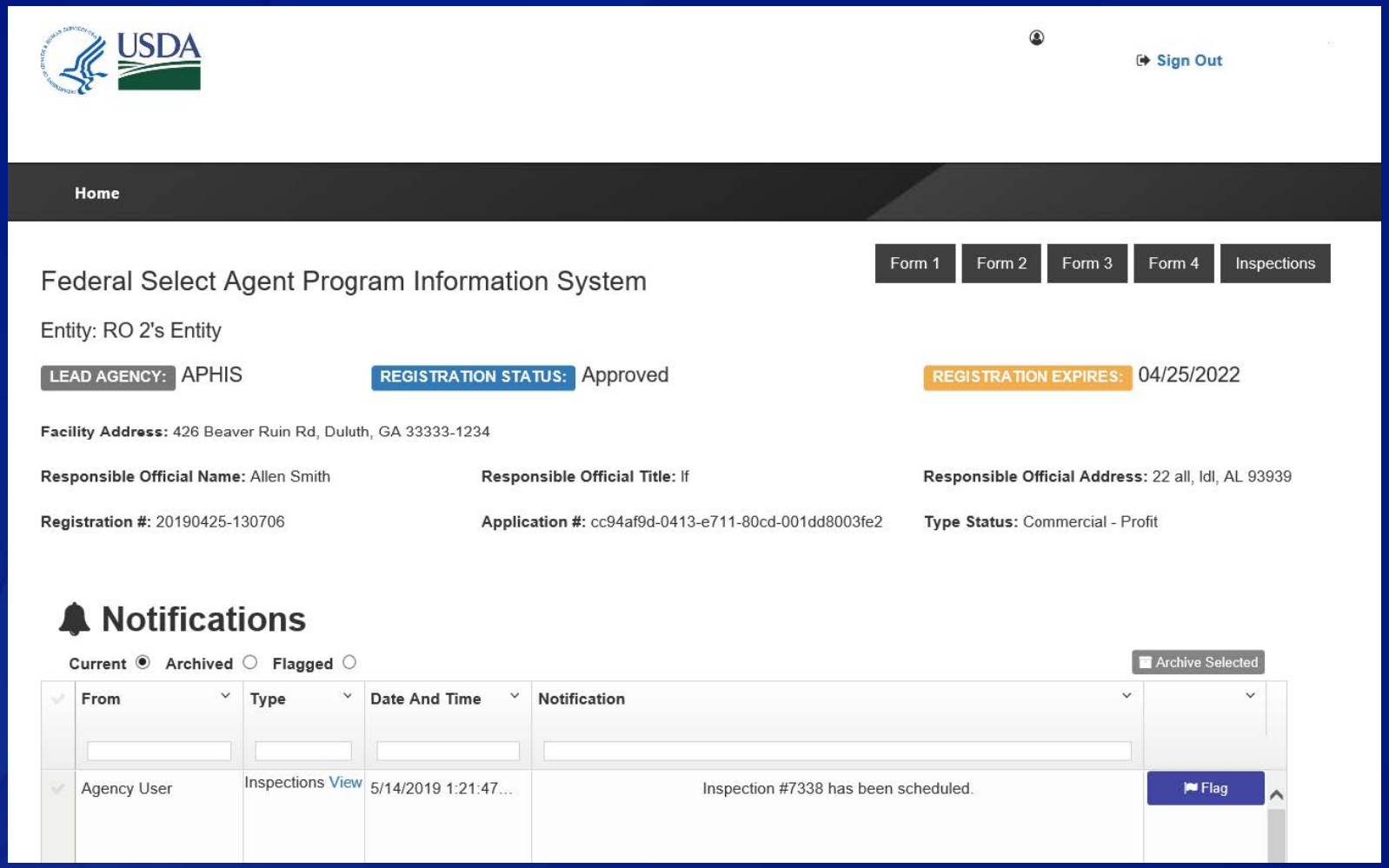
eFSAP and Entity Inspections: What Can We Expect?

