Federal Select Agent Program Responsible Official (RO) Webinar Series, 2022

APHIS/CDC Forms 2-4 Overview and Updates

Security Access Approval

21 September 2022

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- Customer feedback survey for this webinar via ZOOM
- Follow-up SA Gram will contain:
  - Slides
  - Registration link for the remaining FSAP RO Webinars

APHIS/CDC Forms 2-4 Overview and Updates

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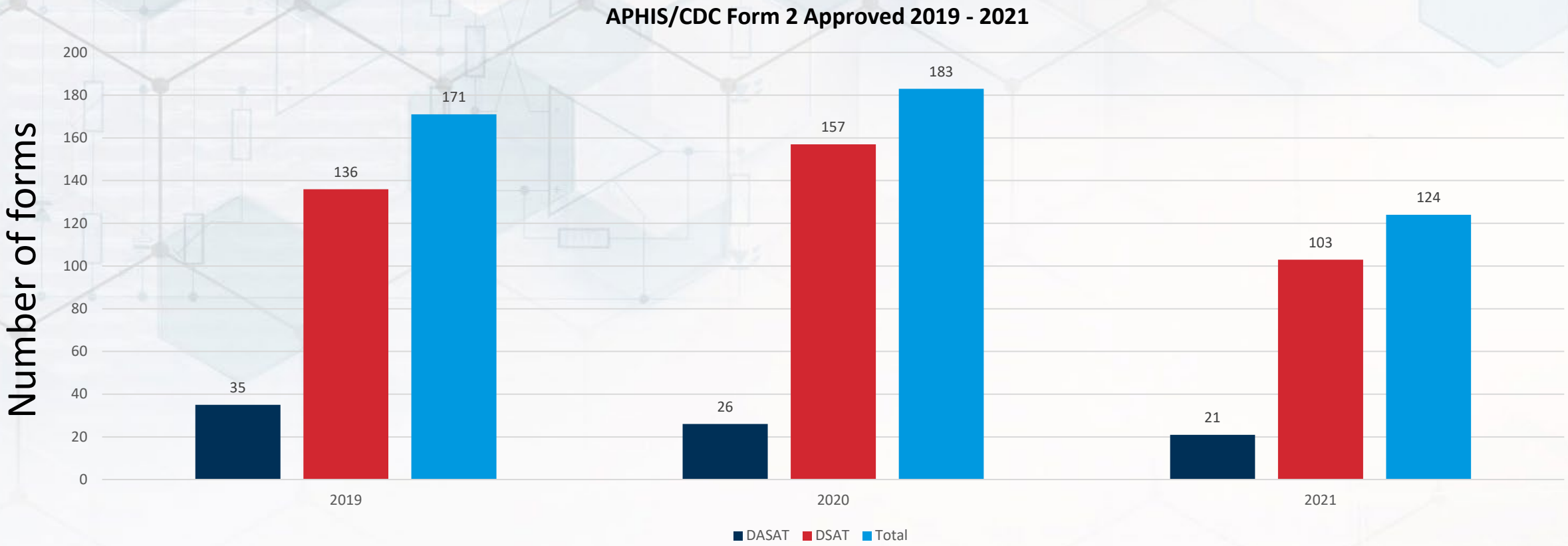
APHIS/CDC Form 2

APHIS/CDC Form 2 Overview

- The APHIS/CDC Form 2, Request to Transfer Select Agents and Toxins, is the form used to authorize the transfer of select agents and toxins
  - Authorized under Section 16 of the Select Agent and Toxin Regulations
  - Entities request prior authorization from the Federal Select Agent Program (FSAP)
    - The authorization is valid for 30 days after issuance
  - The APHIS/CDC Form 2 also provides documentation of the transfer

