




APHIS/CDC Form 3
Incident Notification and Reporting
(Theft, Loss, Release)

Form 3 Team
Federal Select Agent Program

Multi-Agency Informational Meeting to Discuss Select Agent and Toxin Reporting Requirements

September 23, 2020

APHIS/CDC Form 3 – Incident Notification and Reporting (Theft, Loss, Release)

- **Reporting Requirements**
- **What to Report (Theft, Loss, and Release)**
- **Who Reports, and How (NREs vs Registered Entities (REs))**
- **When to Report, Timelines**
- **Immediate Notifications**
  - Contact with FSAP
- **APHIS/CDC Form 3 Overview**
  - What are we looking for, common issues and errors
- **Root Causes**
  - Releases
- **Scenarios, Questions and Answers**

APHIS/CDC Form 3 Reporting Requirements

(a) Upon the discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify [FSAP] and the appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(b) Upon discovery of the release of an agent or toxin causing occupational exposure, or release of the select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify [FSAP].

***42 CFR §73.19, 7 CFR §331.19, 9 CFR §121.19**

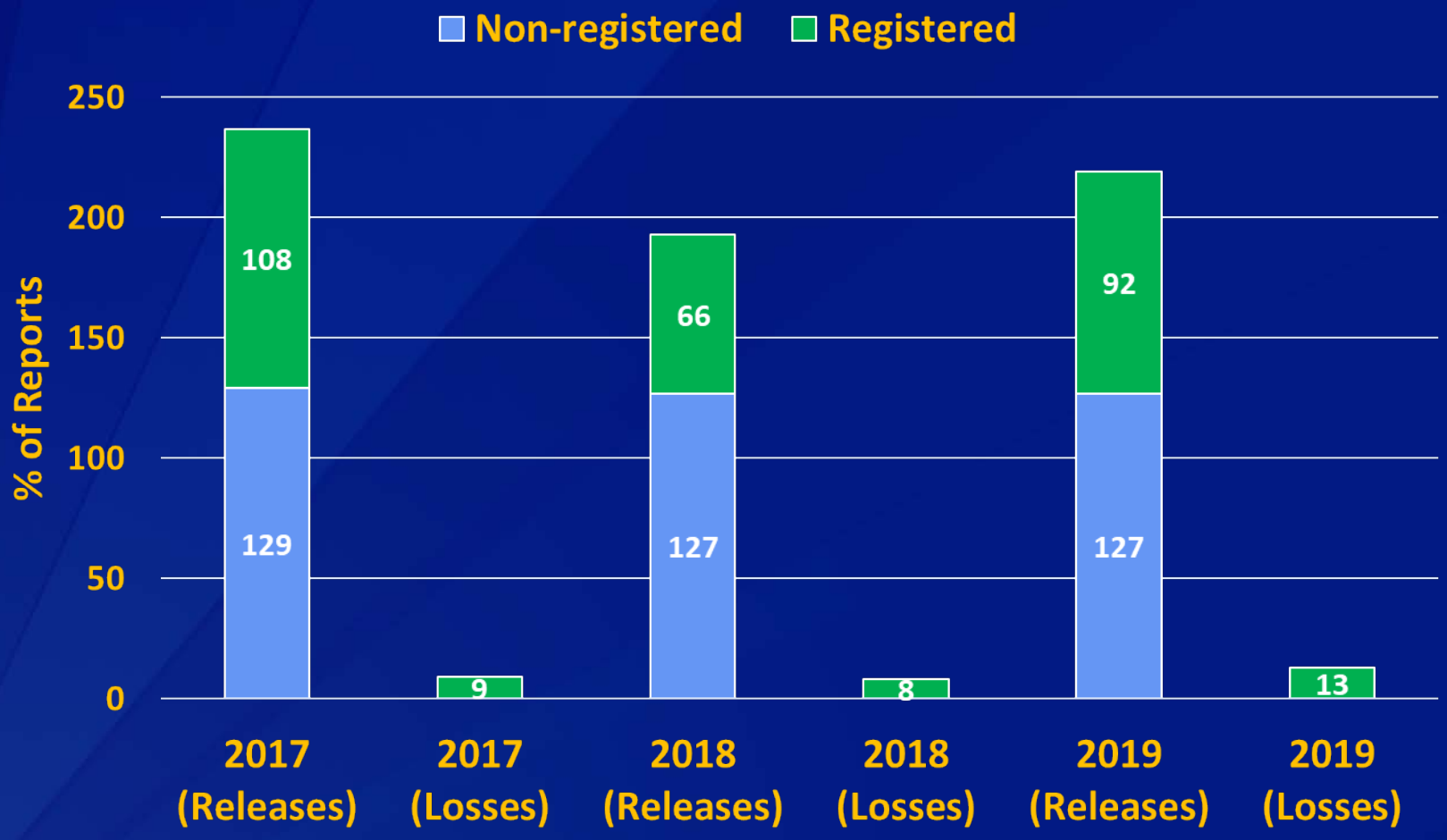
APHIS/CDC Form 3 – What to Report

- Release
  - A release of biological select agent and toxin (BSAT) causing **occupational exposure**, or
  - A release of BSAT **outside of the primary barriers of the biocontainment area**

- Theft/Loss
  - **Theft**: Unauthorized removal of BSAT
  - **Loss**: Failure to account for BSAT

