Electronic Federal Select Agent Program (eFSAP)

Information System

2022 User Manual

Chapter 1 – Obtaining Access to eFSAP

To gain access to the eFSAP information system, users must establish a Secure Access Management System (SAMS) account. SAMS protects integrated applications, such as eFSAP, by requiring users to enter a user ID and password before being allowed access. For applications with higher security requirements, such as eFSAP, users must submit identification proofing documents, such as a passport or driver's license, as part of the application process in order to verify the user's identity.

Information regarding the SAMS account process is available here on the Federal Select Agent Program (FSAP)website.

I: Obtaining a SAMS Account

1. The Responsible Office (RO)/Alternate Responsible Official (ARO) must have their FSAP point of contact (POC) request the SAMS account invitation by emailing efsapsupport@cdc.gov with the following information:
   A. First and last name
   B. Email address
   C. Full entity name
   D. Role requested based on the below chart (RO/ARO, Super Admin, Read-Only, Principal Investigator):

		RO/ARO	Super Admin	Prinicpal Investigator	Read-Only
APHIS/CDC Form 1	Draft Technical Amendments	✓	✓	✓ *	x
	Submit/Withdraw Technical Amendments	✓	x	x	x
	Submit Administrative Amendments	✓	x	x	x
APHIS/CDC Form 2	Draft Form 2s	✓	✓	n/a	x
	Submit/Withdraw Form 2s	✓	x	n/a	x
APHIS/CDC Form 3	Draft Form 3s	✓	✓	n/a	x
	Submit/Withdraw Form 3s	✓	x	n/a	x
APHIS/CDC Form 4	Draft Form 4s	✓	✓	n/a	x
	Submit/Withdraw Form 4s	✓	x	n/a	x
Inspections	Draft Entity Responses	✓	✓	n/a	x
	Submit Entity Responses	✓	x	n/a	x
File Upload		✓	✓	x	✓
Submit General Discussion		✓	✓	✓	✓

** Principal Investigators cannot initiate technical amemdments, but can complete the information after the RO/ARO or Super Admin user initiates and saves a draft*

1) RO and ARO users have the same permissions throughout the eFSAP system. They are able to make amendments to their registration (APHIS/CDC Form 1), submit transfer requests (APHIS/CDC Form 2), report incidents (APHIS/CDC Form 3), and report the identification of select agents and toxins (APHIS/CDC Form 4). They are also able to upload and reclassify files, send messages via the general discussion boards, and respond to inspection findings.
2) Entity Super Admin users can view all data in Forms 1, 2, 3, and 4; information on the entity landing page; and inspection-related information. To assist RO/ARO users, super admins can view, draft, and save, but not submit, Form 1 technical amendments; Forms 2, 3, and 4; and responses to inspection findings. Like RO/ARO users, super admins can upload and reclassify files and sendmessages via the general discussion boards.
3) Entity Read-Only users cannot submit or modify any data, however, they are able to view all data in Forms 1, 2, 3, and 4; all information on the entity landing page; and all inspection-related information. To assist the RO/ARO users, read-only users can only upload files.

4) Entity Principal Investigator (PI) users are unable to access any entity information other than work objectives and select agent and toxin strains/serotypes to which they are currently assigned (Form 1 Sections 7A/C and 7B). PIs can view, edit, and save, but cannot submit amendments to Form 1 Section 7A/C while listed as a PI on the amendment. PIs can view all select agent and toxin strains/serotypes to which they are assigned. They can add select agent and toxin strains/serotypes. They are also able to modify select agent and toxin strains/serotypes provided that they are the only PI assigned to that strain/serotype. Finally, they are able to remove select agent and toxin strains/serotypes provided 1) they are the only PI assigned to that strain and 2) it is not the last strain/serotype of that particular select agent or toxin possessed by the entity.