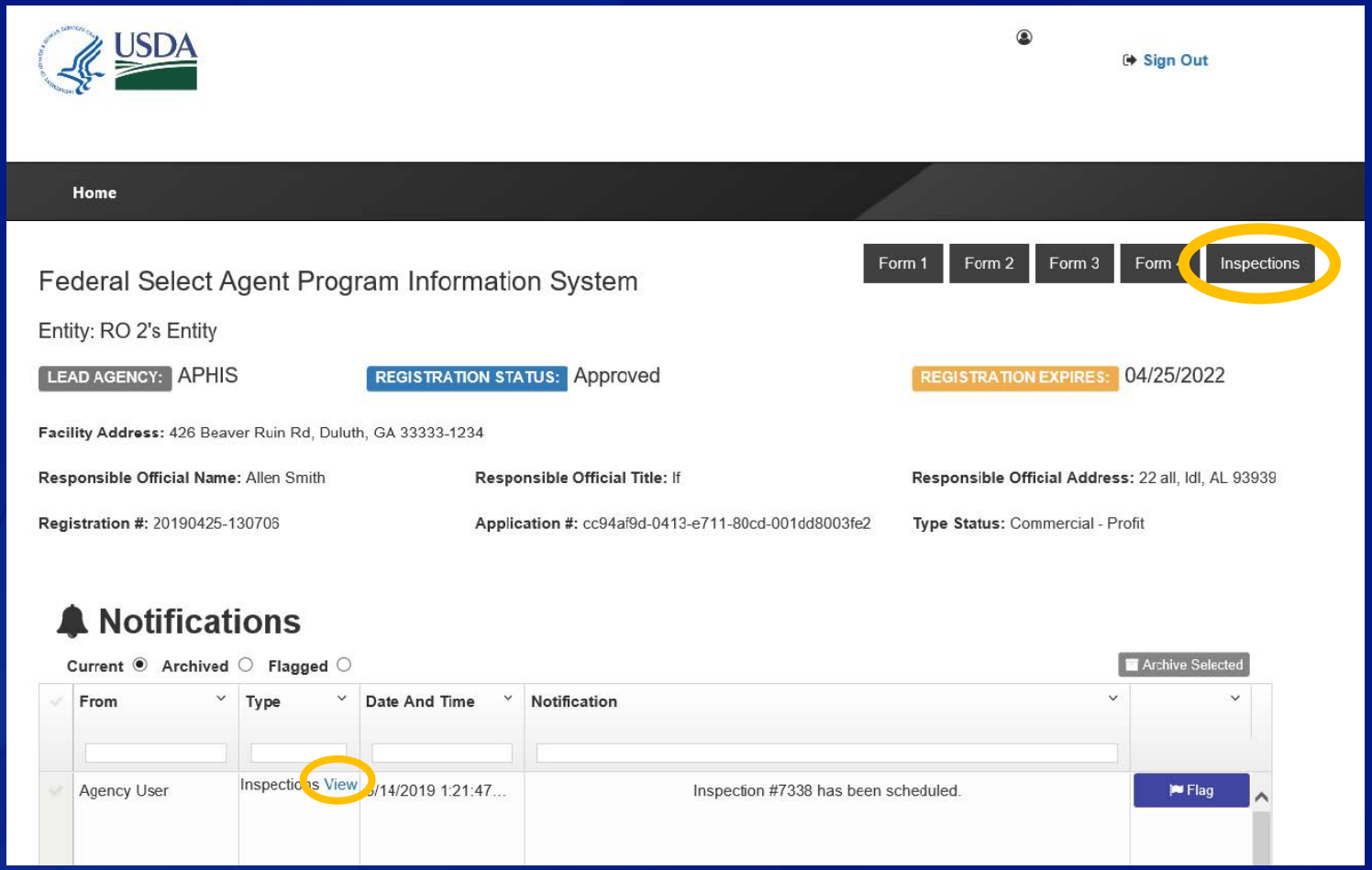
Federal Select Agent Program

Thursday, July 25, 2019

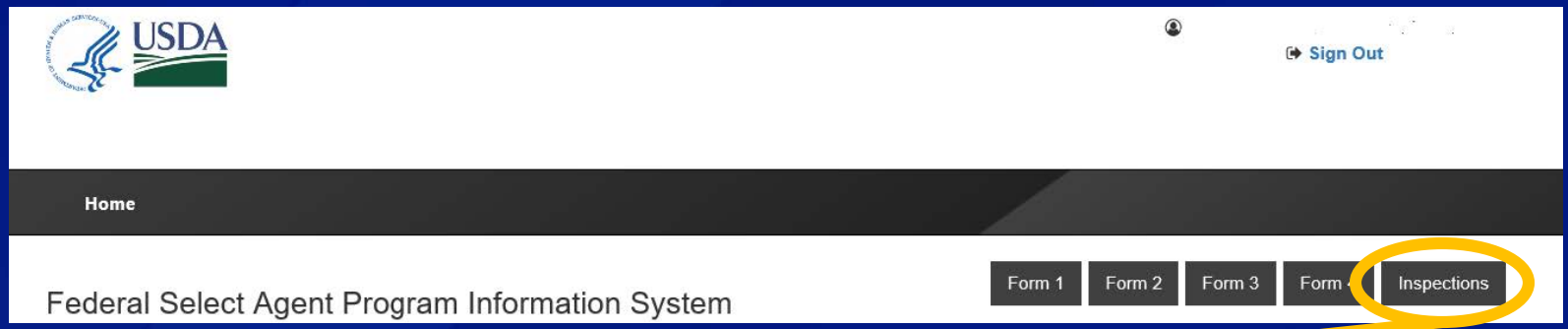
eFSAP Landing Page

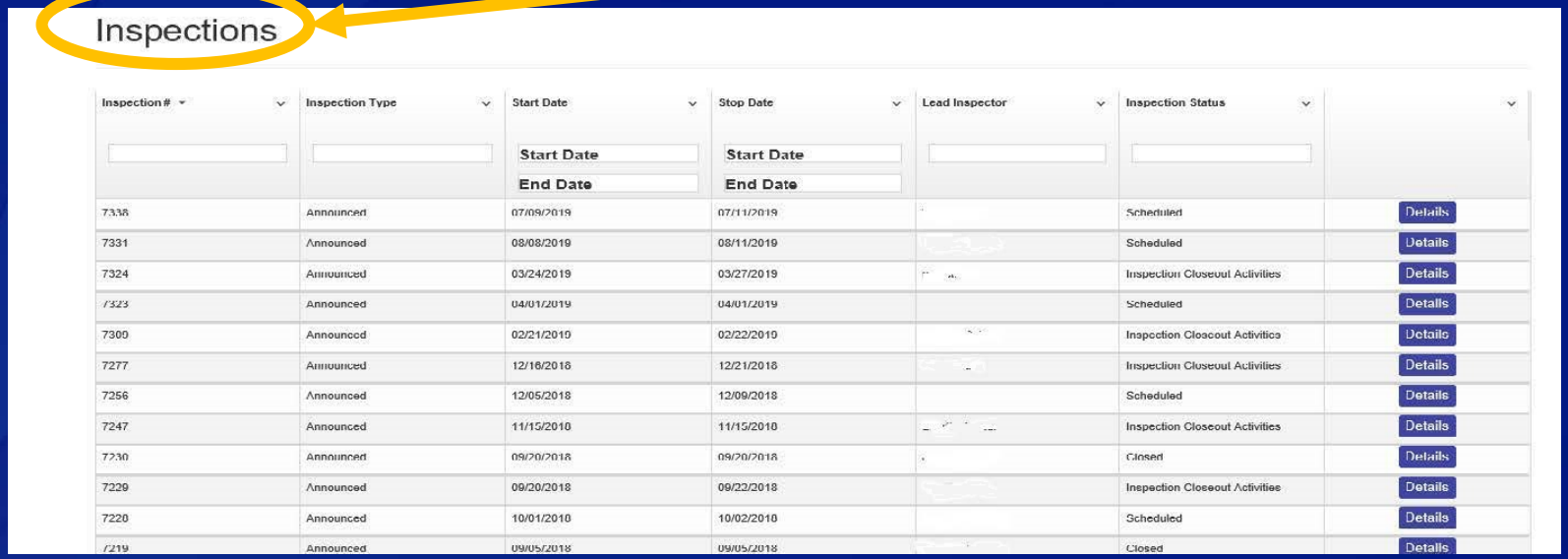


Navigating to Inspections

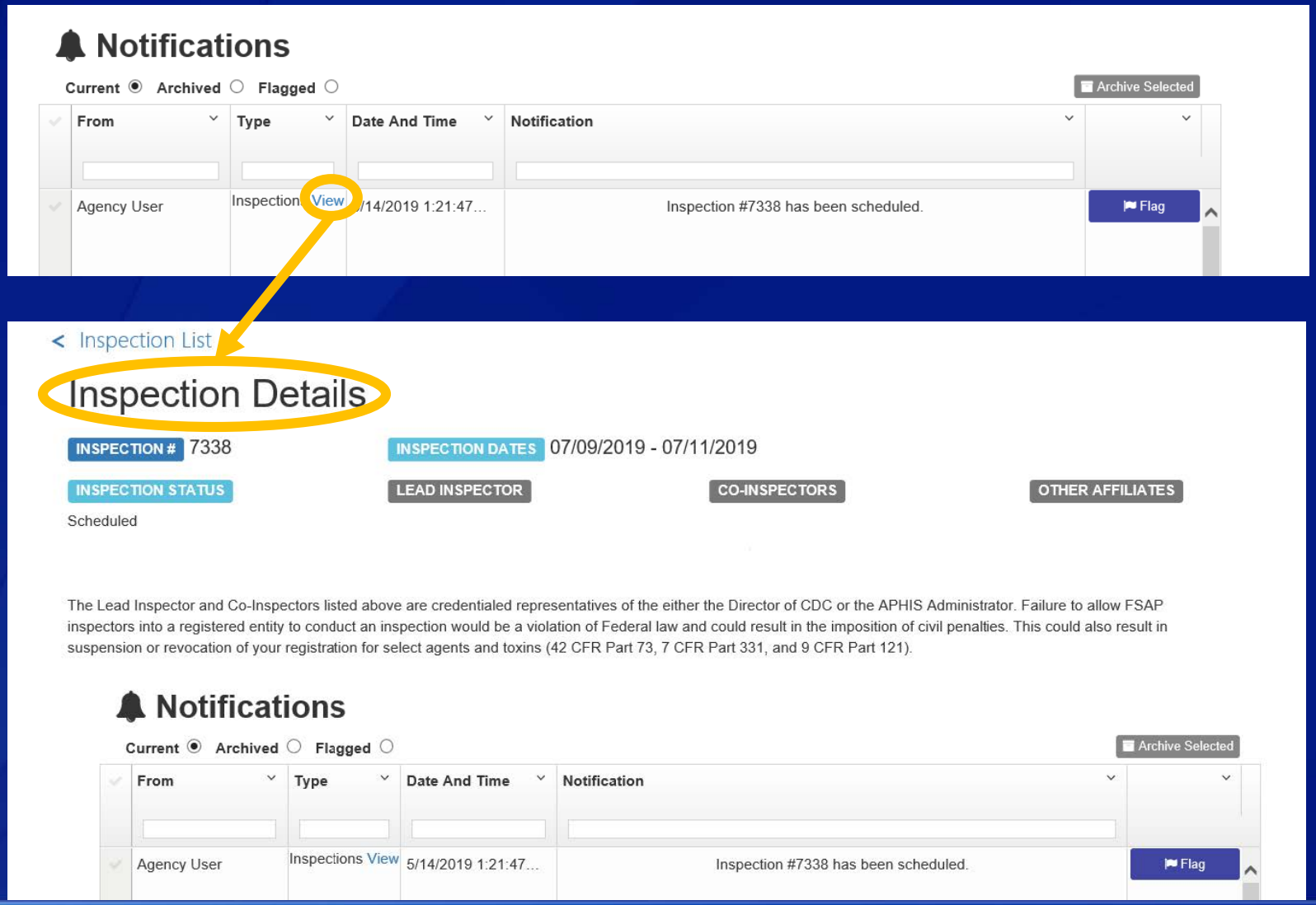


Navigating to Inspections

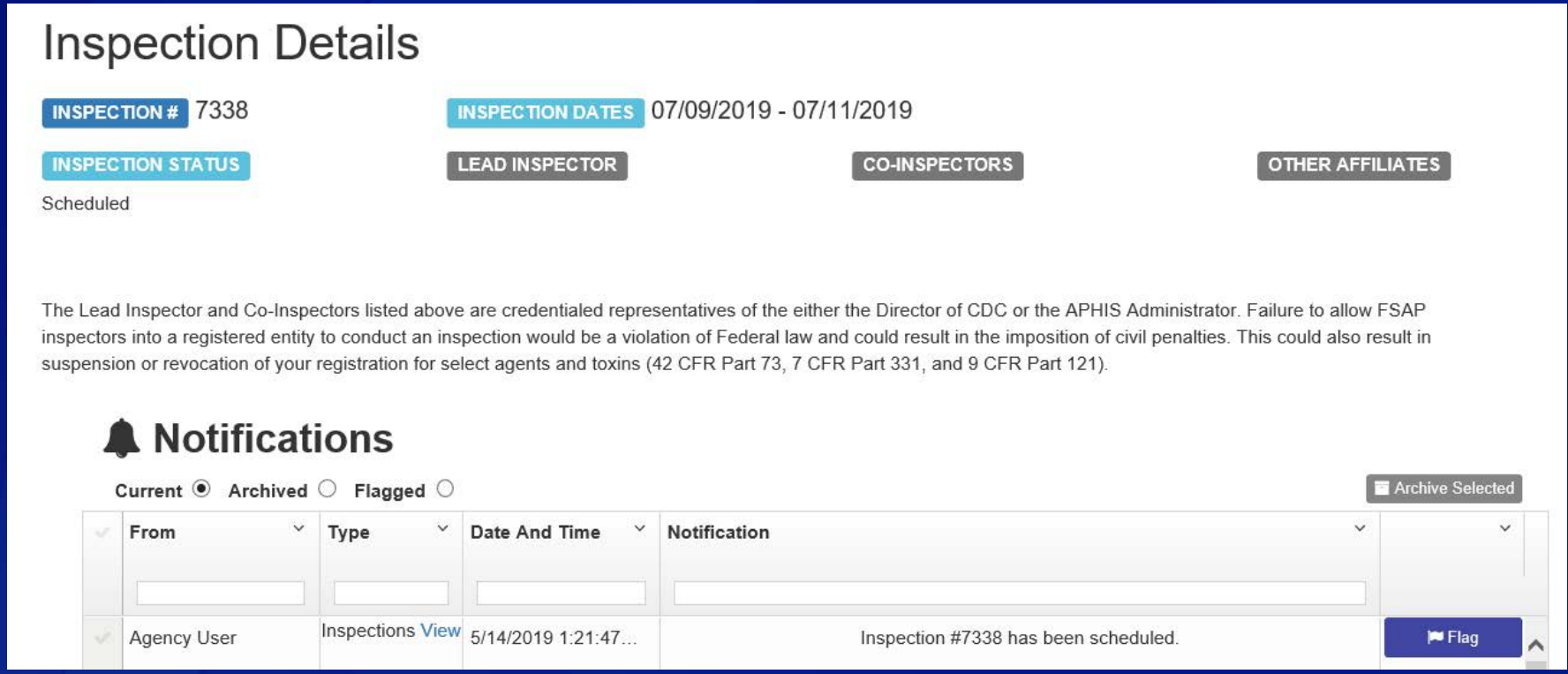




Navigating to Inspections

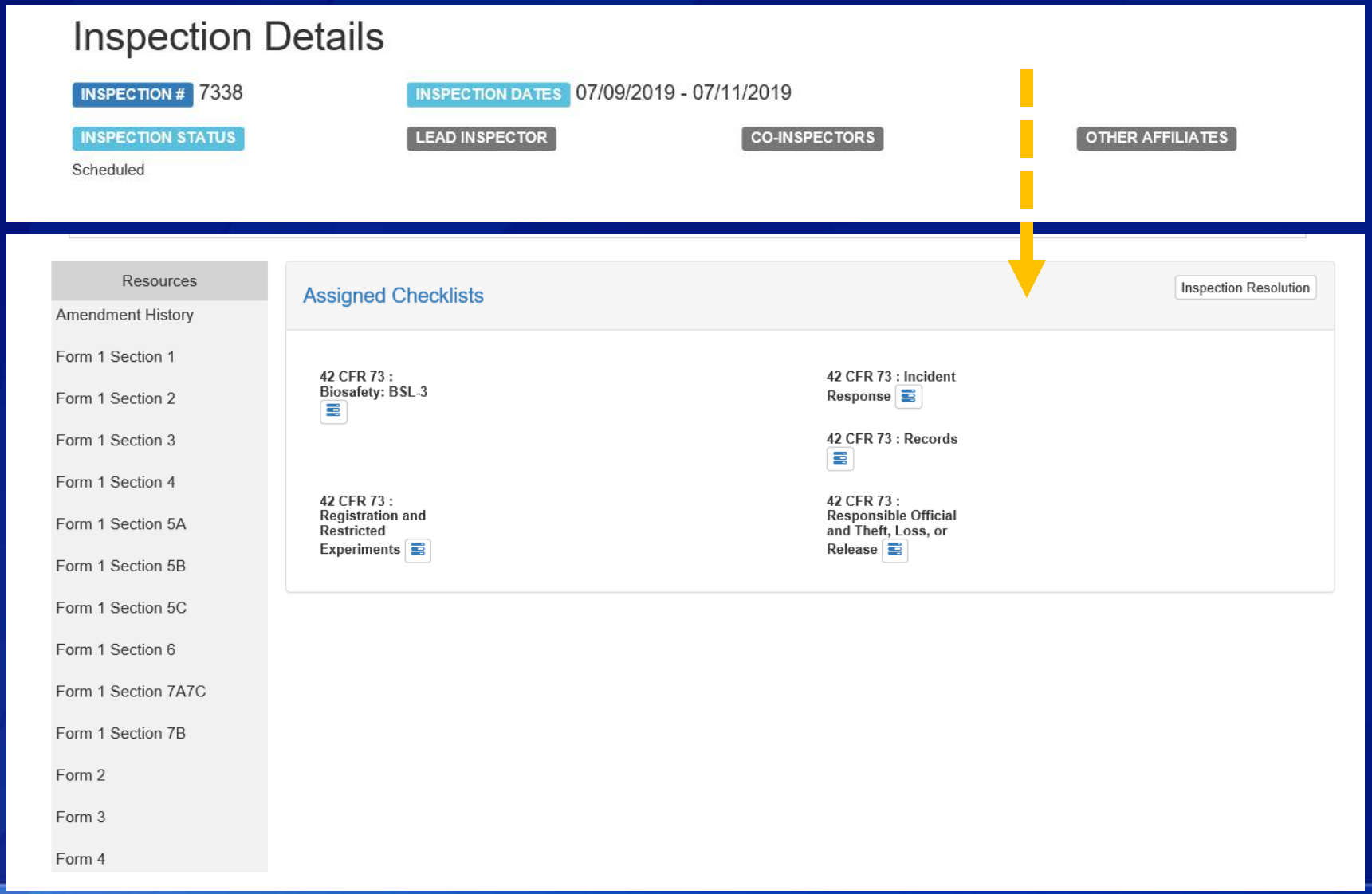


Inspection Details Page