Many more releases are reported than losses

Release vs Loss Reports, 2017-2019



Registered reports = 296

Non-registered reports = 383

Total # of reports = 679

APHIS/CDC Form 3 – Who Reports, and How

- Who needs to complete this form
  - The entity that experiences the theft, loss, or release (TLR) is responsible
    - A state laboratory (registered) should not complete a Form 3 on behalf of an NRE laboratory
    - Events in non-registered diagnostic laboratories affiliated with a registered entity should be reported by the entity
- How to report
  - REs use the electronic Federal Select Agent Program (eFSAP) information system
    - If initial information is incomplete, minimally submit as Immediate Notification
  - NREs – complete PDF and submit to form3@cdc.gov or agsas@usda.gov

APHIS/CDC Form 3 – When to Report, Timelines

- Event Discovery
  - Entity, FSAP, law enforcement
- Immediate Notification to FSAP
  - Email, phone, eFSAP, fax
- Submit Form 3 to FSAP
  - Within 7 calendar days of immediate notification

What Do I Report in the Immediate Notification?

All Incidents

- Entity information
- BSAT involved
- Quantity lost, stolen, or released
- Date of the incident
- Location of incident

Release Incident

- Environment
  - Outside primary/secondary containment
- How many people are considered exposed
  - Personal Protective Equipment (PPE)
- Actions taken to respond
  - Medical surveillance, prophylaxis, etc.
- Hazards posed by the release

Theft/Loss Incident

- Law enforcement agencies contacted

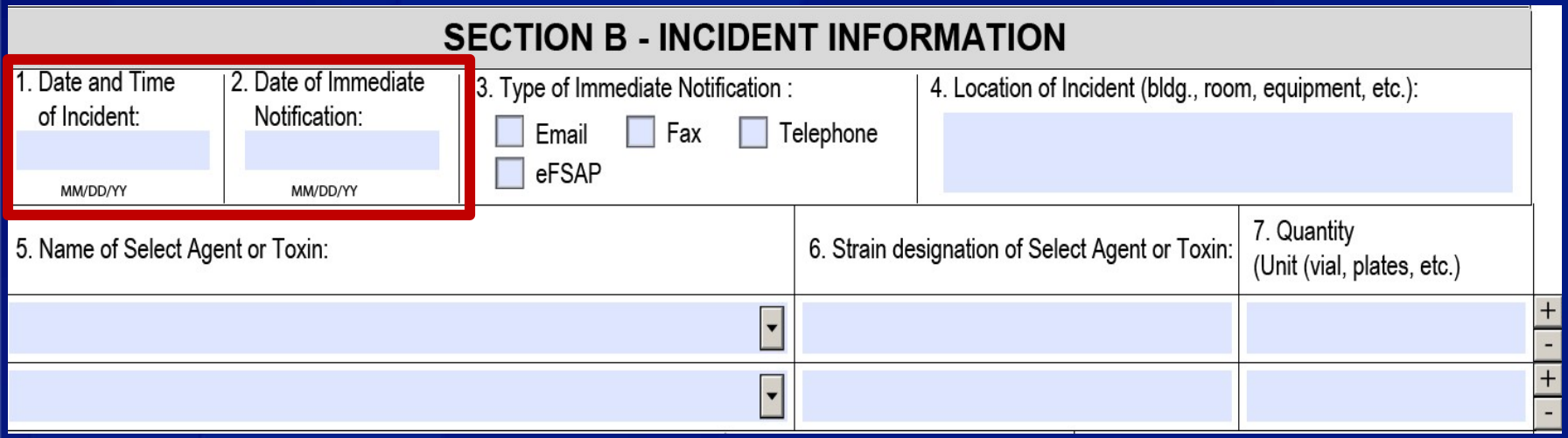
APHIS/CDC Form 3 Section A – Entity Information

SECTION A - ENTITY INFORMATION

1. Name of Entity:		2. Entity Registration/ NRE Number (if applicable):	
3. Physical Address (NOT a post office box):	4. City:	5. State:	6. Zip Code:
7. Name of Responsible Official or Laboratory Supervisor:		8. Name of Principal Investigator:	
9. Telephone Number:	10. Fax Number:	11. Email address:	

- **Block A2**:
  - For registered entities, this auto-populates in eFSAP
  - For non-registered entities, FSAP will provide via email from form3@cdc.gov.

APHIS/CDC Form 3 Section B – Incident Information



SECTION B - INCIDENT INFORMATION

1. Date and Time of Incident: MM/DD/YY	2. Date of Immediate Notification: MM/DD/YY	3. Type of Immediate Notification : ☐ Email ☐ Fax ☐ Telephone ☐ eFSAP	4. Location of Incident (bldg., room, equipment, etc.):

5. Name of Select Agent or Toxin:	6. Strain designation of Select Agent or Toxin:	7. Quantity (Unit (vial, plates, etc.)

- **Blocks B1 and B2**:
  - **B1:** For release, date of earliest exposure/manipulation outside of primary containment
    - Environmental sampling situations
    - For loss, date when inability to account for select agent or toxin first identified
  - **B2:** Currently the largest source of confusion on Form 3 (correct date addressed in next slide)

APHIS/CDC Form 3 – Most Common Submission Concerns and Questions - #1

- **Block B2: What date should be entered as the Immediate Notification date?**

  A) When incident happens

  B) When Responsible Official (RO)/entity leadership is notified

  C) When the entity is notified of BSAT confirmation (e.g., by reference laboratory)

  D) When the entity first informs FSAP of the incident

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Most Common Submission Concerns and Questions - #1

- **Block B2: What date should be entered as the Immediate Notification date?**
  - **D) When the entity first informs FSAP of the incident**

APHIS/CDC Form 3 Section B – Incident Information (cont.)