2. The user follows the instructions in the email and uses the provided username and password when logging into the **SAMS Credentials** login box, accepts the Rules of Behavior upon their initial login to SAMS, and completes the required demographic information for registration with SAMS.
3. Upon submitting, the user receives a confirmation screen indicating "Task Completed." Within an hour, the user receives an email from **SAMS-NO-REPLY(CDC)** with the subject of **CDC: SAMS Partner Portal – Identity Verification Request Form** and completes the **Applicant** section by following the instructions provided in the email.
4. The user takes the printed form, along with appropriate photo identification, to a Proofing Agent (i.e., a Notary Public or person specifically designated by CDC to conduct identity verification), requests identity verification by providing a photo ID with the user's home address and completes the **Proofing Agent – Notary** section. A copy of the photo ID used for the Proofing Agent must be submitted with the user's application packet. If the address does not match (e.g., because the user recently moved), a photocopy of a utility bill, pay stub, voter registration card, or other document which displays the user's current home address can be used for validation.
5. The user must submit the completed form, along with all required supplemental documentation, to SAMS by following the instructions provided in the email. Acceptable mechanisms for submission are:
   A. **Upload** a single PDF that includes all proofing documentation (form, scan(s) of ID, notary stamp, supplemental documentation, etc.)
   B. **Fax** to 877-681-2899 toll-free
   C. **Mail** to:
   Centers for Disease Control and Prevention
   Attn: Proofing Authority
   1600 Clifton Road MS K-94
   Atlanta, GA 30329

   Note: User receives an email notification when the documentation has been successfully delivered to the CDC Proofing Authority.
6. Once the completed form has been processed by the SAMS application administrator, the user receives an email notification indicating that they have been granted access to eFSAP.

II: Requesting Removal of SAMS Account

When the RO needs to remove a user's access to eFSAP, the RO (or the FSAP entity POC on the RO's behalf) can request removal by sending an email to efsapsupport@cdc.gov with the user's first and last name, email address, and the reason for removal.

Chapter 2 – Submitting Registration Application

To apply to possess, use, or transfer select agents and toxins (as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73), entities initiate the application process through the submission of APHIS/CDC Form 1: Registration for Possession, Use, and Transfer of Select Agents and Toxins *via* eFSAP. Information requested in this form includes facility information; a list of select agents and/or toxins to be possessed, used, or transferred by the entity; a list of individuals who will have access or potential access to select agents and toxins; and information about the work to be performed. To start the application process, please contact lrsat@cdc.gov or DASAT@usda.gov.

I. Submitting an Application to Register with FSAP

To begin registration with FSAP, the entity designated user requests access to eFSAP by emailing efsapsupport@cdc.gov. The FSAP Point of Contact (POC) that is assigned to the entity assists the entity with acquiring SAMS accounts as described in Chapter 1 and populating the APHIS/CDC Form 1 (Registration for Possession, Use, and Transfer of Select Agents and Toxins) as described in the chapters below. If additional information is needed to be uploaded in eFSAP, the FSAP POC assists the entity with uploading these documents (e.g., biosafety plan, security plan, incident response plan, facility documents).

II. Withdrawing a Registration Application

If an entity decides that they no longer want to proceed with the registration process, the entity notifies FSAP of their wish to withdraw the application.

To withdraw the application, the user must complete the following tasks:

1. In the General Discussion board on the Home page, provide a statement indicating the entity is requesting to withdraw the registration application from FSAP. The request should state the wish to withdraw from FSAP and the reason for withdrawal.
2. Withdraw all personnel except the RO from Section 4 (reference instructions noted below).

III. Amending the Registration

After the certificate of registration is issued by FSAP, the entity's registration is required to be amended prior to making any changes. There are two types of amendment requests.

Administrative amendment requests (*Add/Remove/Modify/Reapply Personnel; Update Entity Name, Abstract or Type; RO signatures; Add Building/Room or Suite; Add/Reactivate Select Agent or Toxin; Add/Remove/Modify Strain/Serotype*) do not require a cover letter to be submitted by the Responsible Official.

Technical amendment requests (*Change Responsible Official; Modify Building, Room or Suite; Add/Remove/Modify Work Objective; Modify Section 5; Update Entity Address*) must include a cover letter and the amendment must be approved by FSAP before the requested changes can be implemented. Requests that do not clearly explain the changes to be made to registration or those that conflict with the information submitted may require the submission of additional documentation and result in delayed approval of the amendment request.

