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

Multi-Agency Informational Meeting (webinars) to Discuss Select Agent and Toxin Reporting Requirements
October 6 and November 3, 2021

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Program Services Branch
APHIS/CDC Form 3 Team
### APHIS/CDC Form 3 Section B Updates

**Incident Information:**
- Question B6: Recombinant agent selection box
- 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)

#### SECTION B – INCIDENT INFORMATION

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>B6</td>
<td>Recombinant Agent, Large animal (N), Large scale (LS), Plant pathogen (PPQ)</td>
</tr>
<tr>
<td>B8</td>
<td>Order change, None</td>
</tr>
<tr>
<td>B9</td>
<td>None</td>
</tr>
<tr>
<td>B10</td>
<td>Containment levels removed</td>
</tr>
</tbody>
</table>

**Form Sections:**
- **5. Name of Select Agent or Toxin:**
- **6. Strain designation of Select Agent or Toxin:**
- **7. Quantity (Unit, vials, plates, etc.):**
- **8. Type of Incident:**
  - Release/Potential Exposure (After completing Section B. Go to Section C)
  - Loss (After completing Section B. Go to Section D)
  - Theft (After completing Section B. Go to Section E)
- **9. Severity of the incident:**
  - Negligible
  - Low
  - Moderate
  - High
- **10. What Biosafety Level did the incident occur?**
  - BSL1
  - BSL2
  - BSL3
  - BSL4
  - ACL 2
  - ACL 3
  - ACL 4
  - Other
- **11. Is this incident associated with an APHIS/CDC Form 2 (Transfer):**
  - Yes, APHIS/CDC Form 2 transfer # ________________
  - No
- **12. Is this incident associated with an APHIS/CDC Form 4 (Identification):**
  - Yes, APHIS/CDC Form 4 clinical ID# ________________
  - No

Note: Please complete Appendix 1, event timeline, to provide details on the theft/loss/release incident.
• Report of a Release:
  o Question C2: ‘Yes’ or ‘No’ response option
  o Question C4b: Sub-question for the number of laboratory staff
  o Question C6: Types of medical surveillance and treatment options
  o Question C6: Sub-question for the number of individuals
  o Question C7b: Selection for the types corrective action(s)
APHIS/CDC Form 3 Sections D and E Updates

- **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
Clarification for requested information on Section B
- Question B1: Indicate the date and time of earliest exposure
- Question B2: Immediate notification date is when FSAP was notified
- Question B3: How was FSAP notified
- Question B4: Specify the location where the exposure/release occurred
Clarification for the Narrative

- List all manipulations of biological select agents and toxins (BSAT) outside primary containment
- Provide additional dates and times, as needed
- Explain the number of individuals manipulating the BSAT material
- Describe others in the area when BSAT manipulated
- Include dates of medical surveillance or treatment
APHIS/CDC Form 3 Helpful Information

- Form location
- Preferred form type for submission
  - More user-friendly
  - Faster processing
  - Easier to read
  - Does not require faxing

APHIS/CDC Form 3: Report of a Release/Loss/Theft

The APHIS/CDC Form 3, Report of a Release/Loss/Theft, is used by entities to report a theft, loss, or release of a select agent or toxin. The discovery of a theft, loss, or a release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent or toxin is required to be immediately reported. Registered entities report a theft, loss, or release through eFSAP.

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Guidance Document for the Completion of APHIS/CDC Form 3 [PDF - 505 KB]
- Fillable PDF: APHIS/CDC Form 3 [PDF - 291 KB]
- Print Only PDF: APHIS/CDC Form 3 [PDF - 297 KB]