8. Type of Incident:

- ☐ Theft (After completing Section B. Go to Section C)
- ☐ Loss (After completing Section B. Go to Section D)
- ☐ Release/ Potential Exposure

(After completing Section B. Go to Section E)

Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.

9. Severity of the incident:

- ☐ None
- ☐ Negligible
- ☐ Low
- ☐ Moderate
- ☐ High

10. What Biosafety Level did the incident occur?

☐ ABSL2	☐ NIHBL2
☐ ABSL3	☐ NIHBL3
☐ ABSL4	☐ NIHBL4
☐ ACL2	☐ NIHBL2N
☐ ACL3	☐ NIHBL3N
☐ ACL4	☐ NIHBL4N
☐ BSL2	☐ NIHBL2-LS
☐ BSL3	☐ NIHBL3-LS
☐ BSL4	☐ NIHBL4-LS
☐ BSL3 Ag	☐ PPQ Agent

11. Is this incident associated with an APHIS/CDC Form 2 (Transfer):

- ☐ Yes (Fill out Appendix B, if incident occurred during transfer.)
- ☐ No

APHIS/CDC Form 2 transfer #:

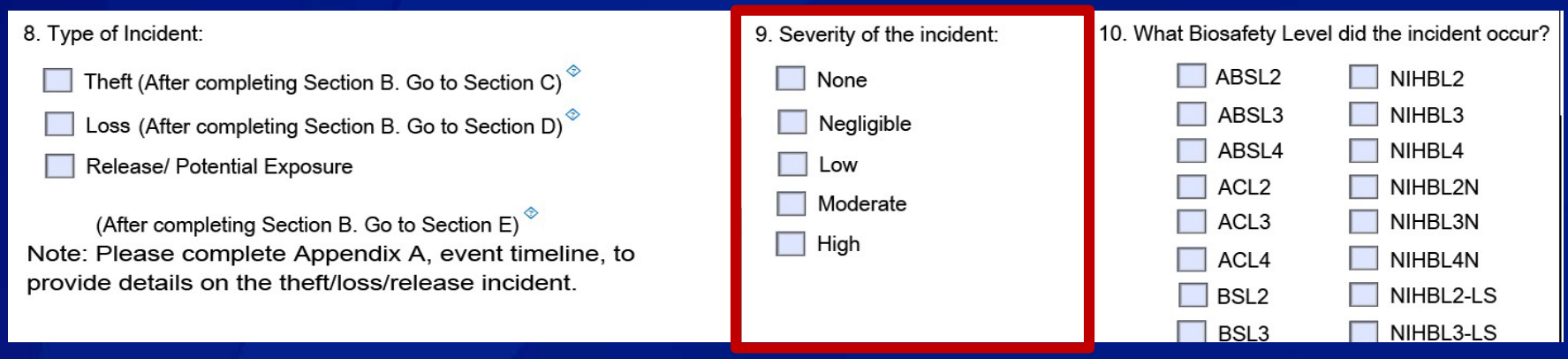
12. Is this incident associated with an APHIS/CDC Form 4 (Identification):

- ☐ Yes
- ☐ No

APHIS/CDC Form 4 clinical ID#:

- **Blocks B8 and B12**:
  - **B8:** If selecting only one type, only need signature for that one section
  - **B12:** Clinical ID# will be provided by Form 4 team—confirm if known

APHIS/CDC Form 3 Section B – Incident Information (cont.)



8. Type of Incident:

- ☐ Theft (After completing Section B. Go to Section C)
- ☐ Loss (After completing Section B. Go to Section D)
- ☐ Release/ Potential Exposure

(After completing Section B. Go to Section E)

Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.

9. Severity of the incident:

- ☐ None
- ☐ Negligible
- ☐ Low
- ☐ Moderate
- ☐ High

10. What Biosafety Level did the incident occur?

☐ ABSL2	☐ NIHBL2
☐ ABSL3	☐ NIHBL3
☐ ABSL4	☐ NIHBL4
☐ ACL2	☐ NIHBL2N
☐ ACL3	☐ NIHBL3N
☐ ACL4	☐ NIHBL4N
☐ BSL2	☐ NIHBL2-LS
☐ BSL3	☐ NIHBL3-LS

- **Block B9**:
  - Assess risk for the entire incident that incorporates exposure risk
    - Severity increases with risk to health of workers, risk to public health
  - Sample factors to consider:
    - Were symptoms or presumptive titers reported by exposed personnel? (High)
    - Was appropriate PPE worn to prevent exposure? Any breaches in PPE? (Negligible to Moderate)
    - Had incubation period elapsed without symptoms? Was medical surveillance/treatment implemented? Did anyone decline?
    - Was BSAT released outside of the laboratory? (High)