IV. Saving and Withdrawing Draft Amendments

Although the technical amendments are slightly different for each type, the user's ability to save and withdraw a draft is the same. The user has four options for amendments:

- **Withdraw Amendment** – draft is removed and no longer appears as an amendment. The amendment status changes to "Deactivated" and appears as a read-only artifact.
- **Review or Make Changes** – able to review and make changes to the information.
- **Save Draft** – information is saved, but not submitted to FSAP.
- **Submit** – information is submitted to FSAP for review.

If FSAP needs additional information, the status of the amendment changes to "Request for Information." The option of "Submit" changes to "Return to Agency." The user selects "Review or Make Changes" to provide additional information requested by FSAP and then "Return to Agency" to resubmit the amendment.

Chapter 3 – Personnel Information

Individuals who require access to select agents and toxins must be listed on the entity's APHIS/CDC Form 1, as well as the RO, ARO, and owner/controller (if required).

I. Adding Individuals (e.g., Principal Investigator (PI), Laboratorian)

To add individuals to registration, the user must complete the following tasks:

1. Log into eFSAP and select the Form 1 tab from the top right of the landing page.
2. Select "Amend."
3. Select "Section 4: Add/Remove/Modify/Reapply Personnel" and click "OK."
4. When "Section 4 – Entity Personnel" opens, select "Add new personnel" to add new personnel.
5. Enter the name and date of birth of the individual to be added.
6. For a new individual, select the "Generate new DOJ number" button. For individuals who already have a unique Department of Justice (DOJ) number, FSAP performs a search after the generate button is pressed. The system alerts the RO to contact the FSAP POC if there is an identical user with the same information. The FSAP POC provides the RO with the assigned DOJ number to input in the DOJ number box.
7. Select a primary role for the individual. **Note:** A laboratorian, animal care staff, or unescorted visitor requires an assigned PI who is responsible for supervising the individual. A drop-down menu appears with the currently approved PIs. Multiple PIs can be selected. After selecting the PI(s), indicate whether the individual should have Tier 1 access and/or inventory responsibilities (both are optional). **Note:** Contact information is required only for individuals assigned as RO, ARO, and owner/controller (if required).
8. Electronically sign by typing your name in the "RO Signature" box. **Note:** An RO signature is not required if the individual is being assigned as a PI or ARO.
9. Select "Add Personnel." **Note:** The new person displays as a "Pending" status until the access status is approved by FSAP. If the person is approved for access, the status is updated to "Approved" and dates when "Access Approved" and "Access Expiration" are recorded by FSAP.

II. Changing Responsible Official

To change the RO, the current RO must complete the following tasks:

1. Log into eFSAP and select the Form 1 tab.
2. Select "Amend."
3. Select the "Section 4 – Change Responsible Official."
4. Select the new Responsible Official from the drop-down list, include information in the "Complete your cover letter for this amendment" regarding the change in the Responsible Official, and select "OK."
5. After the message box appears, select "OK." For the newly appointed Responsible Official, complete Section 4 contact information.
6. Select "Save and Proceed."
7. When the message box appears, select "OK" and "Submit."
8. Review amendment and select "Submit." **Note:** Upon approval of the amendment, the role for the current RO is removed unless the new RO adds a role for the current RO. In the event that an entity loses the services of its RO, an entity may continue to possess, use, or transfer select agents or toxins only if it appoints as the RO another individual who has been approved by FSAP (has a current SRA) and who meets the requirements of the regulations. The owner of the entity must appoint the new RO. The new RO cannot appoint himself/herself.

III. Updating Information for Individuals Approved for Access

If an individual changes their name, role, or title, or is assigned to a new supervising Principal Investigator, the user must complete the following tasks:

Note: Only laboratorians, animal care staff, and unescorted visitors require a supervising PI.

1. Log into eFSAP and select the Form 1 tab.
2. Select "Amend."
3. Select the "Section 4 - Add/Remove/Modify/Reapply Personnel" and click "OK."

4. Select the individual to be modified, click “Edit” and update the information with the changes. For changes to Tier 1 status, select the individual to be modified, select “Edit” and select/deselect the box for Tier 1 access.
5. Provide signature if applicable, and then click “Submit.”

