Back

Acknowledge and View Inspection Findings

# Inspection Resolution Page

The Inspection Resolution page lists findings by severity. Users can filter information by severity, status, departure or compliance determination. The status filter will show open departures, requests for information (RFI) and items under review.

Options to print



The screenshot displays the Inspection Resolution page interface. At the top, there are two blue buttons: "Print Findings" and "Print Findings and Responses". These buttons are circled in red, and a blue arrow points to them from the text "Options to print". Below the buttons are three filter panels:

- Inspection Findings:** Includes radio buttons for "All (8)", "Under Review (1)", "Departure (6)", and "General Concern (1)".
- Departure Type:** Includes radio buttons for "All (6)" and "Final (6)".
- Departure Status:** Includes radio buttons for "All (7)", "Open (6)", and "Closed (1)".

# View and Respond to Inspection Findings

On the Inspection Resolution Page, Responsible Officials (RO) and Alternate Responsible Officials (ARO) can view and respond to findings. Read-only users can view findings but not send the official response.

<b>Departure Type:</b> Final	<b>Severity:</b> Moderate	<b>Response Due:</b> 08/31/2018	<b>Repeat Departure:</b> No	<b>Status:</b> Open
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<b>CFR/Section</b> 9 CFR 121 - 17(a)	<b>Requirement</b> An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part.
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<b>Observation</b> At the time of inspection PI Sanders did not provide a record of his inventory.
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<b>Corrective Action:</b> Provide a copy of all inventory records for PI Sanders.
--

<b>Entity Response</b> <input type="text" value="Type your response here..."/> <input type="button" value="Save Draft"/> <input type="button" value="Send"/>
--

Response Due date is listed.

Entity Response

For items identified as amendment concerns, please respond through the amendment not the inspection module.



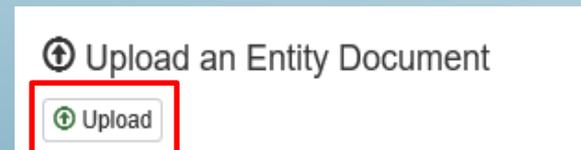
# Upload Inspection Documentation

RO/AROs and Read-only users can upload supporting documentation for an inspection from the Inspection Resolution page.

The screenshot shows a user interface for inspection resolution. At the top right, there are two blue buttons: "Print Findings" and "Print Findings and Responses". Below these are three filter panels:

- Inspection Findings:** Includes radio buttons for "All (8)", "Under Review (1)", "Departure (6)", and "General Concern (1)".
- Departure Type:** Includes radio buttons for "All (6)" and "Final (6)".
- Departure Status:** Includes radio buttons for "All (7)", "Open (6)", and "Closed (1)".

The upload section is at the bottom of the page. Click upload to begin.





# Upload Documentation

Identify document data and upload.

## Upload an Entity Document

### Step 1: Identify Document Data

\* = Required

**Non-Form \***

Inspection

**Inspection # \***

7142

32 characters remaining.

**Post-Inspection Document \***

Response to Final Departure

**Description**

(Must include Departure UID) \*

Inventory Records for UID 09-17-00100

103 characters remaining.

### Step 2: Select the Document

C:\Users\xjf2\Desktop\Up Browse...

•25 megabytes file size limit

Departure UID: 09-17-00100

•The UID can be found on the departure.

**Departure Type:**

Final

**Severity:**

Moderate

**Response Due:**

08/31/2018

**Repeat Departure:**

No

**Status:**

Open

Upload

Close

Avoid the following symbols in the file name: Tilde (~), Number sign (#), Percent (%), Ampersand (&), Asterisk (\*), Braces { }, Backslash (\), Colon (:), Angle brackets (< >), Question mark (?), Slash (/), Plus sign (+), Pipe (|), Quotation mark ("), and Comma (,).



# Response Notification

A notification will appear on the entity home page and the Inspection Details page when a response is submitted.

From responsible [Link](#)  Inspection #7142 UID:09-17-00100 has been responded to by the entity. 🕒 8/15/2018 10:48:07  
official4 on Inspections AM



# Inspection Details - Upload Center

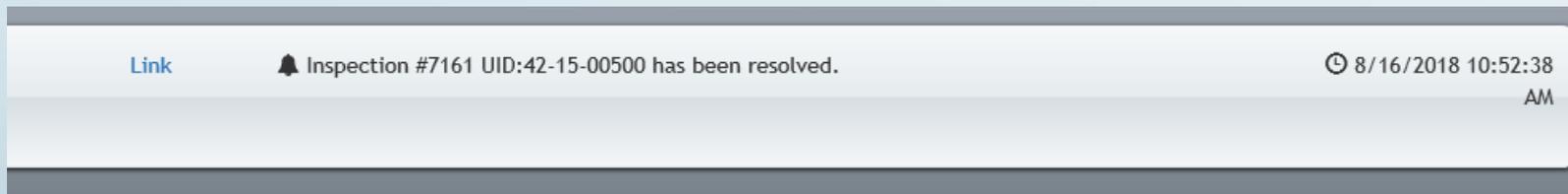
The uploaded files will appear in the upload center on the Inspection Details Page and on the entity home page.

Documents						Search	
	Original Name	Unique Document Identifier	Uploaded Date	Uploaded By	Docume..	Review Status	
	<input type="text"/>	<input type="text"/>	Start Date <input type="text"/> End Date <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
	PI Sanders Inventory...	I-7142-8/15/2018 10:55:53 AM-in...	8/15/2018 10:55:...	responsible.offi...	Inspection	Not Reviewed	



## Mark as Resolved Notification

If FSAP staff find the response sufficient and mark it as resolved, entity users will receive a notification.





## Additional Contact Information

- ❑ For technical assistance with eFSAP, or for assistance with the Secure Asset Management System (SAMS), please submit a help request ticket at [eFSAP Customer Support Request Form](#), email [eFSAPSupport@cdc.gov](mailto:eFSAPSupport@cdc.gov), or call 1 (877) 232-3322.
- ❑ For all other inquiries regarding your entity's registration, please contact your designated FSAP point of contact (POC).