*42 CFR §73.16, 7 CFR §331.16, 9 CFR §121.16

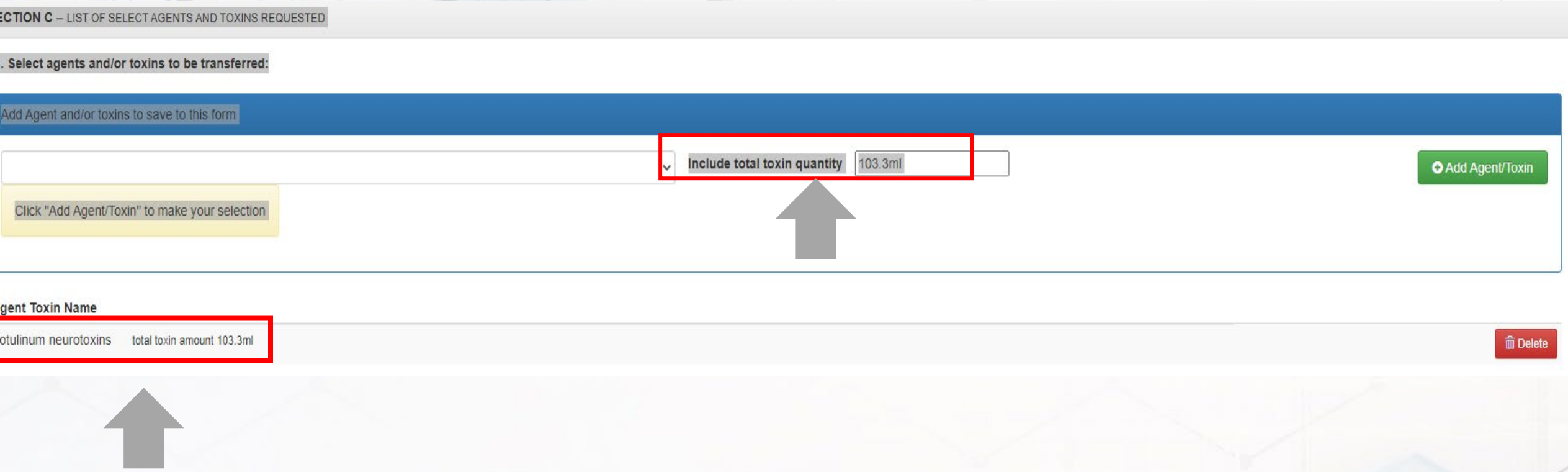
APHIS/CDC Form 2 Approved 2019-2021



APHIS/CDC Form 2 Updates

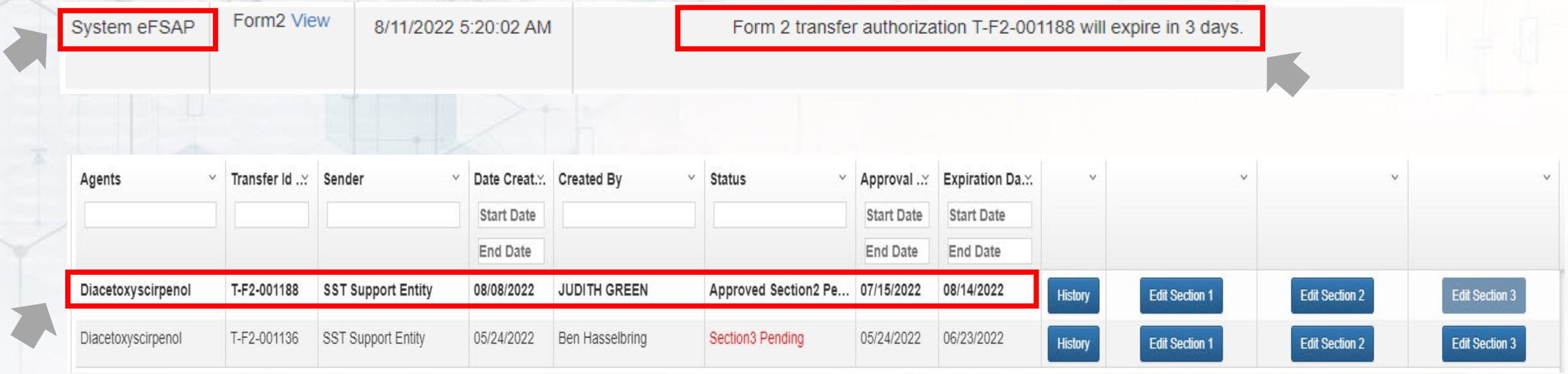
APHIS/CDC Form 2 Updates in eFSAP

- Section 1, question C13: Include total toxin quantity



APHIS/CDC Form 2 Updates in eFSAP

- Authorization expiration notifications



APHIS/CDC Form 2 Future Update in eFSAP

- APHIS/CDC Form 2 recycle
  - Re-using the form is coming soon
  - This will allow an entity to quickly create a new authorization request from a previous request with the same information
    - Eliminates the need to re-enter sender information

APHIS/CDC Form 2 Helpful Information

- Request for Information

Agents	Transfer Id	Sender	Date Created	Created By	Status	Approval Date	Expiration Date				
			Start Date End Date		req	Start Date End Date	Start Date End Date				
Abrin	T-F2-000120		06/22/2020	Panayotta Roberts	Request For Information			History	Edit Section 1	Edit Section 2	Edit Section 3

Signature

Certification: I hereby certify that the information contained in Section 1 on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, and 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official: **Title:** **Date Signed:**

Close | Cancel Transfer | Save Update | Return to Agency

APHIS/CDC Form 2 Helpful Information (continued)

- International shipments
  - The FSAP Transfer Authorization letter and Section 2 information
    - Must be with the package
    - Remind sender to email Section 2 to DSAT or DASAT
- The entity must update their APHIS/CDC Form 1 Sections 3 (list of agents and possession status) and 7B (strain table) when select agent or toxin previously marked as "not possessed" is received

APHIS/CDC Form 2 Scenarios

APHIS/CDC Form 2 Scenario A

Your entity is requesting 1mg of Botulinum neurotoxins from a commercial laboratory located in France. Is an APHIS/CDC Form 2 required?

A. Yes, because it is an international shipment
B. No, because it less than or equal to the exclusion amount of Botulinum neurotoxins
C. Maybe, because the laboratory in France needs the APHIS/CDC Form 2 to ship out
D. I do not know

APHIS/CDC Form 2 Scenario A Response

- Your entity is requesting 1mg of Botulinum neurotoxins from a commercial laboratory located in France. Is an APHIS/CDC Form 2 required?

B. No, because it less than or equal to the exclusion amount of Botulinum neurotoxins

APHIS/CDC Form 2 Regulatory Interpretation

Regulatory Interpretation: Transfer of Excluded or Permissible Amounts of HHS Toxins. An approved APHIS/CDC Form 2 is not required for a registered entity to receive less than or equal to a permissible amount of toxin under §73.3(d) via import from outside of the U.S.

Source: https://www.selectagents.gov/regulations/interpretations/excluded-transfer-hhs.htm

APHIS/CDC Form 2 Scenario B

Your entity identified *Francisella tularensis* from a patient sample received and tested 4 weeks ago. The patient returns after treatment, and your entity isolates suspected *Francisella* from the patient's new sample. Your entity wants to send the new sample isolates to a reference laboratory for further testing. Is an APHIS/CDC Form 2 required?

A. Yes, because the patient is known to have a *F. tularensis infection*
B. No, because the new sample isolates have not been identified by your entity
C. Maybe, because your entity suspect the isolates to be *F. tularensis*
D. I do not know

APHIS/CDC Form 2 Scenario B Response

Your entity identified *Francisella tularensis* from a patient sample received and tested 4 weeks ago. The patient returns after treatment, and your entity isolates suspected *Francisella* from the patient's new sample. Your entity wants to send the new sample isolates to a reference laboratory for further testing. Is an APHIS/CDC Form 2 required?

B. No, because the new sample isolates have not been identified by your entity

APHIS/CDC Form 2 Scenario C

Today, your entity is prepared to ship an authorized transfer of select agents and the APHIS/CDC Form 2 Section 2 has been completed and signed; however, the commercial carrier informed your entity this morning that they will not arrive until next week. What should your entity do?

A. Contact the commercial carrier to let them know they cannot change the date
B. Nothing, because the package has not shipped
C. Contact FSAP to update information in Section 2
D. I do not know

APHIS/CDC Form 2 Scenario C Response

Today, your entity is prepared to ship an authorized transfer of select agents and the APHIS/CDC Form 2 Section 2 has been completed and signed in eFSAP; however, the commercial carrier informed your entity this morning that they will not arrive until next week. What should your entity do?

C. Contact FSAP to update information in Section 2

APHIS/CDC Form 2 Scenario D

On Friday, your entity received and unpacked a shipment of select toxins. Before completing and signing APHIS/CDC Form 2 Section 3, what must the entity do?

A. Verify that the package contains the select toxin material stated on APHIS/CDC Form 2 Section 2
B. Nothing, because it's Friday and we can complete the form on Monday
C. Verify that the package contains the select toxin material stated on the Shipper's Declaration of Dangerous Goods form
D. I do not know

APHIS/CDC Form 2 Scenario D Response

Friday your entity received and unpacked a shipment of select toxins. Before completing and signing APHIS/CDC Form 2 Section 3, what must the entity do?

A. Verify that the package contains the select toxin material stated on APHIS/CDC Form 2 Section 2

APHIS/CDC Form 3

APHIS/CDC Form 3 Overview

- The APHIS/CDC Form 3 is the mechanism used by entities to report whenever there is a theft, loss, or release of a select agent or toxin.
- The APHIS/CDC Form 3 is also used to report if an occupational exposure occurred due to the release.
- The eFSAP Information System is the preferred method for registered entities to report a theft, loss or release.

