

2021 Federal Select Agent Program (FSAP)
Responsible Official Webinar Series

APHIS/CDC Form 3

Updates and Common Concerns

October 13, 2021



APHIS/CDC Form 3 – Report of a Release/Loss/Theft of a Select Agent or Toxin

Overview of Presentation

- Summary of APHIS/CDC Form 3 changes
- Most common concerns
 - Incident date
 - Immediate notification
 - Uploading response to **Request for Information (RFI)** letter
 - **Return to Agency** button
- Scenarios (3)



Summary of Form 3 Changes



Summary of APHIS/CDC Form 3 Changes

- **Incident Information:**

- Question B6:
Recombinant agent
selection box

Section B - INCIDENT INFORMATION

1. Date and Time of Incident:

Date:

05/07/2021

Time:

02

15

PM

2. Date of Immediate Notification:

05/07/2021

3. Type of Immediate Notification:

- Email
- Fax
- Telephone
- eFSAP

4. Location of Incident:

123 - D Test - Work Only

123 - D Test - Work Only

231 of 255 characters left

5. Name of Select Agent or Toxin:

6. Strain Designation:

- Recombinant
- PPQ Agent

Quantity

Unit (vial, plates, etc.)

Name of Select Agent or Toxin

Francisella tularensis

Strain Designation of Select Agent or Toxin

KY99-3387

- Recombinant
- PPQ Agent

Quantity

1 vial

+ Add Row

Delete



Summary of APHIS/CDC Form 3 Changes

- **Incident Information:**

- Question B8: Order change
- Question B9: 'None' selection removed
- Question B10: Containment levels removed
 - Recombinant (NIH)
 - Large animal (N)
 - Large scale (LS)
 - Plant pathogen (PPQ)

The screenshot displays a portion of the APHIS/CDC Form 3 interface. Three sections are highlighted with red boxes:

- 8. Type of Incident:** This section contains three radio button options: Release/ Potential Exposure (After completing Section B. Go to Section C), Loss (After completing Section B. Go to Section D), and Theft (After completing Section B. Go to Section E).
- 9. Severity of the incident:** This section features a dropdown menu with a blue highlight on the selected option. The visible options are: --Select an option--, Negligible, Low, Moderate, and High.
- 10. What Biosafety Level did the incident occur?:** This section contains two columns of radio button options. The left column includes BSL2, BSL3, BSL4, ABSL2, ABSL3, BSL3Ag, and ABSL4. The right column includes ACL2, ACL3, ACL4, Storage Area, and Other. Below the 'Other' option is a text input field labeled 'Describe Other'.

Below these sections are two more questions:

- 11. Is this incident associated with an APHIS/CDC Form 2:** Yes, No
- 12. Is this incident associated with an APHIS/CDC Form 4:** Yes, No



Summary of APHIS/CDC Form 3 Changes

- **Report of a Release:**

- Question C1: Accidental addition of 'Release' box selection
- Question C2: 'Yes' or 'No' response option
- Question C4b: Sub-question for the number of laboratory staff

Section C - REPORT OF RELEASE

1. Type of Potential Exposure/Release(choose all that apply):

- | | |
|--|--|
| <input type="checkbox"/> Animal bite/scratch | <input type="checkbox"/> Equipment/mechanical failure |
| <input type="checkbox"/> PPE failure | <input type="checkbox"/> Package damaged in transit/ complete B-11 |
| <input type="checkbox"/> Spill | <input type="checkbox"/> Unintended Animal/Plant Pathogen |
| <input type="checkbox"/> Needle stick/Sharps | <input type="checkbox"/> Work performed on an open bench |
| <input checked="" type="checkbox"/> Release | <input type="checkbox"/> Other |
| <input type="checkbox"/> Decontamination failure | |
| <input type="checkbox"/> Inactivation failure | |

2. Was there a release outside containment barriers?

- Yes
 No

If yes, (choose all that apply)