APHIS/CDC Form 3 Section E – Report of Release

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

- ☐ Animal bite/scratch
- ☐ PPE failure
- ☐ Spill
- ☐ Needle stick/Sharps
- ☐ Decontamination failure
- ☐ Inactivation failure
- ☐ Equipment/mechanical failure
- ☐ Package damaged in transit (fill out Appendix B)
- ☐ Unintended Animal Infection
- ☐ Unintended Plant Pathogen Release
- ☐ Work performed on an open bench
- ☐ Other:

2. Was there a release outside containment barriers?
(choose all that apply)

- ☐ Release outside primary containment (e.g., biosafety cabinet, leaking storage vial within storage unit)
- ☐ 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)

- ☐ Hand Protection (e.g., gloves)
- ☐ Head Protectors/Covers
- ☐ Body Protection
- ☐ Other/None:
- ☐ Foot Protection (e.g., boots, shoe covers)
- ☐ Eye/Face Protection (e.g., goggles, face shield)
- ☐ Respiratory Protection Type:

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

- ☐ Yes

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

- ☐ No

- **Block E1**:
  - NREs – **Work performed on an open bench** appropriate for any manipulation outside primary containment before BSAT confirmation
  - REs – **Other** field appropriate for procedural errors (e.g., worker removes respiratory protection while manipulating BSAT)

APHIS/CDC Form 3 Section E – Report of Release (cont.)

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

- ☐ Animal bite/scratch
- ☐ PPE failure
- ☐ Spill
- ☐ Needle stick/Sharps
- ☐ Decontamination failure
- ☐ Inactivation failure
- ☐ Equipment/mechanical failure
- ☐ Package damaged in transit (fill out Appendix B)
- ☐ Unintended Animal Infection
- ☐ Unintended Plant Pathogen Release
- ☐ Work performed on an open bench
- ☐ Other:

2. Was there a release outside containment barriers?
(choose all that apply)

- ☐ Release outside primary containment (e.g., biosafety cabinet, leaking storage vial within storage unit)
- ☐ 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)

- ☐ Hand Protection (e.g., gloves)
- ☐ Head Protectors/Covers
- ☐ Body Protection
- ☐ Other/None:
- ☐ Foot Protection (e.g., boots, shoe covers)
- ☐ Eye/Face Protection (e.g., goggles, face shield)
- ☐ Respiratory Protection Type:

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

- ☐ Yes

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

- ☐ No

- **Block E2:**
  - **Release outside primary containment** – most common selection
    - Exposure within *shared primary barrier* (e.g., needlestick in biosafety cabinet (BSC))
  - **Release beyond secondary containment** refers to degree of BSAT release
    - Not shipment of material outside laboratory for confirmation

APHIS/CDC Form 3 Section E – Report of Release (cont.)

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

- ☐ Animal bite/scratch
- ☐ PPE failure
- ☐ Spill
- ☐ Needle stick/Sharps
- ☐ Decontamination failure
- ☐ Inactivation failure
- ☐ Equipment/mechanical failure
- ☐ Package damaged in transit (fill out Appendix B)
- ☐ Unintended Animal Infection
- ☐ Unintended Plant Pathogen Release
- ☐ Work performed on an open bench
- ☐ Other:

2. Was there a release outside containment barriers?
(choose all that apply)

- ☐ Release outside primary containment (e.g., biosafety cabinet, leaking storage vial within storage unit)
- ☐ 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)

- ☐ Hand Protection (e.g., gloves)
- ☐ Head Protectors/Covers
- ☐ Body Protection
- ☐ Other/None:
- ☐ Foot Protection (e.g., boots, shoe covers)
- ☐ Eye/Face Protection (e.g., goggles, face shield)
- ☐ Respiratory Protection Type:

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

- ☐ Yes

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

- ☐ No

- **Block E3**: Restrict to PPE worn by individuals at the time of release/exposure, not cleanup afterward
  - Respiratory protection is appropriate for equipment with a filter for biological agents (not a surgical mask) while working with select agents
- **Block E4**:Include both laboratory workers and other individuals at the facility (e.g., ER staff) who were considered exposed to the select agent contained within the patient's samples.

APHIS/CDC Form 3 Section E – Report of Release (cont.)

5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?	6. Has medical surveillance been initiated?	7. Has prophylaxis or treatment been provided?
☐ Yes ☐ No ☐ Not currently known	☐ Yes ☐ No	☐ Yes ☐ No

8. 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

9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?

10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident.

11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).

- **Block E6 and E7**: If monitoring/treatment implemented, do not leave these blank (raises risk profile)
  - **E6** – Examples of surveillance: fever/symptom watch, serology
  - **E7** – Examples of treatment: antibiotic prophylaxis, toxoid

APHIS/CDC Form 3 Section E – Report of Release (cont.)

5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?	6. Has medical surveillance been initiated?	7. Has prophylaxis or treatment been provided?
☐ Yes ☐ No ☐ Not currently known	☐ Yes ☐ No	☐ Yes ☐ No

8. 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

9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?

10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident.