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

Select Agent Regulations: Section 19(a) (Theft or Loss)

- Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts and losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.
- A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

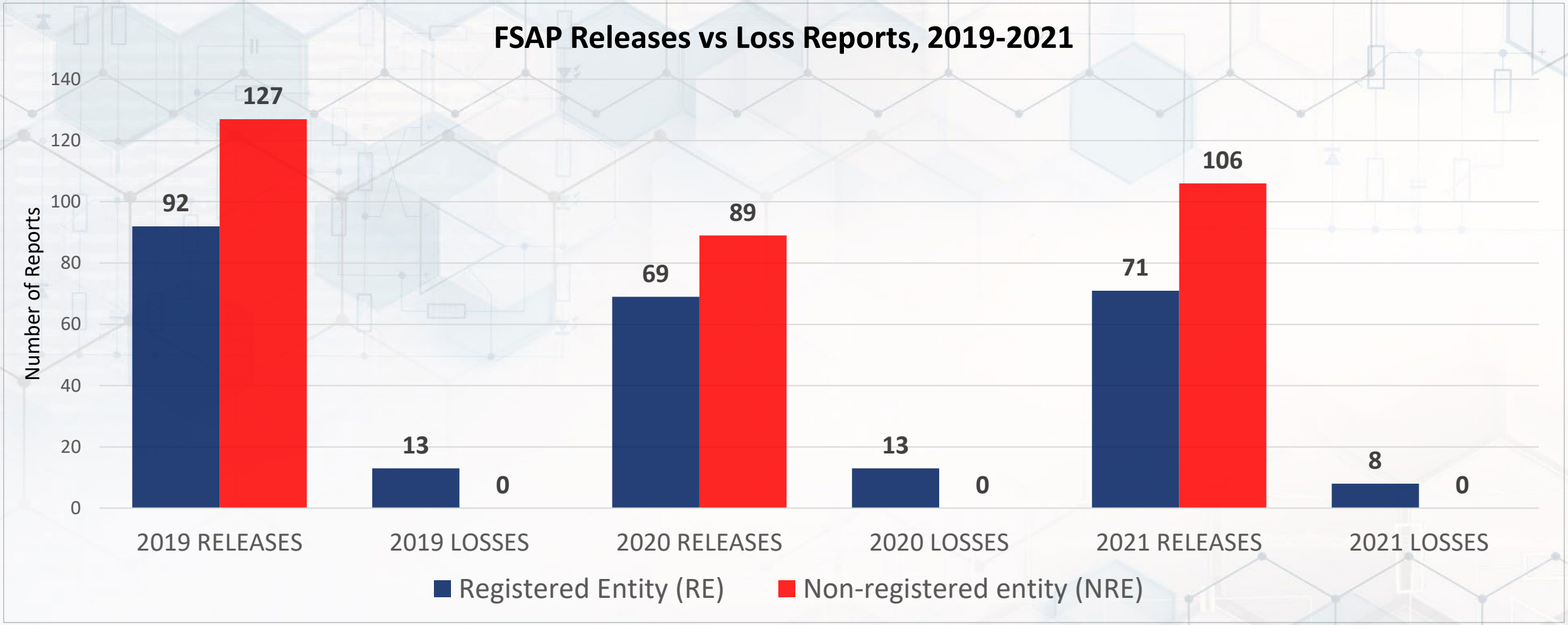
*42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 1

Select Agent Regulations: Section 19(b) (Release)

- 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 CDC or APHIS.
- A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

*42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121

APHIS/CDC Form 3 Statistical Information

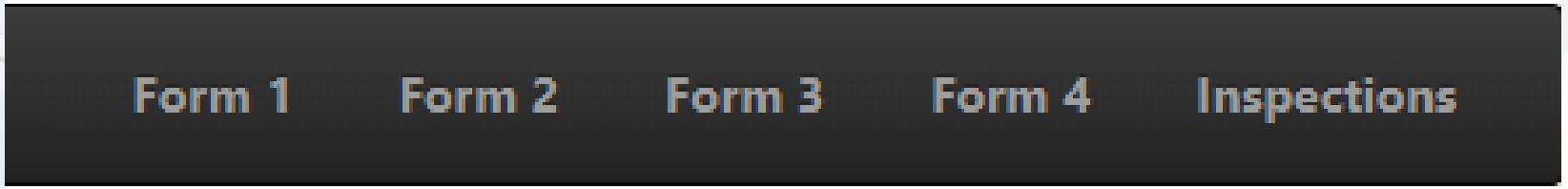


APHIS/CDC Form 3 – Making an Immediate Notification

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

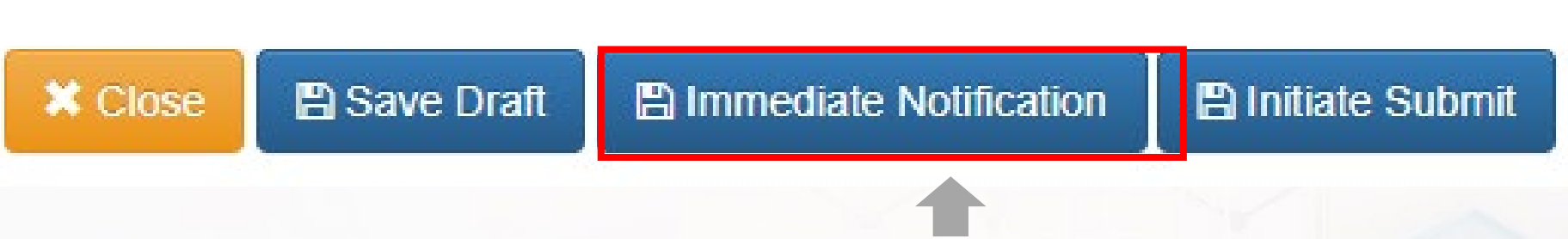
APHIS/CDC Form 3 – Basics of Submitting an Immediate Notification