- Release outside primary containment (e.g., biosafety cabinet)
 Release beyond secondary containment (e.g., laboratory)
 Release outside all containment barriers of the facility (e.g., resulting in possible agricultural/environmental/public health threat)

3. What PPE was worn at the time of the Incident? (choose all that apply)

- | | |
|--|---|
| <input checked="" type="checkbox"/> Hand Protection (e.g., gloves) | <input type="checkbox"/> Foot Protection (e.g., booties, shoe covers) |
| <input type="checkbox"/> Head Protectors/Covers | <input type="checkbox"/> Respiratory Protection: |
| <input type="checkbox"/> Body Protection (e.g., lab coat) | <input type="checkbox"/> Other |

4. Did the release result in potential exposure(s)?

- Yes

4a. If yes, how many individuals/animals/plants were exposed?

4

4b. Of the number in 4a, how many individuals were laboratory staff:

3

- No



Summary of APHIS/CDC Form 3 Changes

- **Report of a Release:**

- Question C6: Types of medical surveillance and treatment options
- Question C6a: Sub-question for the number of individuals
- Question C7b: Selection for the types of corrective action(s)

5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?

Yes
 No
 Not currently known

6. What medical surveillance and/or treatment was provided to individuals, if any?

No Treatment
 Physical evaluation
 Fever/symptom watch
 Serology screening
 Antibiotics or other prophylaxis
 Other

6a. Total number of individuals medical surveillance and/or treatment provided to:

5 _____

7a. Has an internal investigation been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity?

Yes (if yes, please provide additional details)
 No

Describe the internal investigation initiated following the incident (if any), and any root cause(s) identified.

7b. What corrective actions have been initiated to lessen the likelihood of recurrence of incident involving the select agents and toxins at this entity? (choose all that apply)

Must answer at least one of the below

<input type="checkbox"/> Retraining on existing policy	<input type="checkbox"/> New/modified policy	<input type="checkbox"/> New training developed	<input type="checkbox"/> New/updated SOP
<input type="checkbox"/> New PPE provided	<input type="checkbox"/> New equipment provided	<input type="checkbox"/> Equipment repair	<input type="checkbox"/> Remodel lab/facility
<input type="checkbox"/> Audit/remove faulty PPE	<input type="checkbox"/> Audit/remove faulty equipment	<input type="checkbox"/> None	<input type="checkbox"/> Other: Describe Other _____



Summary of APHIS/CDC Form 3 Changes

- **Report of a Loss and Theft:**

- Question D10: Switches order of questions
- Question E9: Adds 'Date of recovery' for a 'Yes' response
- Question E10: Removes the 'unsure' box as a response selection

Section D

9. Was the lost select agent or toxin material found?

- Yes
- No

10. How long was the select agent or toxin material missing?

Date Recovered:

mm/dd/yyyy

Duration of loss (hours/days)

11. Give the date of the last inventory/audit performed:

mm/dd/yyyy

Section E

9. Was the stolen select agent or toxin material recovered:

- Yes
- No

10. Was there a potential exposure:

- Yes/Unknown at this time (go to Section C)
- No



A close-up photograph of a scientist in a laboratory. The scientist is wearing a white lab coat over a blue shirt and a dark tie. They are also wearing clear safety glasses and a white surgical mask. The scientist is holding a clipboard and a pen, looking down at the clipboard. The background is a blurred laboratory setting with various pieces of equipment.

Form 3: Most Common Concerns



APHIS/CDC Form 3 – Most Common Concerns #1

- **Question B1: Incident date**

- For release, date of earliest exposure/manipulation outside of primary containment
- For loss, date when inability to account for Biological Select Agent or Toxin (BSAT) first identified

Section B - INCIDENT INFORMATION

1. Date and Time of Incident:

Date:

05/07/2021

Time:

02

15

PM

3. Type of Immediate Notification:

- Email
- Fax
- Telephone
- eFSAP

2. Date of Immediate Notification:

05/07/2021

4. Location of Incident:

123 - D Test - Work Only

123 - D Test - Work Only

231 of 255 characters left



APHIS/CDC Form 3: Most Common Concerns #2

Section B - INCIDENT INFORMATION

1. Date and Time of Incident:

Date:

05/07/2021

Time:

02

15

PM

2. Date of Immediate Notification:

05/07/2021

3. Type of Immediate Notification:

- Email
- Fax
- Telephone
- eFSAP

4. Location of Incident:

123 - D Test - Work Only

123 - D Test - Work Only

231 of 255 characters left

•Question B2: What date constitutes Immediate Notification? (select one)

- A) When incident happens
- B) When Responsible Official or entity leadership is notified
- C) When internal investigation is completed
- D) When the entity first informs FSAP of the incident



APHIS/CDC Form 3: Most Common Concerns #2

- **Block B2: What date constitutes Immediate Notification?**

- A) When incident happens
- B) When Responsible Official or entity leadership is notified
- C) When internal investigation is completed
- D) When the entity first informs FSAP of the incident



APHIS/CDC Form 3 – Making an Immediate Notification

- **eFSAP information system Immediate Notification (Preferred Method)**
 - When selecting the agent/toxin and if unclear what BSAT was manipulated, select the BSAT last worked with at time of incident
 - Complete the required questions on the form and click the ‘Immediate Notification’ button
- **eFSAP information system General Discussion**
 - FSAP may ask initial questions
 - FSAP may request for minimal submission as Immediate Notification using the APHIS/CDC Form 3
- **Email / Phone call**
 - FSAP will acknowledge on entity homepage



Immediate Notification in eFSAP information system

- Where is the 'Immediate Notification' button?
- What happens after Immediate Notification?
- Can changes be made after Immediate Notification?

Last signed by RO/ARO

Last modified by

[✕ Close](#) [Save Draft](#) [Immediate Notification](#) [Initiate Submit](#)



APHIS/CDC Form 3 – Most Common Concerns #3

- **What is the best way to respond to a Request for Information (RFI) letter? (select one)**
 - A) Upload to Entity Documents section for the specific APHIS/CDC Form3
 - B) Upload to entity home landing page
 - C) Send response through email or fax



APHIS/CDC Form 3 – Most Common Concerns #3

- **What is the best way to respond to a RFI letter?**
 - A) Upload to Entity Documents section for the specific APHIS/CDC Form3
 - B) Upload to entity home landing page
 - C) Send response through email or fax



Uploading a Response to RFI Letter

Home

Form 3

Select an action for the APHIS/CDC FORM 3 TO REPORT A THEFT, LOSS, OR RELEASE OF A SELECT AGENT OR TOXIN.

The discovery of a theft, loss, or a release of a select agent or toxin is required to be immediately reported (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73).

Open Completed All

Create Form 3

Exit

Case ID	Agent Or Toxin	TLR	Status	Incident Date	Immediate Notifica...	Incident ...	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Start Date End Date	Start Date End Date	<input type="text"/>	<input type="text"/>
TLR-F3-001051	Francisella tularensis	true	Submitted	09/09/2020	09/09/2020	Loss	Edit History
TLR-F3-001034	Abrin, Eastern Equine Encephalitis virus	true	Submitted	09/08/2020	09/08/2020	Theft	Edit History
TLR-F3-001042	Sheep pox virus	true	Submitted	09/01/2020	09/02/2020	Loss	Edit History



Uploading a Response to RFI Letter

General Discussion

Type your message here...

Previous 1 Next

Send

Upload an Entity File

Step 1: Identify File Data

* = Required

Case ID-Date Reported *
14 characters remaining.

Document Type *

Description
140 characters remaining.