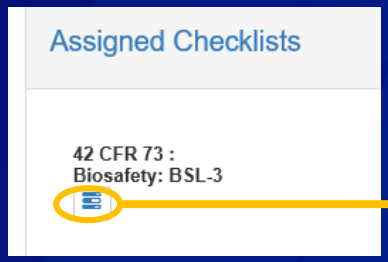


- Inspection number, dates, status and inspectors (including affiliates)
- Authorization for inspectors to conduct an inspection

Inspection Details Page



Inspection Checklist View



Inspections - Checklist

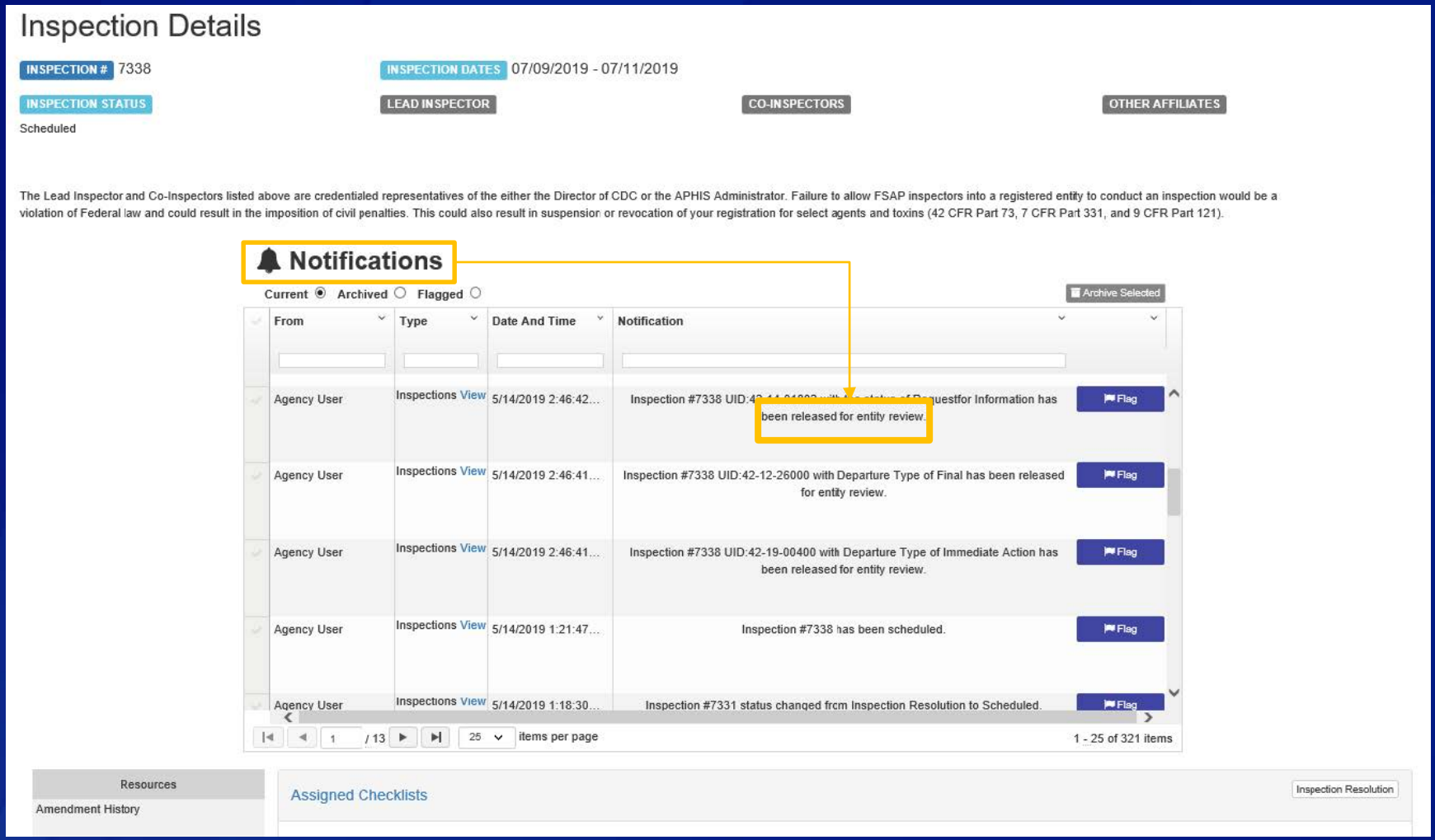
INSPECTION #: 7338 **CHECKLIST:** 42 CFR 73 - Biosafety: BSL-3

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.