Step 1



Step 2

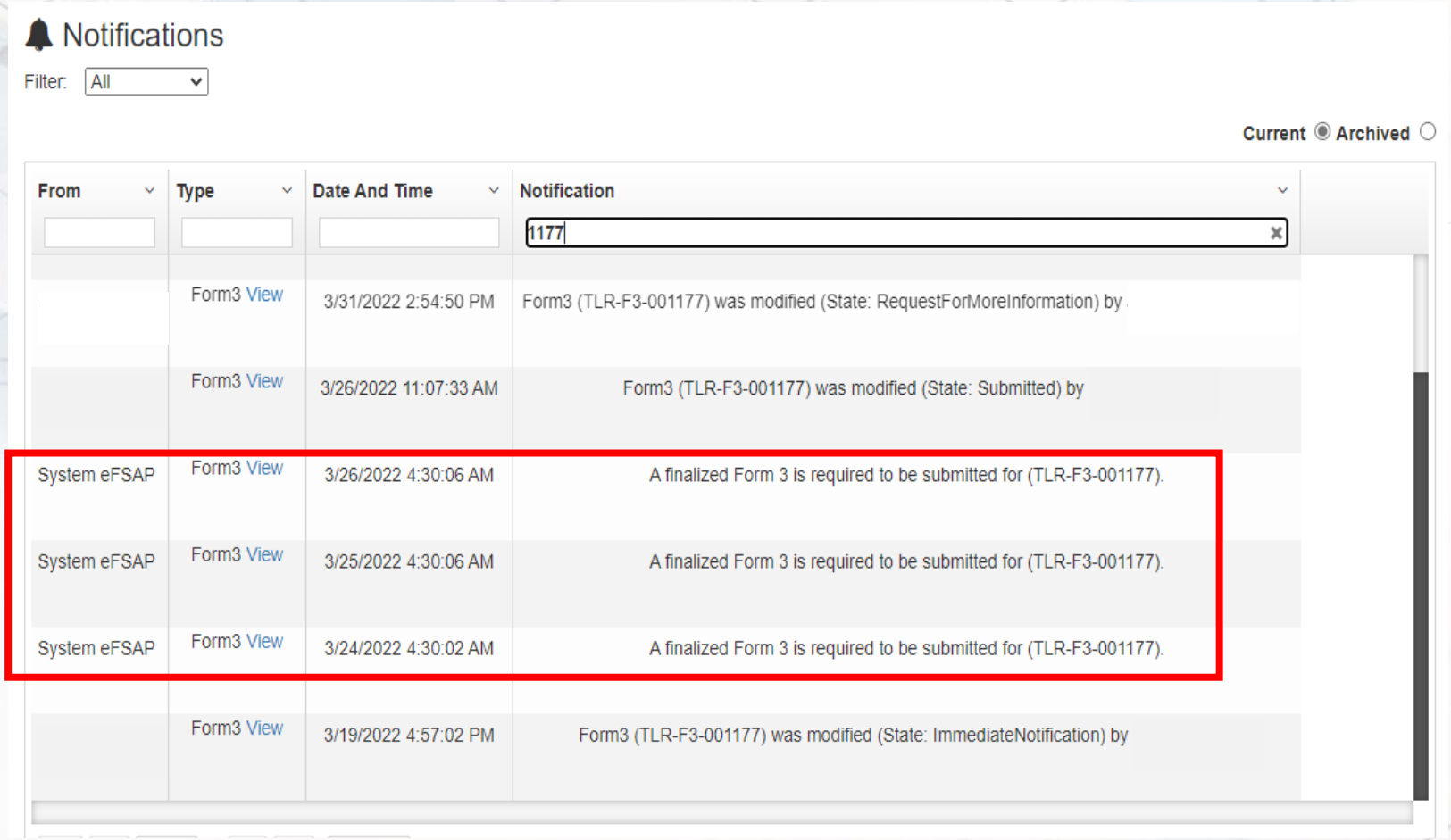
Step 3



APHIS/CDC Form 3 – Submission Status Notifications

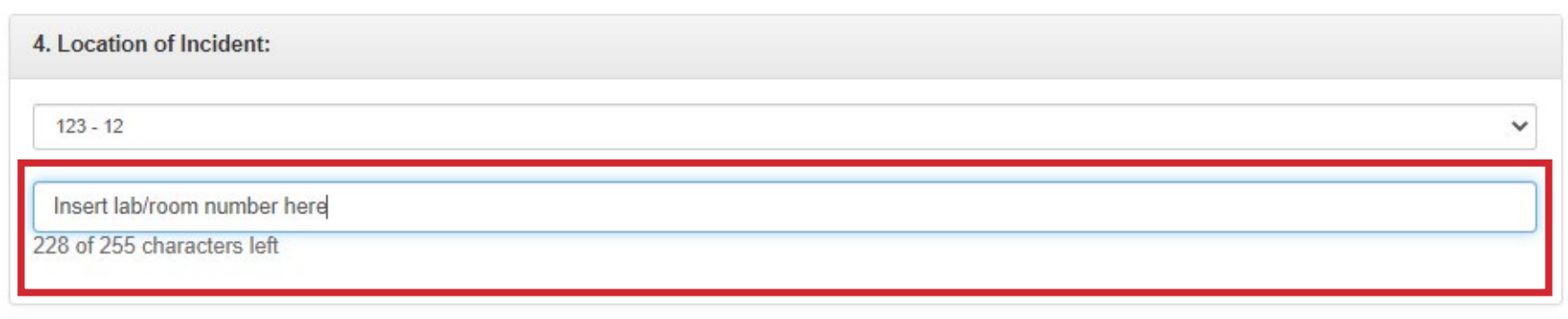
Submission notifications

Finalized Form 3 submission reminders are autogenerated daily as a notification on the entity's homepage, beginning 3 days prior to the 7-day requirement

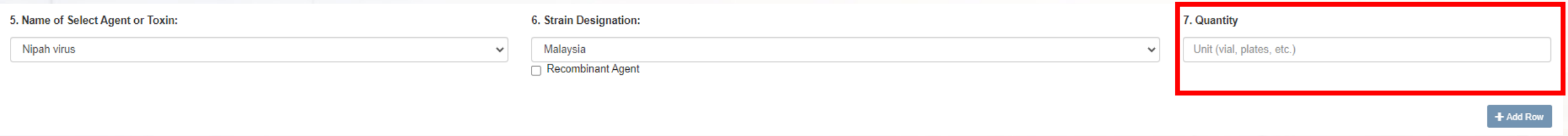


APHIS/CDC Form 3 Helpful Information

- Block B4. Location of Incident



- Block B7. [BSAT] Quantity



APHIS/CDC Form 3 Helpful Information (continued)

- Block C6. Medical surveillance and/or treatment

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

- [ ] None
- [x] Physical evaluation
- [ ] Fever/symptom watch
- [ ] Serology screening
- [ ] Antibiotics or other prophylaxis
- [x] Other

114 character limit (with spaces)

- Block C7b. Corrective actions

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)

- [ ] Retraining on existing policy
- [ ] New PPE provided
- [ ] Audit/remove faulty PPE
- [ ] New/modified policy
- [ ] New equipment provided
- [ ] Audit/remove faulty equipment
- [ ] New training developed
- [ ] Equipment repair
- [ ] None
- [ ] New/updated SOP
- [ ] Review/revise risk assessment
- [x] Other:

<100 characters

APHIS/CDC Form 3 – Submitting Completed Form 3

- Submitting the report prompts the FSAP to begin its comprehensive review of the incident
- Following review of the Form 3 report, it will either be closed, or additional information will be requested via a Request For Information (RFI) letter

APHIS/CDC Form 3 RFI Responses – Responding to RFI and Returning to Agency

- If additional information is needed, an RFI letter is uploaded into eFSAP information system by the Form 3 team and 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 that prompts the Form 3 team to review the responses

APHIS/CDC Form 3 Scenarios

APHIS/CDC Form 3 Scenario A

Today, your entity submitted a complete APHIS/CDC Form 3 in eFSAP information system for a select agent release that was discovered 4 days ago. Is your entity compliant with the requirements of Section 19 of the select agent regulations?