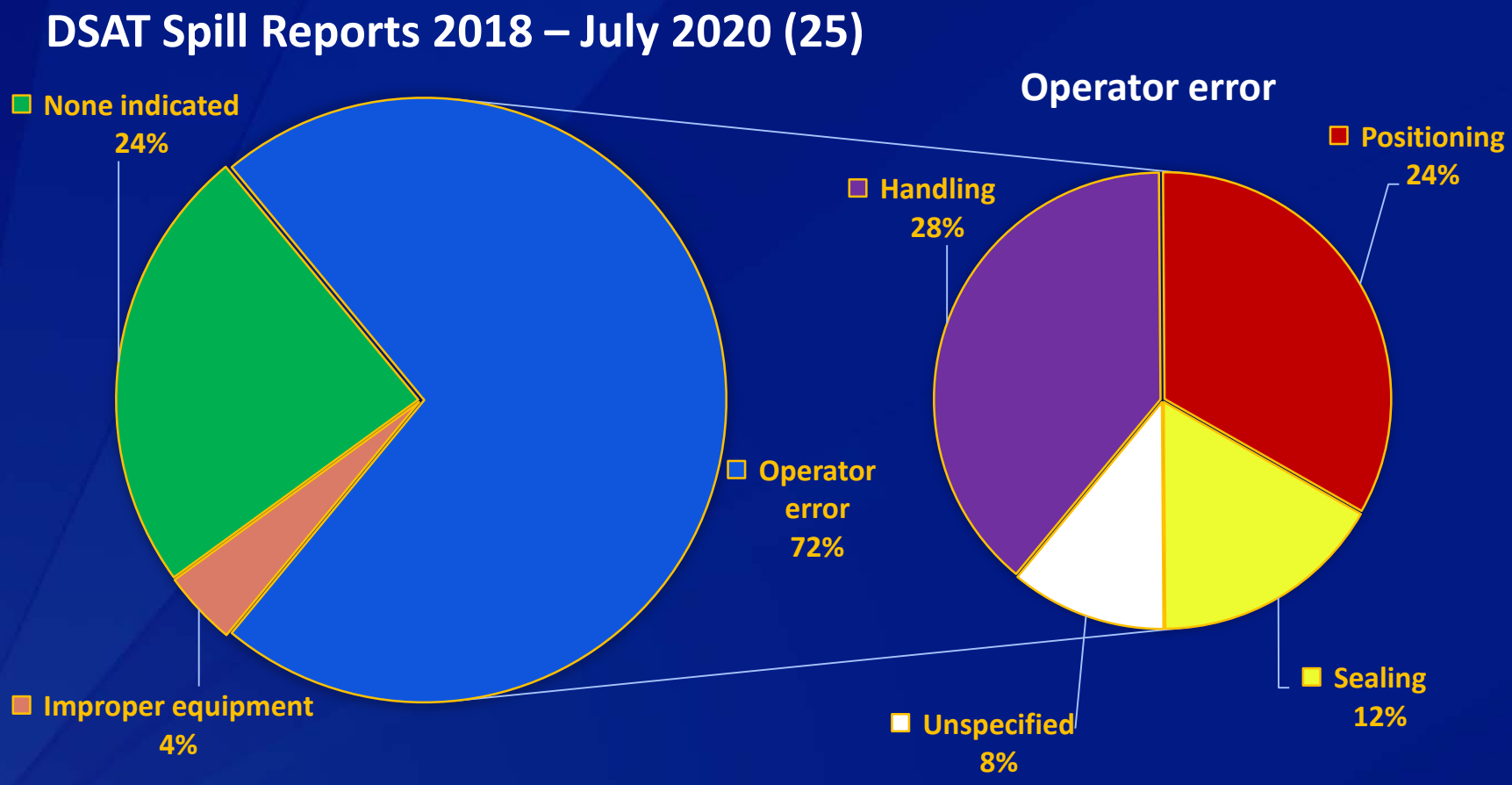
11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).

- **Block E8**: Describe any root cause(s) identified underlying the incident. Describe any changes or improvements to procedures following the incident (e.g., updated standard operating procedure (SOP), new equipment, new policy/procedures)
  - **For training/retraining –** specify the means used to verify understanding of training (e.g., proficiency demonstration, quiz)
  - **NREs** – If applicable, include information on BSAT presentation and growth

APHIS/CDC Form 3 – Root Causes

- **Root causes**
  - Please describe any root cause(s) identified in Appendix A or block E8 (Release only).
  - Closure letters uploaded to eFSAP may provide recommendations to mitigate recurrence (e.g., use thicker gloves when handling taped culture plates) based on assessment of root cause.

APHIS/CDC Form 3 – Root Cause Analysis



APHIS/CDC Form 3 Section E – Report of Release (cont.)

5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?	6. Has medical surveillance been initiated?	7. Has prophylaxis or treatment been provided?
☐ Yes ☐ No ☐ Not currently known	☐ Yes ☐ No	☐ Yes ☐ No

8. 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

9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?

10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident.

11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information).

