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

APHIS/CDC Form 3
Updates and Common Concerns

October 13, 2021
Overview of Presentation

• Summary of APHIS/CDC Form 3 changes
• Most common concerns
  o Incident date
  o Immediate notification
  o Uploading response to Request for Information (RFI) letter
  o 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
**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)
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
### 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)

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C6</td>
<td>Types of medical surveillance and treatment options</td>
</tr>
<tr>
<td>C6a</td>
<td>Sub-question for the number of individuals</td>
</tr>
<tr>
<td>C7b</td>
<td>Selection for the types of corrective action(s)</td>
</tr>
</tbody>
</table>

**Form 3 Changes:**

- **5.** Was 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 prophylactics
  - Other

- **7a.** Has an internal investigation been initiated to lessen the likelihood of recurrence of incident involving the select agents and toxins at this entity?
  - Yes (if yes, please provide additional details)
  - No

- **7b.** Describe the internal investigation initiated following the incident (if any), and any root cause(s) identified.

- **7c.** 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)
  - Retraining on existing policy
  - New PPE provided
  - Audit/review faulty PPE
  - New protocol policy
  - New equipment provided
  - Audit/review faulty equipment
  - New training developed
  - Equipment repair
  - None
  - New updated SOP
  - Renovated laboratory
  - Other
  - Describe Other
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
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
**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
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 informing FSAP of the incident
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?
• **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
What is the best way to respond to a RFI letter?

A) Upload to Entity Documents section for the specific APHIS/CDC Form 3

B) Upload to entity home landing page

C) Send response through email or fax
### 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).

<table>
<thead>
<tr>
<th>Case ID</th>
<th>Agent Or Toxin</th>
<th>TLR</th>
<th>Status</th>
<th>Incident Date</th>
<th>Immediate Notification</th>
<th>Incident Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR-F3-001051</td>
<td>Francisella tularensis</td>
<td>true</td>
<td>Submitted</td>
<td>09/09/2020</td>
<td>09/09/2020</td>
<td>Loss</td>
</tr>
<tr>
<td>TLR-F3-001034</td>
<td>Abrin, Eastern Equine Encephalitis virus</td>
<td>true</td>
<td>Submitted</td>
<td>09/08/2020</td>
<td>09/08/2020</td>
<td>Theft</td>
</tr>
<tr>
<td>TLR-F3-001042</td>
<td>Sheep pox virus</td>
<td>true</td>
<td>Submitted</td>
<td>09/01/2020</td>
<td>09/02/2020</td>
<td>Loss</td>
</tr>
</tbody>
</table>
Uploading a Response to RFI Letter
• 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
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)
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)
• **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
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
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
• **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