A. Yes, because the form was submitted within 7 days
B. No, because the form was not submitted within 3 days
C. No, because FSAP was not immediately notified of the release
D. I do not know

APHIS/CDC Form 3 Scenario A Response

Today, your entity submitted a complete APHIS/CDC Form 3 in eFSAP information system for a select agent release that was discovered 4 days ago. Is your entity compliant with the requirements of Section 19 of the select agent regulations?

C. No, because FSAP was not immediately notified of the release

APHIS/CDC Form 3 Scenario B

A laboratorian at your entity noticed a small hole in the right index finger of their BSL-4 suit glove while handling Ebola infected mice in the biosafety cabinet (BSC) of the ABSL-4 laboratory. Is this reportable using an APHIS/CDC Form 3? If so, when?

A. Yes, because it is a breach in containment and must be reported immediately
B. No, because it is not a breach in containment while working in the BSC
C. Maybe, it depends if the mice showed symptoms of Ebola disease
D. Not sure

APHIS/CDC Form 3 Scenario B Response

A laboratorian at your entity noticed a small hole in the right index finger of their BSL4 suit gloves while handling Ebola infected mice in the biosafety cabinet (BSC) of the ABSL-4 laboratory. Is this reportable using an APHIS/CDC Form 3? If so, when?

A. Yes, because it is a breach in containment and must be reported immediately

APHIS/CDC Form 3 Scenario C

What criteria does your entity use to determine incident severity for APHIS/CDC Form 3, question B9?

A. A documented risk assessment only
B. A combination of a documented risk assessment and biosafety resources
C. Multiple resources, but no documented risk assessment
D. No criteria, just the knowledge and experience of Biosafety Officers

APHIS/CDC Form 3 Scenario C

What criteria does your entity use to determine incident severity for APHIS/CDC Form 3, question B9?

B. A combination of a documented risk assessment and biosafety resources

APHIS/CDC Form 3 Scenario D

A dried leak is observed on the floor beneath an inlet plumbing fixture to the holding tank of the effluent decontamination system (EDS) by maintenance staff. The EDS is connected to several BSL-3 registered rooms where select agent work is frequently performed. Is this reportable using an APHIS/CDC Form 3?

A. No, because the leak was dry and probably not infectious

B. Maybe, it depends on whether there was select agent work performed at the time of the leak

C. Yes, unless the presence of select agent is ruled out

D. No, because the maintenance personnel did not come in direct contact with the dried leak

APHIS/CDC Form 3 Scenario D Response

A dried leak is observed on the floor beneath an inlet plumbing fixture to the holding tank of the effluent decontamination system (EDS) by maintenance staff. The EDS is connected to several BSL-3 registered rooms where select agent work is frequently performed. Is this reportable using an APHIS/CDC Form 3?

C. Yes, unless the presence of select agent is ruled out

APHIS/CDC Form 3 Scenario D (continued)

For the same dried leak observed on the previous scenario, the Responsible Official completed and submitted the APHIS/CDC Form 3 in eFSAP. What information should be provided for Block B4 (location) and Block B7 (quantity) on the form?

A. Block B4 = BSL3 laboratory number; Block B7 = Unknown
B. Block B4 = Unknown; Block B7 = Unknown
C. Block B4 = Unknown; Block B7 = Estimate of leak volume
D. Block B4 = EDS room number; Block B7 = Estimate of leak volume

APHIS/CDC Form 3 Scenario D Response (continued)

For the same dried leak observed on the previous scenario, the Responsible Official completed and submitted the APHIS/CDC Form 3 in eFSAP. What information should be provided for Block B4 (location) and Block B7 (quantity) on the form?

D. Block B4 = EDS room number; Block B7 = Estimate of leak volume

BREAK

APHIS/CDC Form 4

APHIS/CDC Form 4 Overview

- The Responsible Official (RO) must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification
  - Tier 1 select agents and toxins (42 CFR §73.9(c)), must be immediately reported by telephone, fax or email*
  - A completed and signed APHIS/CDC Form 4A must be submitted within **seven calendar** days after identification

*7 CFR §331.9(c) and *9 CFR §121.9(c) there are some non-tier 1 USDA VS and PPQ select agents that also require immediate reporting.

Image of thumbtack on calendar day 7

APHIS/CDC Form 4 Overview (continued)

- The RO is required to report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing
  - A completed and signed APHIS/CDC Form 4B must be submitted within **90 calendar days of receipt of the agent or toxin**

42 CFR §73.9(d), 9 CFR §121.9(d)

APHIS/CDC Form 4 Helpful Information – Notification Type

- Immediate Notification
  - Immediate Notification (IN) is required for Tier 1 select agents and toxins (42 CFR §73.9(c))*
  - Type of IN

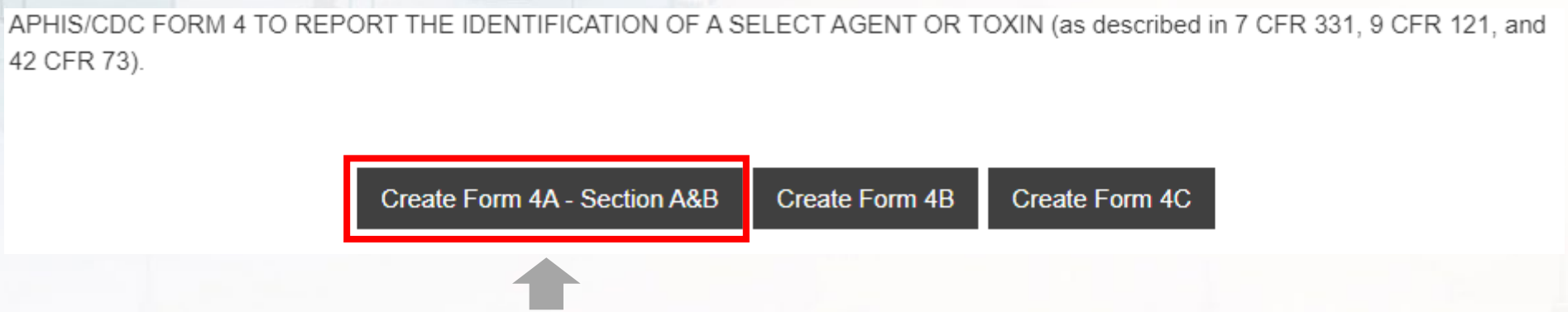
4. Type of notification:

☐ E-mail ☐ Fax ☐ Telephone ☐ eFSAP ☐ N/A

*There are some non-tier 1 USDA VS and PPQ select agents that also require immediate reporting.