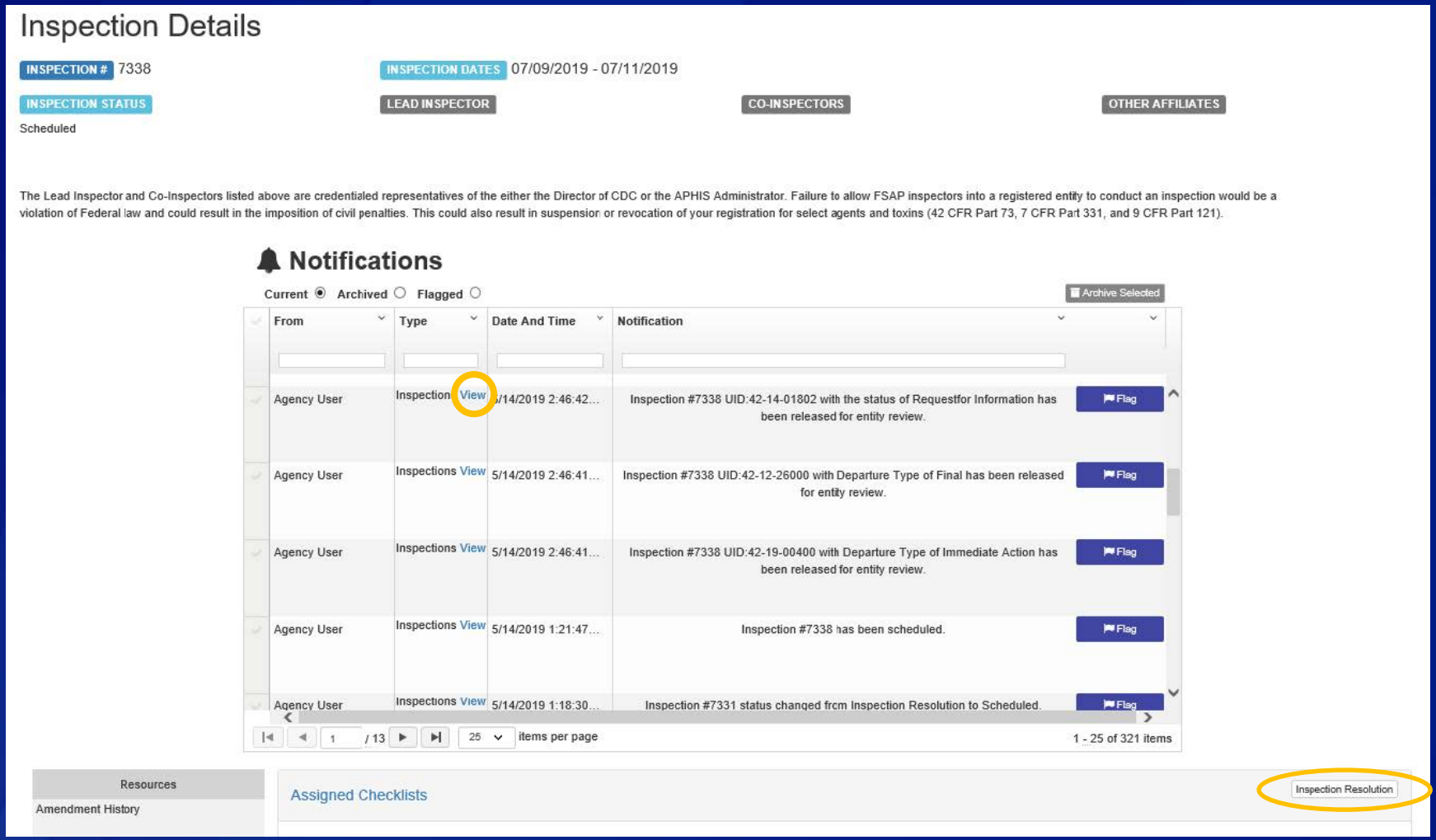
Return to Inspection Details

AFTER THE INSPECTION

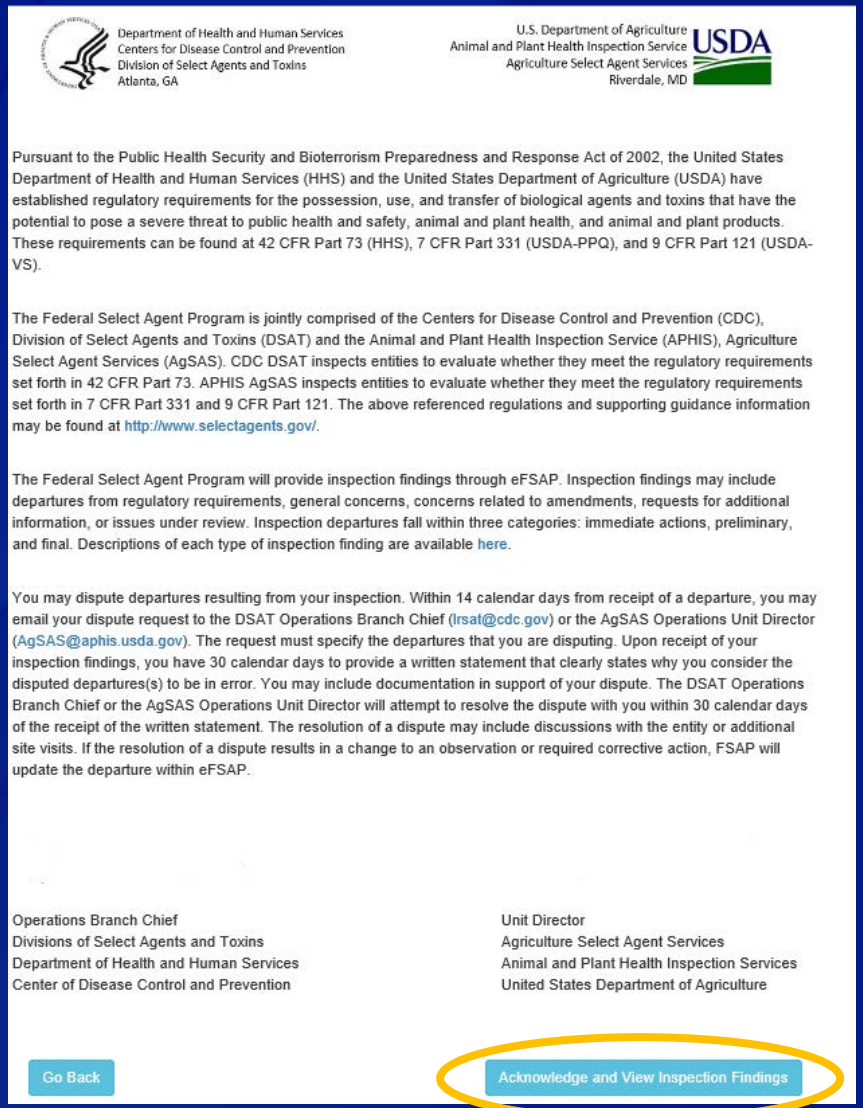
Notification of Released Findings



View Released Findings



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.