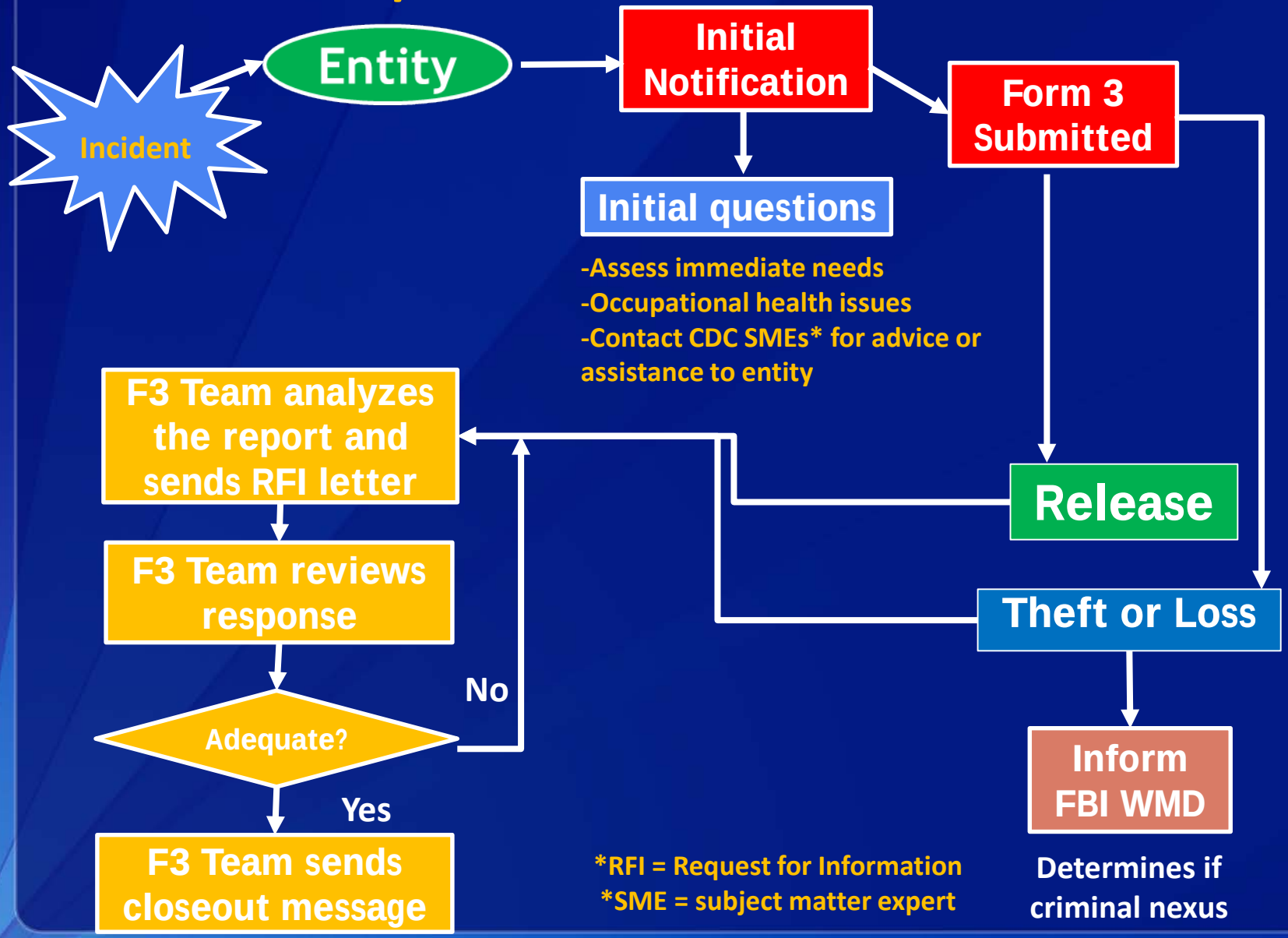
- **Block E10:** Specify the contact time and concentration of disinfectant(s) used for work surfaces.
- **Block E11:** Specify any medical surveillance/treatment provided for all potentially exposed staff (e.g., temperature/symptom watch). Include the length of time surveillance (and/or treatment) lasted.
  - Information should be consistent with block E6, block E7.

APHIS/CDC Form 3 Appendix A – Events Timeline

- **Appendix A**:
  - Describe the release, listing any and all manipulations outside of primary containment (e.g., subculturing, biochemical testing).
  - If release events occurred on multiple dates, please include date(s) of each release event, and how many individuals were considered exposed for each event (if any).
  - Also helpful to include date(s) individuals were evaluated by occupational health, date BSAT confirmation conveyed to reporting laboratory, and date(s) of contact with external public health agencies.

APPENDIX A **EVENTS TIMELINE**
Provide a detailed summary of events, including a timeline of what occurred.

APHIS/CDC Form 3 Workflow Overview



APHIS/CDC Form 3 Workflow Overview

Example Request for Information (RFI) Letter/Email

The Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) received a Form 3 report from your facility describing an incident that occurred on February [redacted]0 involving the potential release of a select agent. Relating to this incident, DSAT requests that the following items be addressed:

Note: Do not provide any personally identifiable information in your response.

1. Notify DSAT immediately at form3@cdc.gov if there are any adverse changes in the health status of the individual(s) involved in this incident.
2. Have the potentially exposed individuals remained asymptomatic? Were they counselled in person about the signs and symptoms of brucellosis, including the variable incubation period?
3. What was the length of time potentially exposed staff monitored their health? What constituted health checks (e.g., fever/symptom watch)? How were such checks reported to the Occupational Health group?
4. Why was an internal review of laboratory procedures not performed following this incident, as indicated by your response to block E8?
5. Regarding the Form 3 submission, address the following. An updated Form 3 is not necessary.

   Block B12: Confirm the associated APHIS/CDC Form 4 clinical identification number, if known (CID-F4-003194).

   Block E2: "Release outside primary containment" appears solely appropriate. Confirm this box.

   Block E4: If needed, please update the total number of potentially exposed staff to include both laboratory workers and other individuals at the hospital (e.g., ER staff) who were considered exposed to the select agent contained within the patient's samples.