Step 2: Select the File

No file chosen

Show file naming rules

Upload an Entity File

Current Files Archived Files

Send to Archive

Select All	Original Name	Unique File Identifier	Uploaded Date	Uploaded By	File Category	Review Status
<input type="checkbox"/>			Start Date End Date			



APHIS/CDC Form 3 – Most Common Concerns #4

- When RFI letter is uploaded into eFSAP information system by the Form 3 team, the status of the report is changed to Request For More Information
- In this status, the report can be edited to change/correct information on the APHIS/CDC Form 3
- After making changes and uploading the responses to the RFI in the entity documents section of the report, select the Return to Agency button

 Close

 Save Update

 Return to Agency



A close-up photograph of a scientist in a laboratory. The scientist is wearing a white lab coat over a blue shirt and a dark tie. They are also wearing clear safety glasses and a white surgical mask. Their hands are wearing blue nitrile gloves. The scientist is looking down at a clipboard or piece of paper they are holding. The background is a blurred laboratory setting with various pieces of equipment.

APHIS/CDC Form 3 Scenarios



APHIS/CDC Form 3 – Scenario 1

- **Scenario 1 – Needle stick**

- A laboratorian vaccinated for anthrax stuck their finger after loading a syringe with *Bacillus anthracis* spores while working in the biosafety cabinet
- The laboratorian immediately stopped work and noticed blood in their double gloves
- After applying first aid and following appropriate doffing procedures to exit the laboratory, the laboratorian reported the incident to the Responsible Official (RO) before proceeding to Occupational Health

- **How should this be reported on the APHIS/CDC Form 3 for questions C2 and C4? (select one)**

- A) C2: Yes, there was a release outside containment barriers and C4: No, the release did not result in potential exposure(s)
- B) C2: No, there was not a release outside containment barriers and C4: No, the release did not result in potential exposure(s)
- C) C2: No, there was not a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)
- D) C2: Yes, there was a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)



APHIS/CDC Form 3 – Scenario 1

- **Scenario 1 – Needle stick**

- **How should this be reported on the APHIS/CDC Form 3 for questions C2 and C4?**

- A) C2: Yes, there was a release outside containment barriers and C4: No, the release did not result in potential exposure(s)
- B) C2: No, there was not a release outside containment barriers and C4: No, the release did not result in potential exposure(s)
- C) C2: No, there was not a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)
- D) C2: Yes, there was a release outside containment barriers and C4: Yes, the release did result in potential exposure(s)



APHIS/CDC Form 3 – Scenario 2

- **Scenario 2 – Cage injury**

- An animal care technician scratches their hand on a piece of metal on the cage rack while bagging dirty mice cages used for non-BSAT work in the registered ABSL-3 laboratory
- One week prior, a *Brucella abortus* study with mice in this laboratory concluded and there has not been any work with select agents since that time
- All work surfaces including cages are routinely disinfected
- The next day the animal care technician noticed some swelling at the scratched area and reported to the Occupational Health Office where the physician prescribed antibiotic prophylaxis

- **Is this reportable?** Yes or No



APHIS/CDC Form 3 – Scenario 2

- **Scenario 2 – Cage injury**

- **No**

- No recent work with BSAT, no spills reported, no BSAT-infected animals present
- Work surfaces and caging were disinfected
- Initial questions likely



APHIS/CDC Form 3 – Scenario 3

- **Scenario 3 – Loss**

- During an inventory audit, the Responsible Official notices that there are multiple records for vials not in the physical select agent inventory. Multiple vials of *B. anthracis* are missing. All the missing vials involve a specific Principal Investigator (PI), who cannot explain why the vials are missing.

- **When must this be reported and to whom?**

- A) Immediately report to law enforcement and FSAP
- B) After internal investigation then report to FSAP
- C) Next week report to campus police
- D) After completing an inventory audit under the control of the PI, then report to FSAP



APHIS/CDC Form 3 – Scenario 3

- **Scenario 3 – Loss**
- **When must this be reported and to whom?**
 - A) Immediately report to law enforcement and FSAP
 - B) After internal investigation then report to FSAP
 - C) Next week report to campus police
 - D) After completing an inventory audit under the control of the PI, then report to FSAP



www.selectagents.gov

CDC Contact Information
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APHIS Contact Information
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