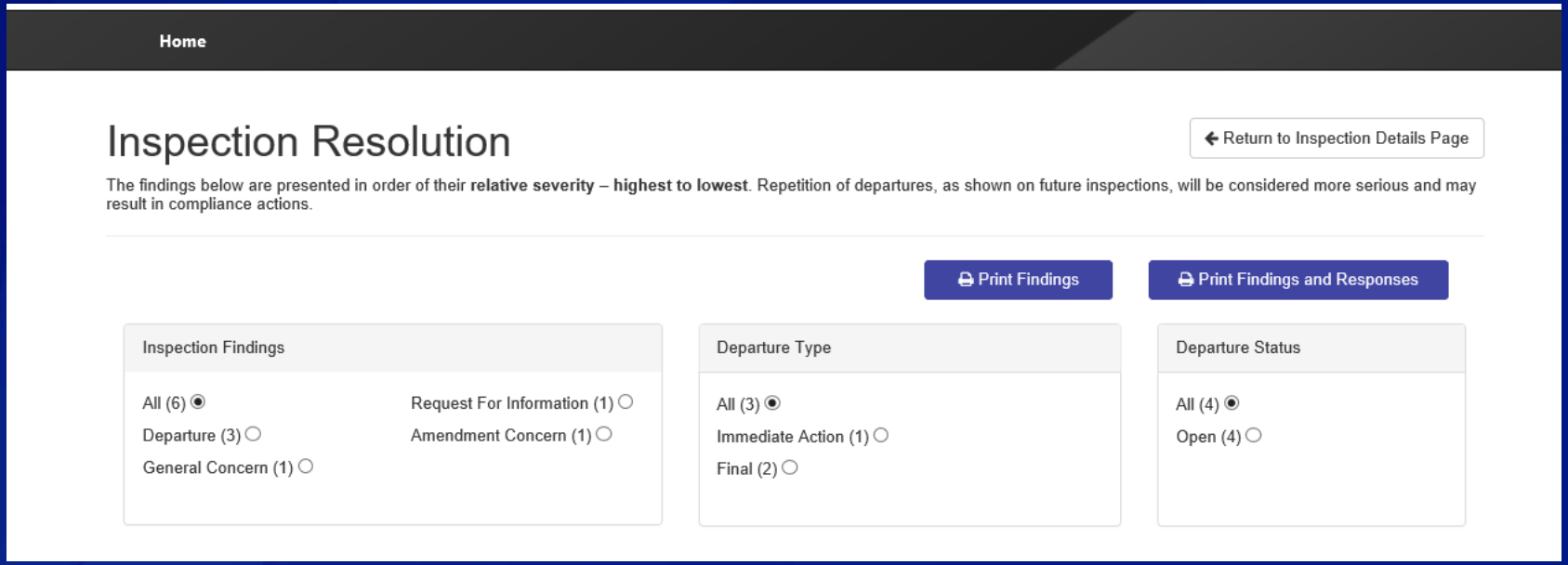
Operations Branch Chief
Divisions of Select Agents and Toxins
Department of Health and Human Services
Center of Disease Control and Prevention

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

Go Back

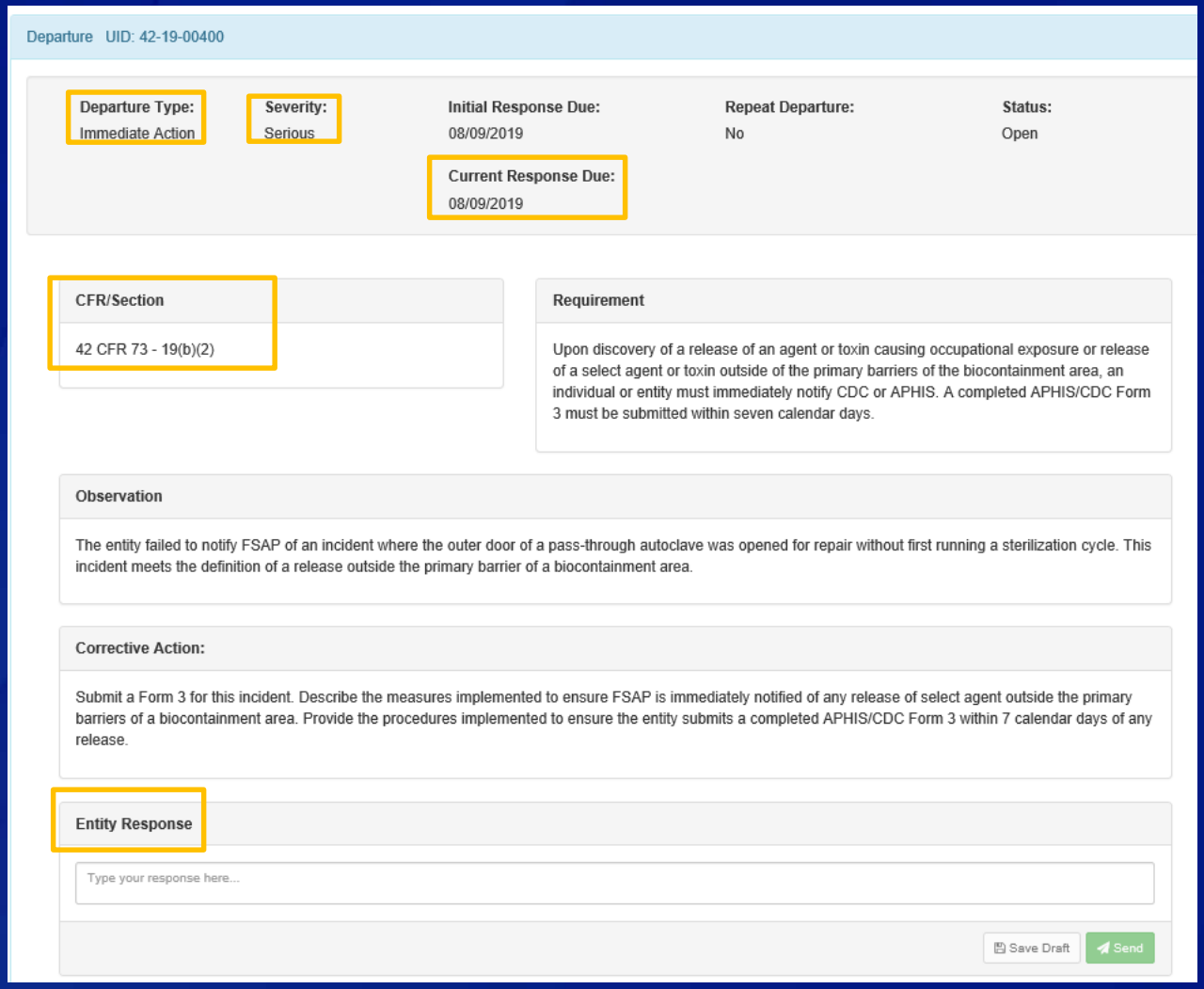
Acknowledge and View Inspection Findings

Inspection Resolution

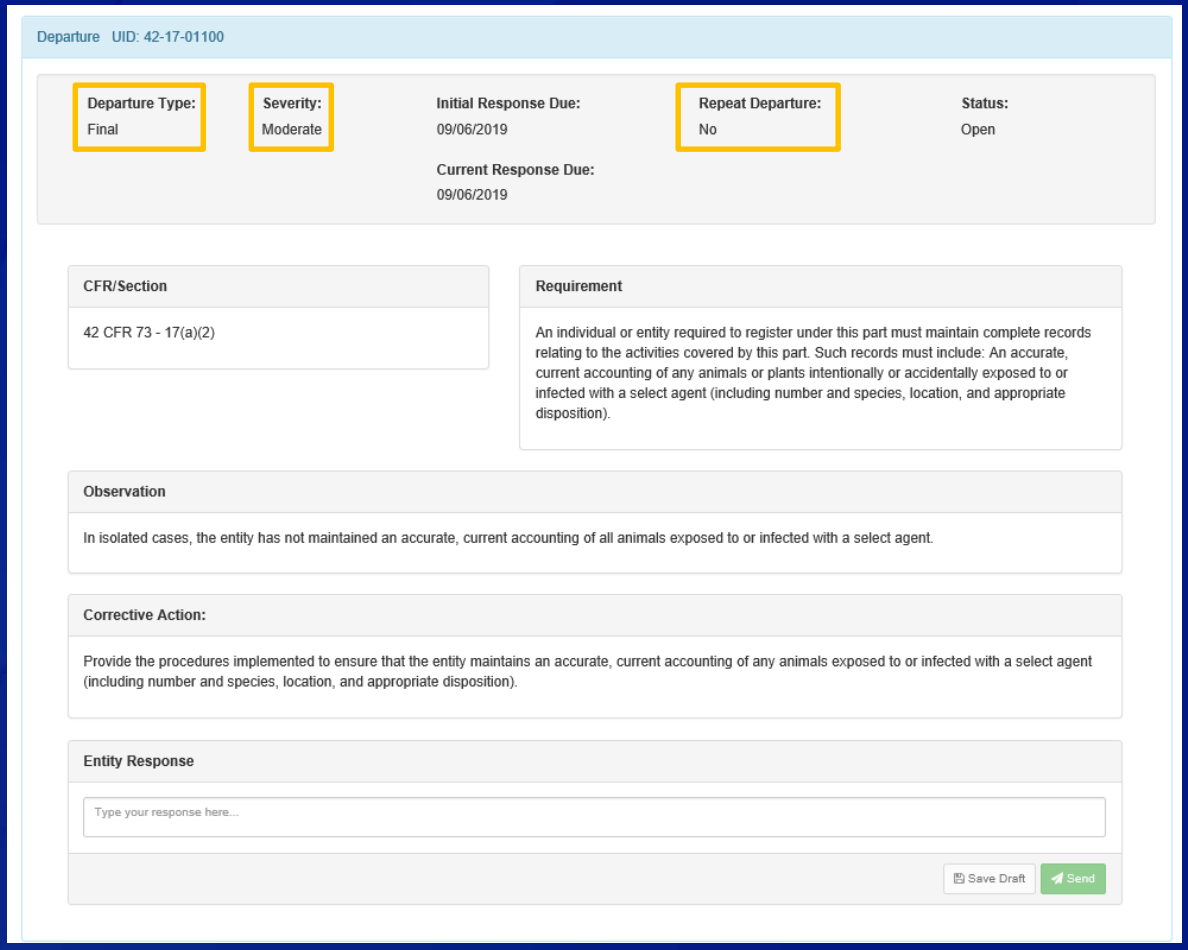


- **Print Capabilities**
- **Toggles:**
  - Inspection Finding
  - Departure Type
  - Departure Status