   Block E10: Specify the disinfectant used to decontaminate work surfaces following potential exposures, as well as the contact time.

Acknowledge receipt of this email and respond to the above-listed questions within five (5) business days of receipt of this letter (form3@cdc.gov). Use the following number for future DSAT correspondence on this incident: **TLR-F3-[redacted] Please reference the above NRE number in Block A2 on future (APHIS/CDC Form 3) reports relating to this entity.**

- **Initial RFI questions** will usually concern medical follow-up on exposures

APHIS/CDC Form 3 Workflow Overview

Example Request for Information (RFI) Letter/Email

The Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) received a Form 3 report from your facility describing an incident that occurred on February [redacted] involving the potential release of a select agent. Relating to this incident, DSAT requests that the following items be addressed:

Note: Do not provide any personally identifiable information in your response.

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   Block E2: "Release outside primary containment" appears solely appropriate. Confirm this box.

   Block E4: If needed, please update the total number of potentially exposed staff to include both laboratory workers and other individuals at the hospital (e.g., ER staff) who were considered exposed to the select agent contained within the patient's samples.

   Block E10: Specify the disinfectant used to decontaminate work surfaces following potential exposures, as well as the contact time.

Acknowledge receipt of this email and respond to the above-listed questions within five (5) business days of receipt of this letter (form3@cdc.gov). Use the following number for future DSAT correspondence on this incident: **TLR-F3-[redacted] Please reference the above NRE number in Block A2 on future (APHIS/CDC Form 3) reports relating to this entity.**

- **Additional questions** on root cause investigation, corrective actions, corrections to Form 3 (if any)

APHIS/CDC Form 3 Workflow Overview

- **Example Closeout Letter/Email**

RE: Closure of APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins

The incident that occurred at your entity on June 19, s been approved for closure and no further action is required at this time.

If there are any adverse changes in health of the potentially exposed worker(s) relating to this incident, please notify DSAT immediately via e-mail at form3@cdc.gov. If subsequent serology testing is performed, please inform us immediately if serology results indicate exposure to a select agent. Note that DSAT frequently follows up on the serology testing results six months after they have been initiated.

Direct all questions related to this incident to (contact information below), or form3@cdc.gov.

Please reference the above NRE number in Block A2 on future (APHIS/CDC Form 3) reports and all correspondences relating to this entity.

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 1 – Diagnostic work at non-registered entity**
  - A patient reports to a local hospital after returning from travel in Southeast Asia. The patient is evaluated in the emergency room but attending physicians do not communicate BSAT suspicions to the hospital laboratory. The hospital microbiology laboratory performs a gram stain, with smearing on the open bench (gram negative rods). A Microscan® panel and MALDI-ID® are also performed on the open bench. The MALDI-ID® verified as *Burkholderia thailandensis*.
  - A technician is concerned the organism was misidentified on the MALDI-ID®, and performs new biochemical tests, all in the BSC. When unable to rule out BSAT, specimens are collected and forwarded to the state laboratory, where they are confirmed to be *Burkholderia pseudomallei*.
- **Part A: Is this reportable?**

  A) Yes

  B) No

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 1 – Diagnostic work at non-registered entity**
- **Part A: Is this reportable?**
  - **Yes – upon the identification of the select agent**
  - All manipulations outside of primary containment constitute a release, as the organism was identified as BSAT.
- **Part B: Who should submit the APHIS/CDC Form 3?**

  A) Registered state public health laboratory

  B) Non-registered diagnostic laboratory

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 1 – Diagnostic work at non-registered entity**
- **Part B – Who should submit the Form 3?**

B) Non-registered diagnostic laboratory

- The entity that experiences the release is responsible for completing the APHIS/CDC Form 3 and submitting to form3@cdc.gov.

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 1 – Diagnostic work at non-registered entity**

APPENDIX A **EVENTS TIMELINE**
Provide a detailed summary of events, including a timeline of what occurred.
6/12/20 – Micro lab received order for cultures from patient's liver abscess. Primary culture plates (Blood agar, Chocolate agar, MacConkey agar) setup inside the BSC. 6/13/20 – Cultures observed for the first time on the open bench and noted to be no growth on MAC. Growth observed on BA, CA. Re-incubated. 6/14/20 – A gram stain was performed, smeared and read on an open bench (Gram negative rods). 6/15/20 – MALDI-ID performed on small colonies on plates, along with conventional Microscan panel. Both performed on open bench. 6/16/20 – MALDI-ID verified for Burkholderia thailandensis, 6/18/20 - culture finalized as Burkholderia species. 6/17/20 – Tech concerned about misidentification, performs biochemical tests in BSC. Cultures sent off to state lab for identification. 6/21/20 – State reference lab sends Burkholderia pseudomallei confirmation to hospital lab. All remaining cultures and specimens in hospital lab disposed of by autoclaving. Potential exposures discussed with microbiology techs. Referred to employee health for follow up. 6/22/20 – A completed APHIS/CDC Form 3, Form 4 sent to DSAT.