APHIS/CDC Form 4 Helpful Information – How to create an immediate notification step 1

- How to create an APHIS/CDC Form 4A report in the eFSAP Information System and an IN:
  - Open your entity's homepage, click on the "Form 4" tab, and select the "Create Form 4A-Section A&B" button



APHIS/CDC Form 4 Helpful Information – How to create an immediate notification step 2

- Complete Section B questions 1,2,3 and 10

SECTION B – SELECT AGENT OR TOXIN IDENTIFIED FROM CLINICAL/DIAGNOSTIC SPECIMEN(S)

1. Select Agent or Toxin Identified:

Francisella tularensis

2. Date identified:

02/02/2022

3. Date of Immediate Notification for Tier 1 agents

02/02/2022

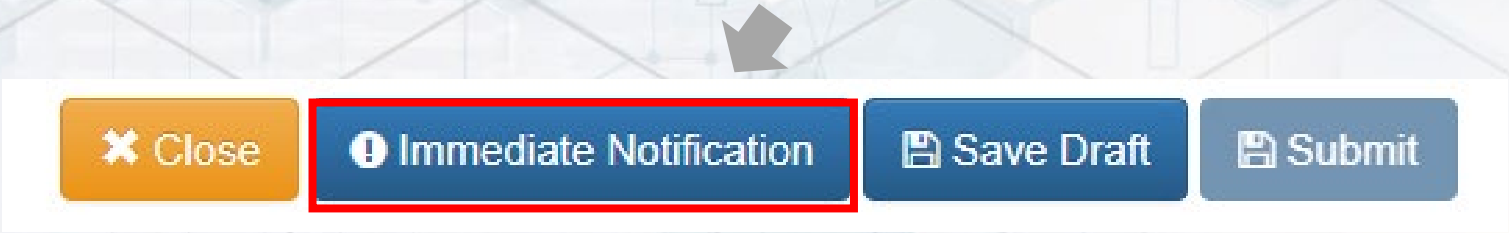
10. Were any of the samples containing a select agent or toxin handled outside of primary containment which may have led to an unintentional release and/or exposure to the select agent or toxin? ○ No ○ Yes

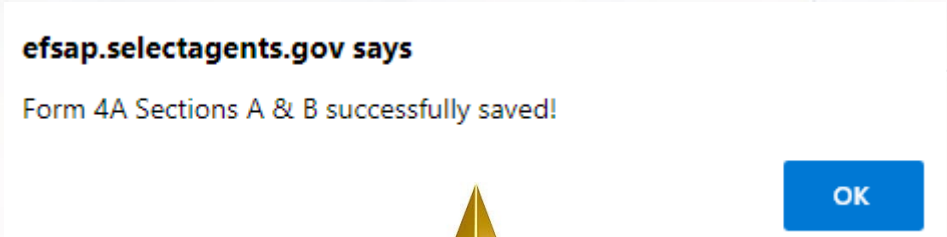
11. Has the sender(s) (i.e., sample provider(s)) of the specimen(s) been notified of the identification of the select agent or toxin?

○ No ○ Yes

APHIS/CDC Form 4 Helpful Information - How to create an immediate notification step 3

- Select the “Immediate Notification” button





- Reasons to use Immediate Notification button
  - Creates and saves record in eFSAP information system
  - Requires minimal information
  - FSAP’s preferred method

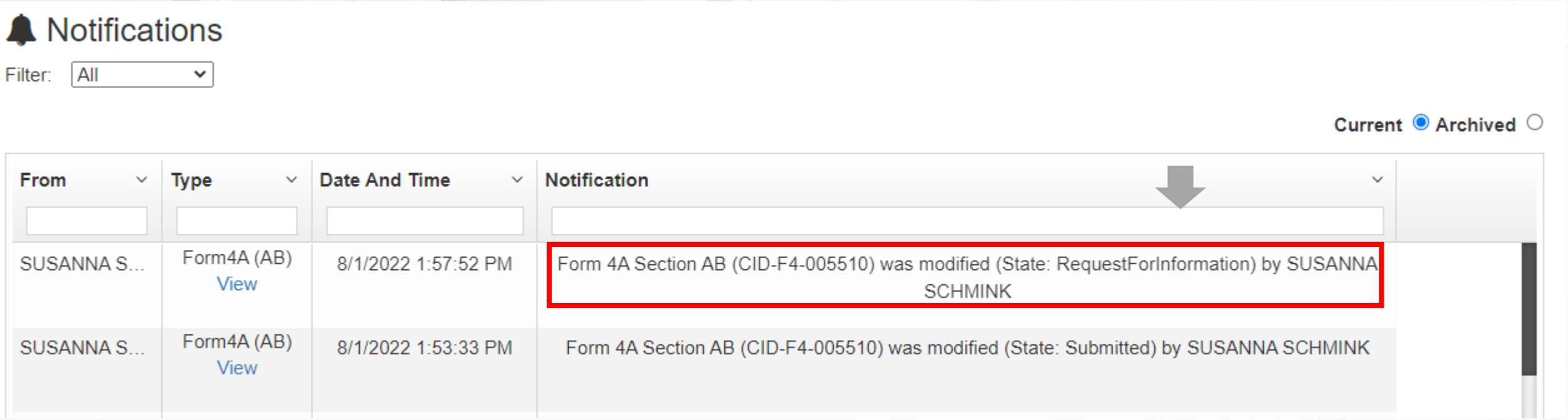
Gold star

APHIS/CDC Form 4 Request for Information #1

- RFI is our process for following up on APHIS/CDC Form 4 information
  - Clarification for date(s), such as immediate notification date
  - Additional information needed for incomplete questions, or incorrect sample provider email
  - Discordant information between APHIS/CDC Form 4A Sections A&B provided by the reference laboratory with information provided on APHIS/CDC Form 4A Sections C&D from the sample provider
    - Common examples include: date of notification, number of samples sent and received, and sample type