Immediate Action Release



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:

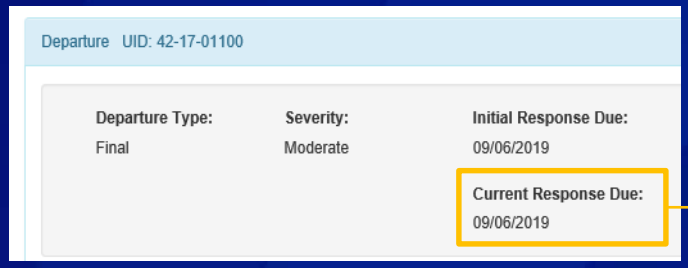
Provide the procedures implemented to ensure that the entity maintains an accurate, current accounting of any animals exposed to or infected with a select agent (including number and species, location, and appropriate disposition).

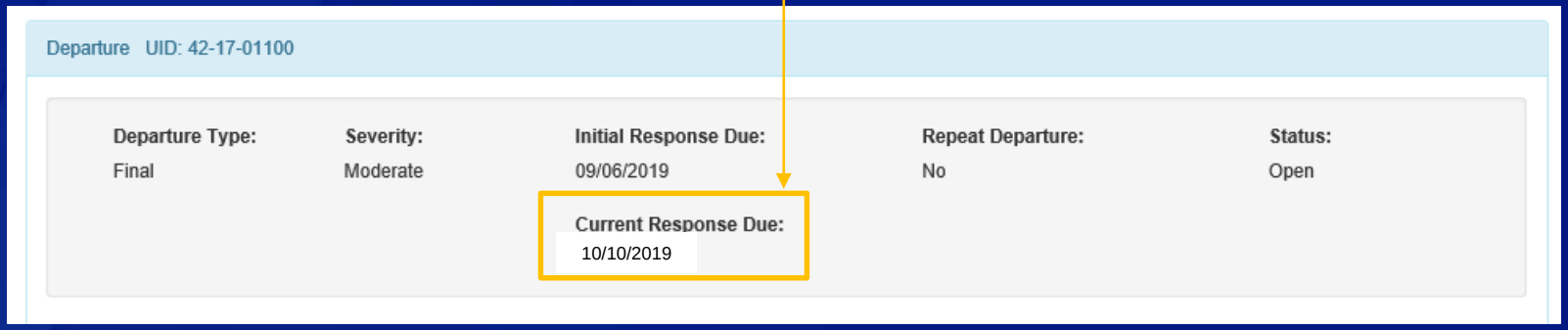
Entity Response

Type your response here...

