Electronic Federal Select Agent Program (eFSAP) Information System

Inspection Module Updates

February 2022

eFSAP Inspection Module Updates

Hybrid Inspections

- **eFSAP now links an initial remote inspection with an on-site follow-up visit**

- **Follow-up inspections are denoted with a ".1" appended to the original inspection number**

- **Inspector's checklists alert them to items previously assessed remotely to reduce redundance during the follow-up visit**

eFSAP Inspection Module Updates

Departures and Concerns from biosafety requirements now display the specific work objective(s) to which the findings are related

- **Provides greater transparency on context of departures and concerns**

- **Allows entities to identify specific activities or Principal Investigators (PIs) that may need additional oversight or support**

General Concern   UID: 42-12-26000

Assigned Work Objective(s): WO002121.001.001

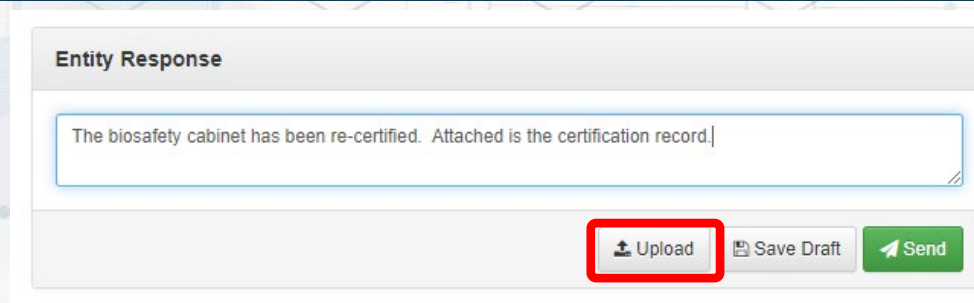| CFR/Section	Requirement
42 CFR 73 - 12(b) - Biosafety: BSL-3	The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

Observation

Prior to commencing select agent work, ensure that the biosafety cabinet has been certified.

eFSAP Inspection Module Updates

Enhancements to Uploads for Supporting Documentation

- **Previously, entities wishing to provide supporting documentation with their inspection responses had to manually enter the checklist unique identifier (UID) to which the document applied**

- **Now, each departure or request for information contains an "upload" button that automatically associates the document with the correct UID**

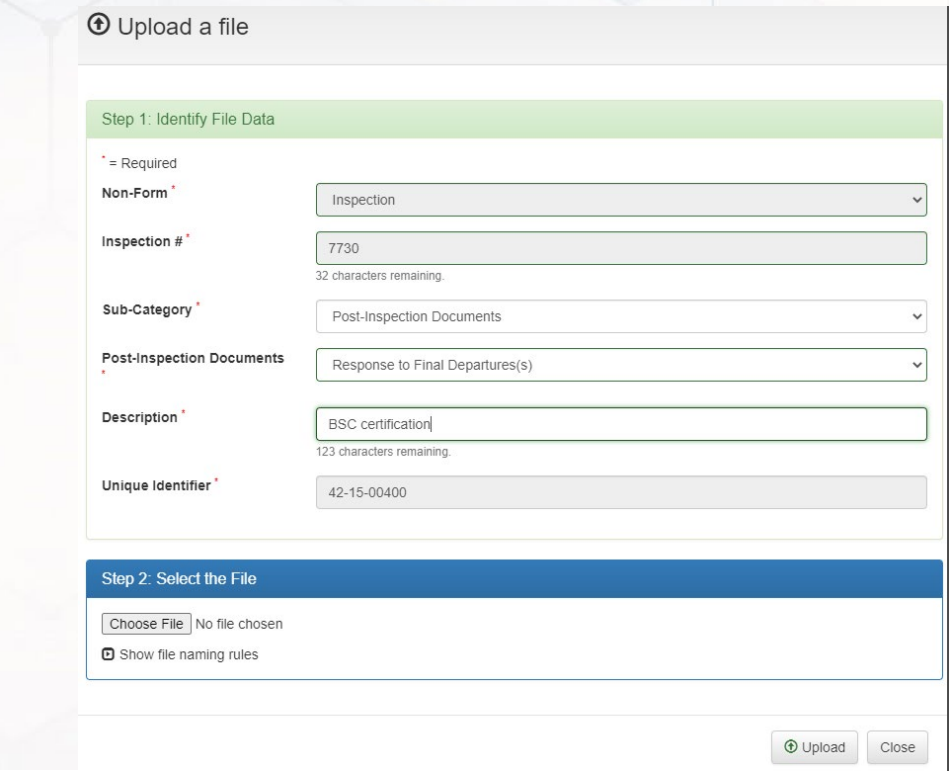- **<u>Note:</u> Entity users must send their text response before the Upload button is available**

Entity Response

The biosafety cabinet has been re-certified. Attached is the certification record.

⬆ Upload   🖫 Save Draft   ⬀ Send

New "upload" button

⬆ Upload a file

Step 1: Identify File Data

* = Required

Non-Form *   Inspection

Inspection # *   7730

32 characters remaining.

Sub-Category *   Post-Inspection Documents

Post-Inspection Documents *   Response to Final Departures(s)

Description *   BSC certification

123 characters remaining.

Unique Identifier *   42-15-00400

Pre-populated checklist UID

Step 2: Select the File

Choose File | No file chosen

⊡ Show file naming rules

⊕ Upload   Close

eFSAP Inspection Module Updates

New "Closed Conditionally" status for inspections and departures

- **eFSAP supports a new "Closed Conditionally" status for inspections and departures**

- **Inspection will have the new "Closed Conditionally" status if one or more departures is closed conditionally**

- **No further action is needed at this time from the entity, but** may be necessary in the future to fully close the requirement

Inspections

Inspection # ▾	Inspection Type	Start Date	Stop Date	Lead Inspector	Inspection Status		
		Start Date / End Date	Start Date / End Date				
7761	Announced	08/11/2021	08/11/2021	Branch Chief	Closed Conditionally	Details	History
7760	Unannounced	08/11/2021	08/11/2021	Branch Chief	Inspection Closeou...	Details	History

New Inspection Status

Departure   UID: 42-12-39700

Departure Type:	Severity:	Initial Response Due:	Repeat Departure:	Status:
Final	Low	08/14/2021	No	Closed Conditionally
		Current Response Due: 08/14/2021		

Assigned Work Objective(s): WO002045.001.003

New Departure Status

CFR/Section	Requirement
42 CFR 73 - 12(b) - Biosafety: General	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

Did not provide evidence that BSCs were certified for the year 2020.

eFSAP Inspection Module Updates

Closed Conditionally Status for Departures

- **FSAP will provide a justification when a departure is closed conditionally**

New Status for departures

Agency response with justification

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 <u>eFSAP Customer Support Request Form</u>, email <u>eFSAPSupport@cdc.gov</u>, or call 1 (877) 232-3322.**

- **For all other inquiries regarding your entity's registration, please contact your designated FSAP point of contact (POC).**

www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins
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404-718-2000

APHIS Contact Information
Division of Agricultural
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