- **Part C: What is the incident date applicable to block B1?**

  A) 6/12/20

  B) 6/13/20

  C) 6/14/20

  D) 6/16/20

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 1 – Diagnostic work at non-registered entity**

APPENDIX A **EVENTS TIMELINE**
Provide a detailed summary of events, including a timeline of what occurred.
6/12/20 -- Micro lab received order for cultures from patient's liver abscess. Primary culture plates (Blood agar, Chocolate agar, MacConkey agar) setup inside the BSC. 6/13/20 -- Cultures observed for the first time on the open bench and noted to be no growth on MAC. Growth observed on BA, CA. Re-incubated. 6/14/20 -- A gram stain was performed, smeared and read on an open bench (Gram negative rods). 6/15/20 -- MALDI-ID performed on small colonies on plates, along with conventional Microscan panel. Both performed on open bench. 6/16/20 -- MALDI-ID verified for Burkholderia thailandensis, 6/18/20 - culture finalized as Burkholderia species. 6/17/20 -- Tech concerned about misidentification, performs biochemical tests in BSC. Cultures sent off to state lab for identification. 6/21/20 -- State reference lab sends Burkholderia pseudomallei confirmation to hospital lab. All remaining cultures and specimens in hospital lab disposed of by autoclaving. Potential exposures discussed with microbiology techs. Referred to employee health for follow up. 6/22/20 -- A completed APHIS/CDC Form 3, Form 4 sent to DSAT.

- **Part C: What is the incident date applicable to block B1?**

  B) 6/13/20

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 1 – Diagnostic work at non-registered entity**

APPENDIX A **EVENTS TIMELINE**
Provide a detailed summary of events, including a timeline of what occurred.
6/12/20 -- Micro lab received order for cultures from patient's liver abscess. Primary culture plates (Blood agar, Chocolate agar, MacConkey agar) setup inside the BSC. 6/13/20 -- Cultures observed for the first time on the open bench and noted to be no growth on MAC. Growth observed on BA, CA. Re-incubated. 6/14/20 -- A gram stain was performed, smeared and read on an open bench (Gram negative rods). 6/15/20 -- MALDI-ID performed on small colonies on plates, along with conventional Microscan panel. Both performed on open bench. 6/16/20 -- MALDI-ID verified for Burkholderia thailandensis, 6/18/20 - culture finalized as Burkholderia species. 6/17/20 -- Tech concerned about misidentification, performs biochemical tests in BSC. Cultures sent off to state lab for identification. 6/21/20 -- State reference lab sends Burkholderia pseudomallei confirmation to hospital lab. All remaining cultures and specimens in hospital lab disposed of by autoclaving. Potential exposures discussed with microbiology techs. Referred to employee health for follow up. 6/22/20 -- A completed APHIS/CDC Form 3, Form 4 sent to DSAT.

- **Part D: What is the immediate notification date (block B2)?**

  A) 6/21/20

  B) 6/22/20

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 1 – Diagnostic work at non-registered entity**

APPENDIX A **EVENTS TIMELINE**
Provide a detailed summary of events, including a timeline of what occurred.
6/12/20 -- Micro lab received order for cultures from patient's liver abscess. Primary culture plates (Blood agar, Chocolate agar, MacConkey agar) setup inside the BSC. 6/13/20 -- Cultures observed for the first time on the open bench and noted to be no growth on MAC. Growth observed on BA, CA. Re-incubated. 6/14/20 -- A gram stain was performed, smeared and read on an open bench (Gram negative rods). 6/15/20 -- MALDI-ID performed on small colonies on plates, along with conventional Microscan panel. Both performed on open bench. 6/16/20 -- MALDI-ID verified for Burkholderia thailandensis, 6/18/20 - culture finalized as Burkholderia species. 6/17/20 -- Tech concerned about misidentification, performs biochemical tests in BSC. Cultures sent off to state lab for identification. 6/21/20 -- State reference lab sends Burkholderia pseudomallei confirmation to hospital lab. All remaining cultures and specimens in hospital lab disposed of by autoclaving. Potential exposures discussed with microbiology techs. Referred to employee health for follow up. 6/22/20 -- A completed APHIS/CDC Form 3, Form 4 sent to DSAT.

- **Part D: What is the immediate notification date (block B2)?**

  A) 6/22/20 (When DSAT was contacted via Form 3)

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 2 – Cage injury**
  - An animal technician scratches their gloved hand on a piece of metal while bagging empty mice cages in an ABSL-3 laboratory. No select agent or toxin work, or infected mice were present at time of incident. All work surfaces and cages were properly disinfected. *Brucella abortus* research was conducted a week prior. The incident was reported to the Occupational Health Office where the physician prescribed antibiotics.

- **Is this reportable?**

  A) Yes

  B) No

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- Scenario 2 – Cage injury
- Is this reportable?

  B) No (The incident did not involve a select agent or toxin)

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 3 – Found BSAT previously unknown to entity**
  - During a routine search of a freezer in a non-registered BSL-2 laboratory, a worker discovers 4 vials of *Bacillus anthracis* Pasteur strain.

- **What do you do with the vials?**

  A) Discard the vials immediately into regular laboratory waste since you are not registered for the agent

  B) Relocate to a secure freezer and contact FSAP for further guidance

  C) Test the material for the presence of plasmid pX02, determine if an excluded strain

Polls are open…Submit your answer now!

APHIS/CDC Form 3 – Scenarios, Questions and Answers

- **Scenario 3 – Found BSAT previously unknown to entity**
  - During a routine search of a freezer in a non-registered BSL-2 laboratory, a worker discovers 4 vials of *B. anthracis* Pasteur strain.

- **What do you do with this material?**

  B) Relocate to a secure freezer and contact FSAP for further guidance