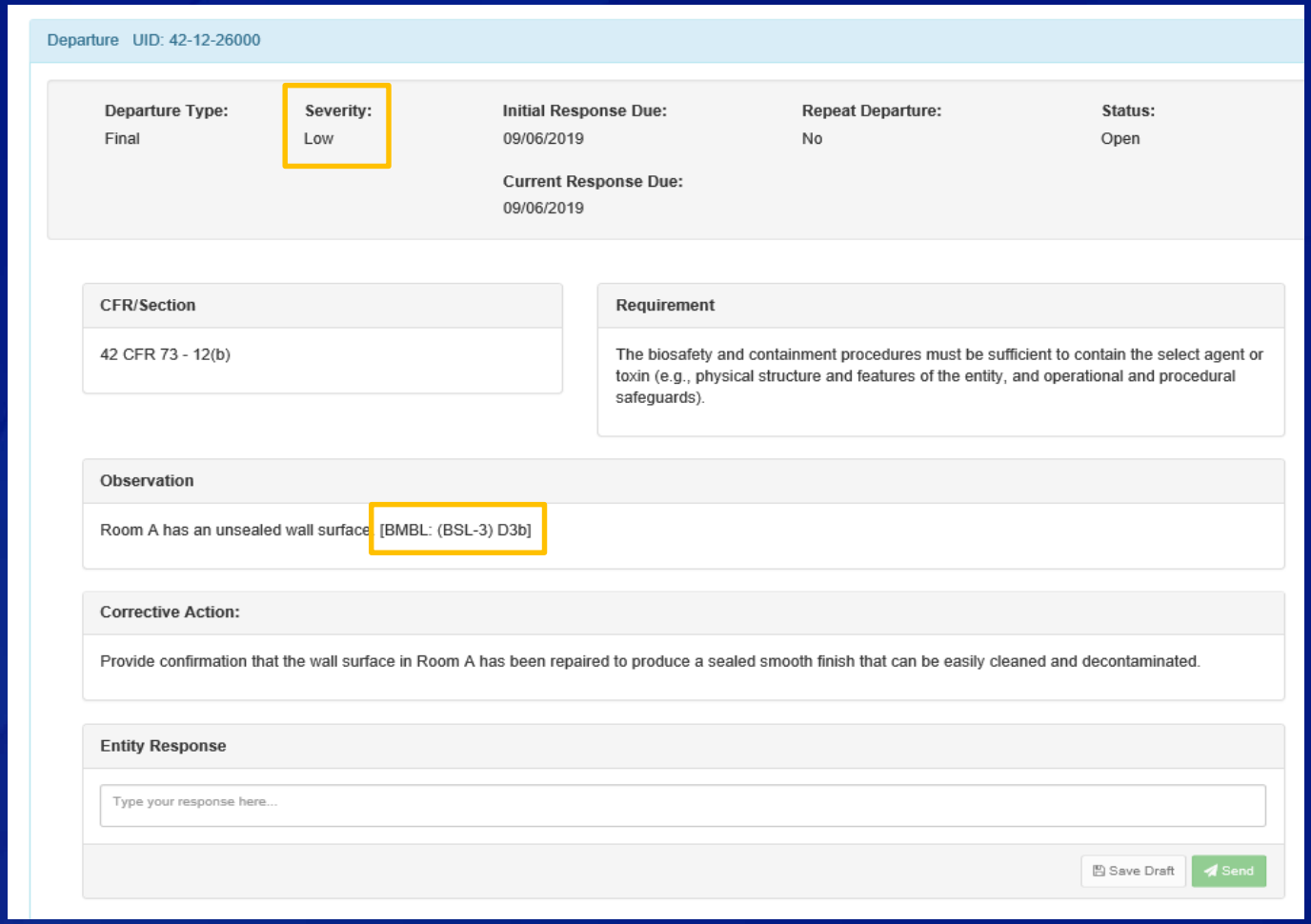
Save Draft | Send

Change in Response Due Date

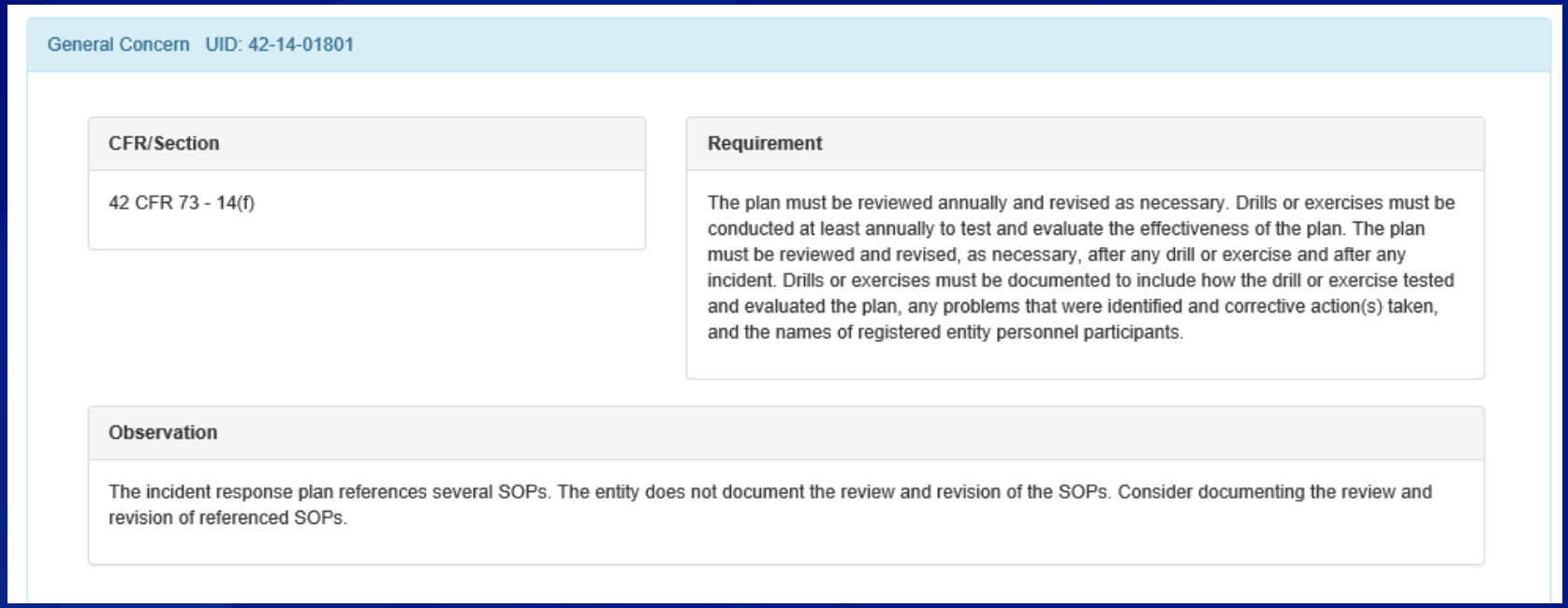




Low Severity Departure



General Concerns



General Concern UID: 42-14-01801

CFR/Section

42 CFR 73 - 14(f)

Requirement

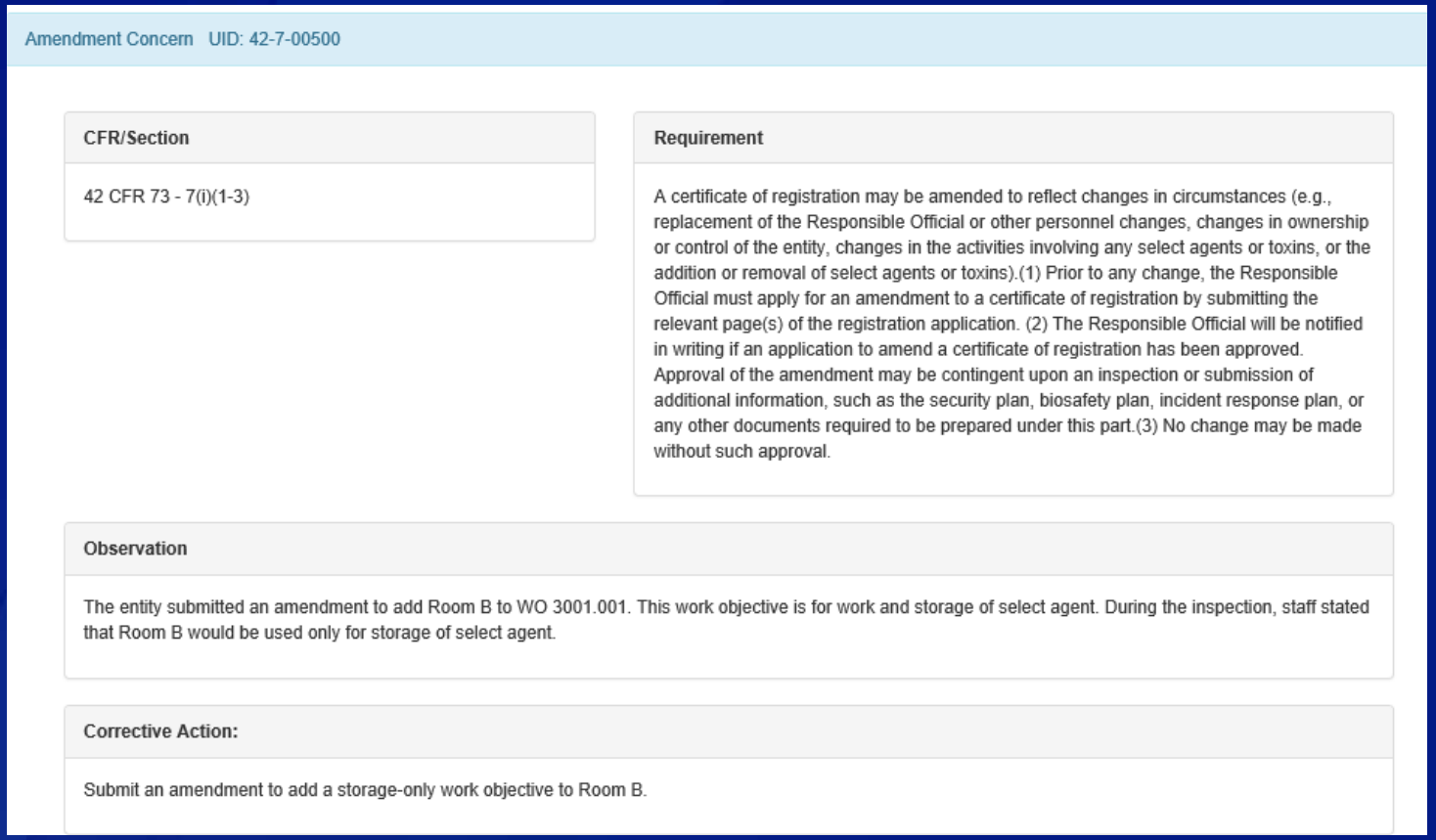
The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be 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

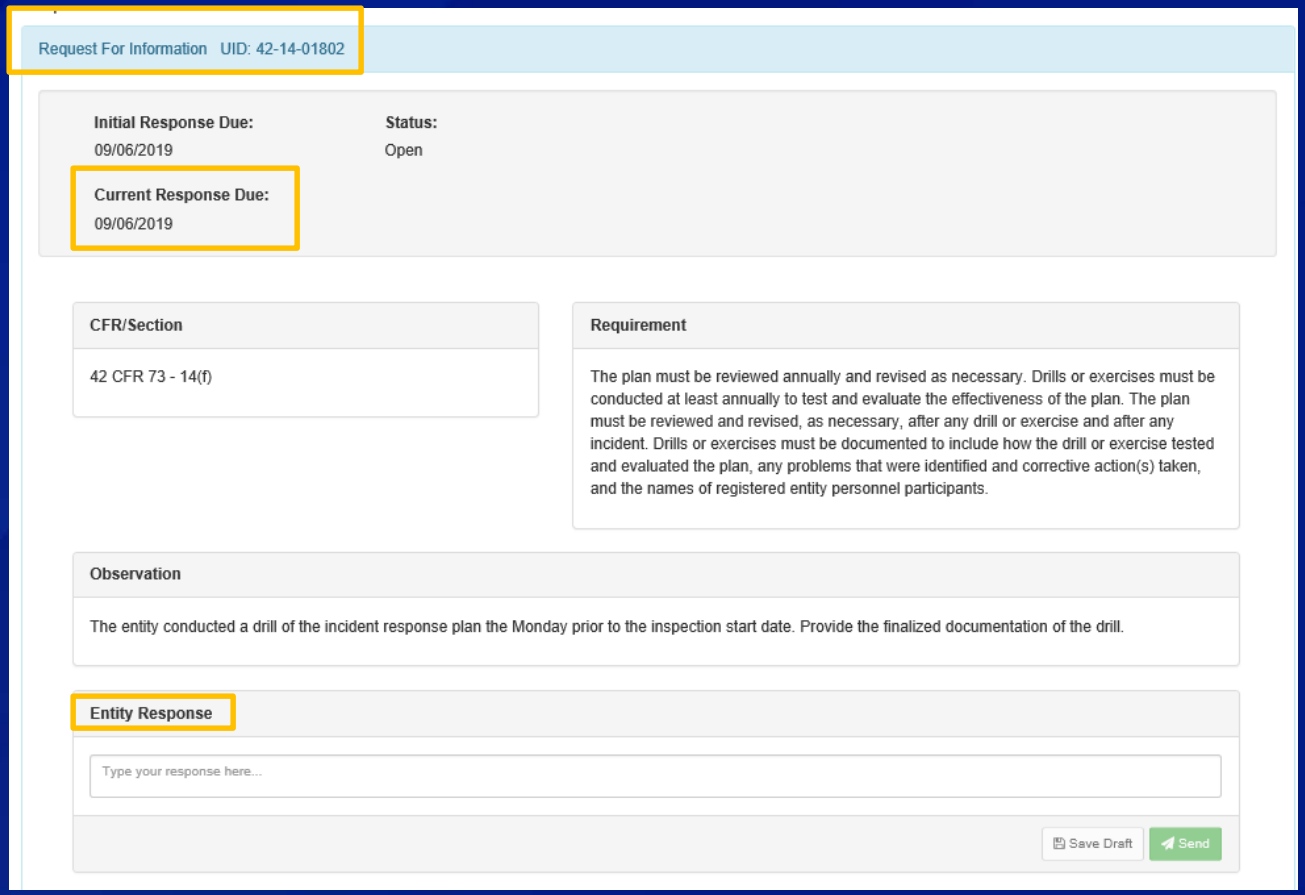
The entity submitted an amendment to add Room B to WO 3001.001. This work objective is for work and storage of select agent. During the inspection, staff stated that Room B would be used only for storage of select agent.