APHIS/CDC Form 4 Request for Information #2

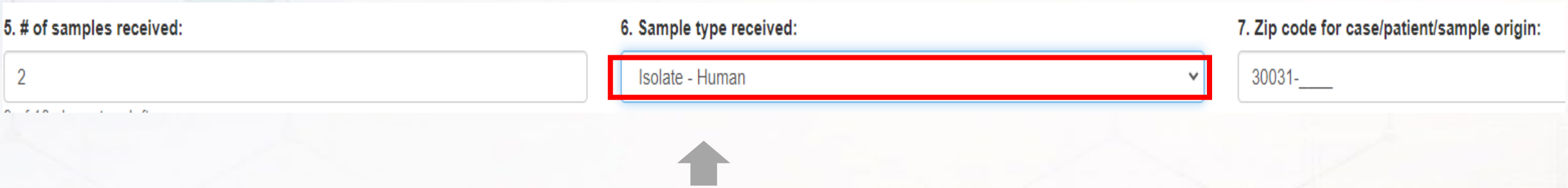
- The entity's homepage Notifications table will list the APHIS/CDC Form 4A status as RFI



APHIS/CDC Form 4 Request for Information #3

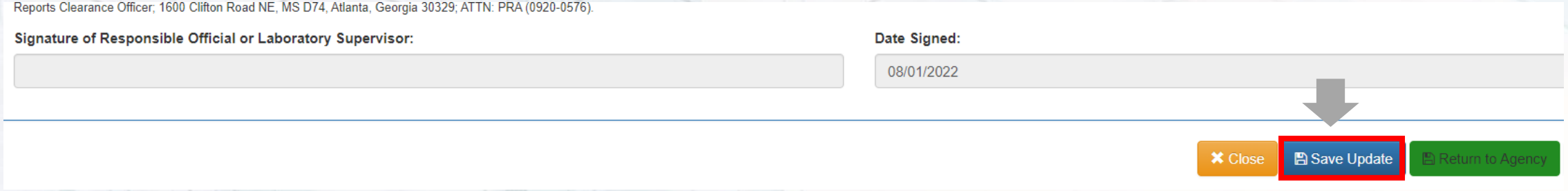
- Review note in “General Discussion” box for the specific APHIS/CDC Form 4

- Update your APHIS/CDC Form 4

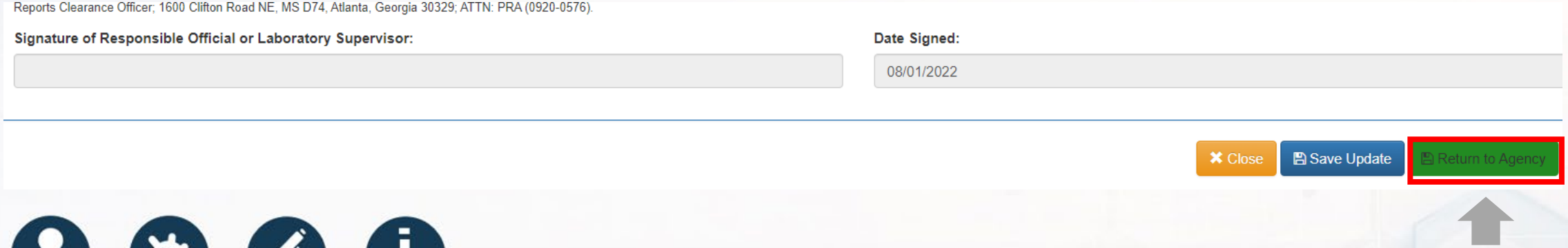


APHIS/CDC Form 4 Request for Information #4

- After updating the form, select the “Save Update” button

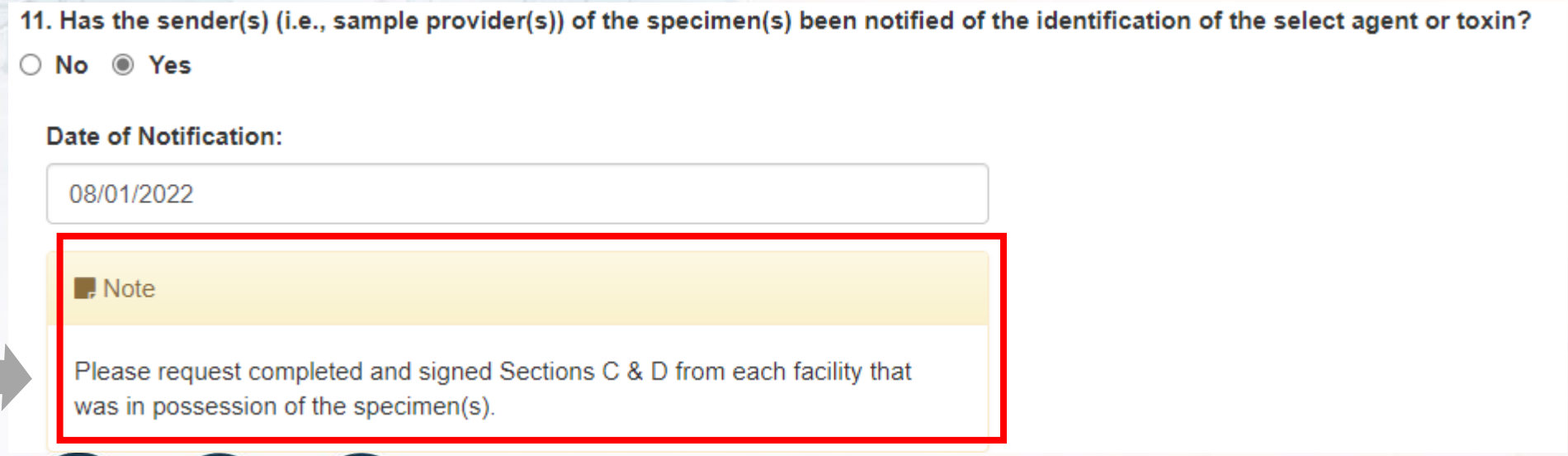


- Select the green “Return to Agency” button to notify FSAP that the form has been updated and is ready for review



APHIS/CDC Form 4 Retaining Select Agents and Toxins

- Selecting Retained for Disposition? (question B9 or D8)
  - Update your APHIS/CDC Form 1 Sections 3 and 7B for any select agents and toxins that were <u>not previously possessed</u>
- Date of sample provider notification (question B11)
  - Notify sample provider and request Sections C & D



APHIS/CDC Form 4 Scenarios

APHIS/CDC Form 4 Scenario A

Your entity identified *Burkholderia pseudomallei* from an environmental sample. Is an APHIS/CDC Form 4 required to be submitted?

A. No, because it is from an environmental sample
B. No, because *Burkholderia pseudomallei* is not a select agent in an environmental sample
C. Yes, because a select agent was identified
D. I do not know

APHIS/CDC Form 4 Scenario A Response

Your entity identified *Burkholderia pseudomallei* from an environmental sample. Is an APHIS/CDC Form 4 required to be submitted?