Corrective Action:

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

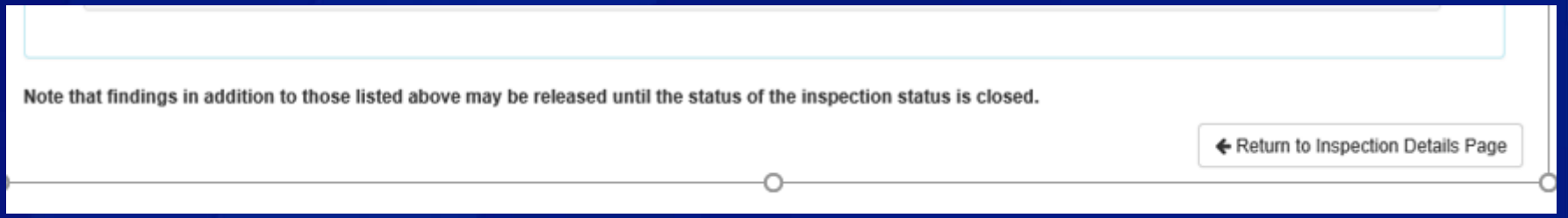
- **Not considered part of the inspection**
  - No response required in the inspection module
- **Corrective action is addressed within the pending amendment**

Request For Information (RFI)



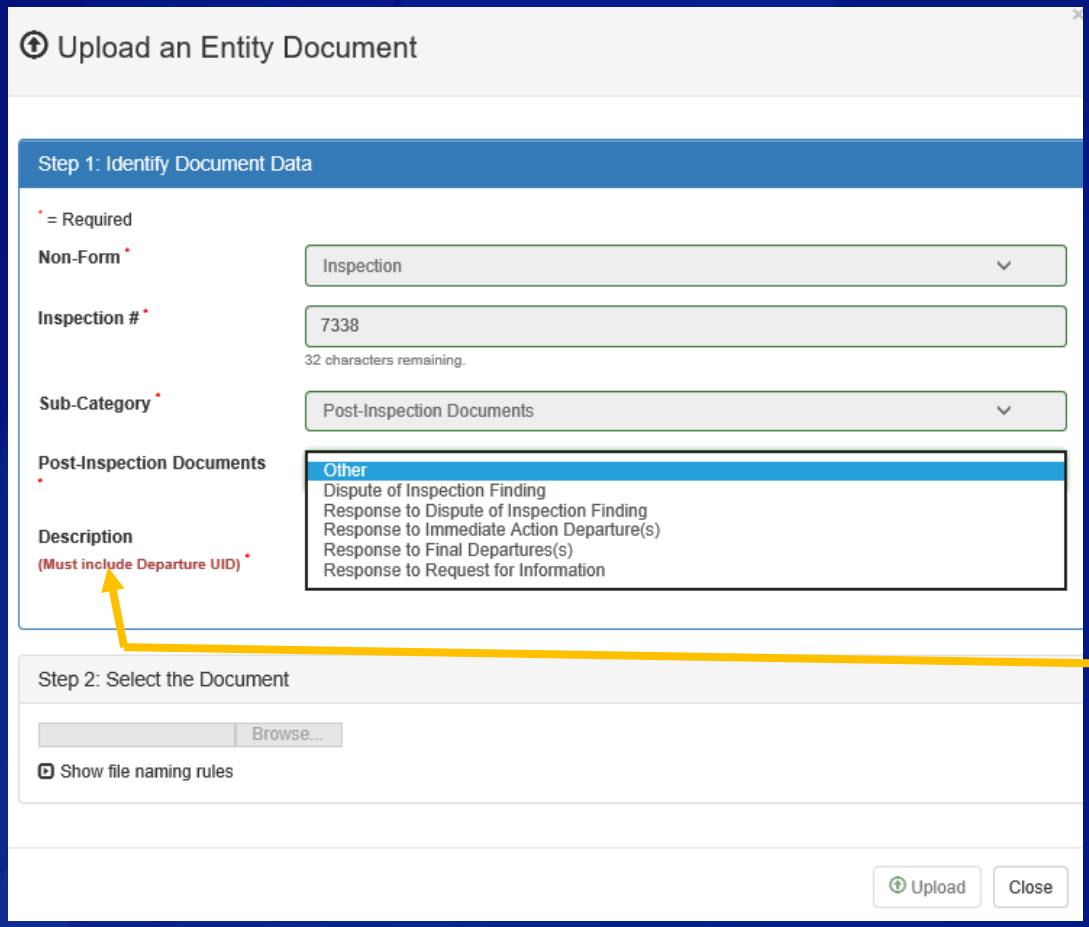
- RFI
- No Severity
- Due Date
- Response
  - FSAP will make a final compliance determination upon the entity's submission of data

Note about Released Findings

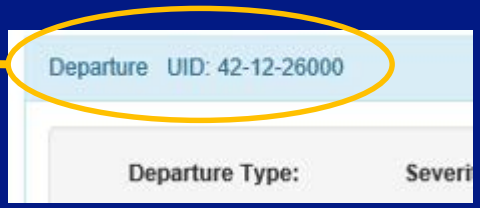


- **Findings may be released at various times depending upon the type**
  - Example: Immediate action items are released prior to other severities
  - Example: Response to an RFI could lead to a new compliance determination
- **Check the notification board for any additional items**
- **Items will not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

Uploading Responses

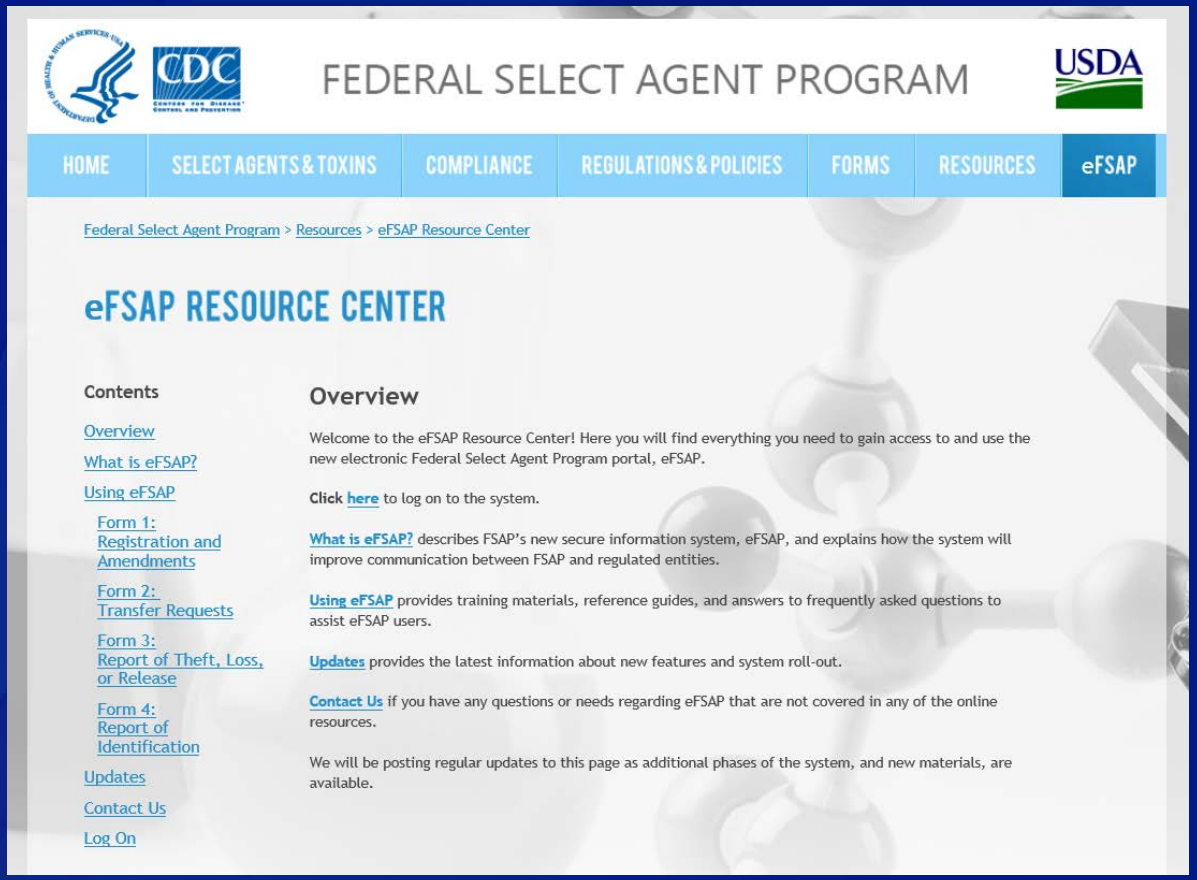


- The upload center is located at the bottom of the page
- Must include the Departure UID in the description



eFSAP Resource Center

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



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: lrsat@cdc.gov or 404-718-2000

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