C. Yes, because a select agent was identified

APHIS/CDC Form 4 Scenario B

Your entity determines that a patient blood culture is presumptive for *Brucella* species and plans to send the isolate to a reference laboratory for further identification. Should you submit a completed APHIS/CDC Form 4A Sections A/B with this select agent identification in eFSAP information system?

A. Yes, because the identification is mostly complete by your entity
B. No, because the identification is not final
C. No, because its rare to isolate *Brucella* species from a patient's blood culture
D. I do not know

APHIS/CDC Form 4 Scenario B Response

Your entity determines that a patient blood culture is presumptive for *Brucella* species and plans to send the isolate to a reference laboratory for further identification. Should you submit a completed APHIS/CDC Form 4A Sections A/B with this select agent identification in eFSAP information system?

B. No, because the identification is not final

APHIS/CDC Form 4 Scenario C

After receiving clinical sample nucleic acid extracts from a non-registered entity for identification, your entity first performs purification testing on the extracts. Three days later, the broth cultures show growth. Your entity isolates and identifies *Francisella tularensis* from the broth cultures. Is an APHIS/CDC Form 4 required?

A. No, because the nucleic acid extracts are excluded from the regulations
B. Yes, because a select agent was identified
C. Maybe, it depends on how the clinical samples were extracted
D. Not sure

APHIS/CDC Form 4 Scenario C Response

After receiving clinical sample nucleic acid extracts from a non-registered entity for identification, your entity first performs purification testing on the extracts. Three days later, the broth cultures show growth. Your entity isolates and identifies *Francisella tularensis* from the broth cultures. Is an APHIS/CDC Form 4 required?

B. Yes, because a select agent was identified

APHIS/CDC Form 4 Scenario D

Your entity received one blood culture bottle, two slants and four plates from the same patient for identification. *Brucella abortus* is identified from one of the slants. How would you record the number of samples received on your APHIS/CDC Form 4 for B5?

A. One, because all samples are from the same patient
B. One, because testing of only one slant resulted in an identification of a select agent
C. Seven, because you received seven samples
D. Not sure

APHIS/CDC Form 4 Scenario D Response

Your entity received one blood culture bottle, two slants and four plates from the same patient for identification. *Brucella abortus* is identified from one of the slants. How would you record the number of samples received on your APHIS/CDC Form 4 for B5?

B. One, because testing of only one slant resulted in an identification of a select agent

Security Access Approval

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Access Approval

Access Approval Overview

- Why update statuses in the eFSAP information system?
  - To align regulatory language with access approval status
  - Old status terms were based on security risk assessment (SRA) statuses
  - To clarify revoked and denied

REVOKED	DENIED
Individual no longer has approval to access select agents and toxins	Individual does not have approval to access select agents and toxins

New Access Approval Statuses

NEW STATUS	MEANING
Approved	HHS Secretary or APHIS Administrator has provided access approval
Denied/Restricted	Access approval is denied for a new applicant identified as being a restricted person
Revoked/Restricted	Access approval is revoked for a currently approved person identified as being a restricted person
Denied or Revoked for Cause	Access approval is denied or revoked for a reason other than being identified as a restricted person
Terminated	Entity removes the individual from the registration
Expired	Access approval has expired
Pending	Applicant is pending access approval

Who to Contact

- For Access approval concerns: Contact Your FSAP Point of Contact (POC)
  - Statuses in eFSAP information system
  - Transfers, reapplying an individual previously terminated from your entity's registration
  - SRA Expedites – written request from RO to FSAP showing good cause
  - eFSAP information system issues
- For SRA processing concerns: Contact the Bioterrorism Risk Assessment Group (BRAG)
  - Cancelled SRA - BRAG will notify you that they cannot process the SRA and the reason
  - BRAG received date - Shows in eFSAP information system
  - SRA processing: BRAG will only inform you if the SRA is processing

Individuals with an Active SRA at BRAG

- FSAP can provide access approval for an individual with an active SRA without the entity sending a new FD 961
- When adding an individual who is currently at another entity
  - You must reach out to the other entity to discuss any concerns
- BRAG will not process a new FD 961 if they already have an active SRA
  - BRAG will notify the entity and sponsor agency
  - Individual access approval will expire based on the current SRA date
- Regularly check access approval expiration dates and eFSAP information system notifications

Access Approval Helpful Information

- Entity terminates person and then decides to add them back
  - Contact your FSAP POC
- Individual not added to the entity's registration or has a terminated status
  - FSAP cannot approve
  - BRAG will continue processing the SRA and FSAP will contact the entity to add or re-apply the individual
- DoJ/UIN in BRAG's database does not match eFSAP information system
  - Entity must use the eFSAP information system number

Access Approval Helpful Information (continued)

- Entity name provided on the FD 961 to BRAG does not match eFSAP information system
  - Entity must use entity name in eFSAP information system
- Individual does not have an active SRA at BRAG but has a DoJ/UIN
  - Individual must submit documentation to BRAG
- The SRA process cannot be expedited without an FD 961 at BRAG

Access Approval Scenarios

Access Approval Scenario A

Your entity hired a new laboratorian. When you add them to eFSAP information system, you find the individual already has a DoJ/UIN. What can you do? Select all that apply:

A. Contact your FSAP POC and request the current DoJ/UIN
B. Submit the FD 961 without the DoJ/UIN
C. Change the individual's date of birth that will generate a new DoJ/UIN in eFSAP information system
D. Contact the other entity for individual's DoJ/UIN

Access Approval Scenario A Response

Your entity hired a new laboratorian. When you add them to eFSAP information system, you find the person already has a DoJ/UIN. What can you do?

Select all that apply:

A. Contact your FSAP POC and request the current DoJ/UIN

D. Contact the other entity for individual's DoJ/UIN

Access Approval Scenario B

Your entity is starting a new research project in two weeks, and you want your new laboratorian's SRA expedited. What should you do?

A. Request the expedite by calling or sending an email to BRAG
B. Contact your FSAP POC and request the individual be expedited
C. Contact your FSAP POC and request the individual be expedited with written good cause

Access Approval Scenario B Response

Your entity is starting a new research project in two weeks, and you want your new laboratorian's SRA expedited. What should you do?

C. Contact your FSAP POC and request the individual be expedited with written good cause

Access Approval Scenario C

An individual on your entity's registration is deployed to Africa and cannot submit a renewal FD 961 until they return 10 days before expiration. What actions can you take?

A. Request the SRA be expedited through BRAG
B. Contact your FSAP POC before the individual returns and request the SRA be expedited
C. FedEx the FD 961 to BRAG knowing it will be complete in 10 days
D. Have a plan for what happens if the individual's access approval expires

Access Approval Scenario C Response

An individual on your entity's registration is deployed to Africa and cannot submit a renewal FD 961 until they return 10 days before expiration. What actions can you take?

D. Have a plan for what happens if the individual's access approval expires

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