IV. Replacing a Principal Investigator (PI)

To migrate strain, work objectives, and personnel from one PI to another PI, the user must complete the following tasks:

1. Log into eFSAP and select the Form 1 tab.
2. Select “Amend.”
3. Select from the drop-down menu “Replace Principal Investigator” and click “OK.”
4. Select the PI to be replaced from drop-down menu.
5. After replacing the PI who is leaving with the new PI (one or more PIs can be named as replacements), eFSAP provides confirmation pages to review. The first page shows the personnel that are supervised by the leaving PI and replacement PI(s). The next screen shows the work objectives that are automatically transferred to the replacement PI. The final review screen shows the strains/serotypes that are automatically transferred to the replacement PI.
6. After reviewing the changes, click “Commit Changes” to have eFSAP automatically process the PI replacement.
7. Add a role to the replaced PI or remove the PI via the following steps in Section V, “Removing a PI.”

V. Removing a PI

To remove a PI, the PI cannot have any strains assigned in Section 7B and cannot be the sole PI on any approved, pending, draft, or suspended work objectives. The alert at the bottom of the screen indicates to the user why the PI cannot be removed. The removal of a PI must be completed in the following order:

- Remove the PI from Section 7B strains and serotypes, if necessary.
- Remove the PI from any Section 7A/C work objectives.

When the PI is no longer assigned to strains and work objectives, the warnings do not appear and the “Remove” button may be selected. Upon clicking “Remove,” the PI is automatically removed as a supervising PI and a popup lists all individuals who need to be assigned to a new PI.

VI. Removing Individuals

To remove individuals from the registration, the user must complete the following tasks:

1. Log into eFSAP and select the Form 1 tab.
2. Select “Amend.”
3. Select the “Section 4 - Add/Remove/Modify/Reapply Personnel" and click “OK.”
4. Select the edit button to the right of the person’s information.
5. Select “Remove” and provide the reason for removal from the drop-down list. Select “Finalize.” A pop-up appears that states the person is inactive and not available for work packages. Select “OK.” The individual’s status changes to “terminated.” **Note:** A new owner/controller must be assigned if no other owner/controller is assigned.

Chapter 4 – Select Agent and Toxin Information

The registration must contain a list of select agents and/or toxins to be possessed, used, or transferred by the entity.

I. Adding a Select Agent or Toxin

To add a select agent or toxin, the user must complete the following tasks:

1. Log into eFSAP and click on the Form 1 tab.
2. Select “Amend.”
3. Use the drop-down to select “Section 3–Add Select Agent or Toxin” and select “OK.”

4. Use the drop-down to select the agent/toxin and click "Add." The agent/toxin displays below the table. **Note:** For an existing registration if the agent you wish to add does not appear in the drop-down list, see instructions for reactivating a select agent/toxin.
5. Select "Save" at the top of the page.
6. The following message appears "*This request will reactivate the select agent(s)/toxin(s) in an unassigned status. The select agent(s)/toxin(s) will change to a "Pending" status when added to a work objective in Section 7A/C. The agent(s)/toxin(s) will not be approved for use or storage until the Section 7A/C amendment is approved.*" After it is displayed, select "Proceed" and select "OK." After selecting OK, the agent/toxin displays on Section 3 as "unassigned." Submit a Section 7A/C amendment to assign the agent/toxin to a work objective. The agent/toxin is officially added to the entity registration when the Section 7A/C amendment is approved.

II. Reactivating a Select Agent/Toxin

To reactivate a select agent or toxin, the user must complete the following tasks:

1. Log into eFSAP and click on the Form 1 tab.
2. Select "Amend."
3. Use the drop-down to select "Section 3 – Reactivate Select Agent and Toxin" and click "OK."
4. Click the "Reactivate" button for the select agent(s) and toxin(s) to reactivate and select "Save."
5. The following message appears "*This request will reactivate the select agent(s)/toxin(s) in an unassigned status. The select agent(s)/toxin(s) will change to a "Pending" status when added to a work objective in Section 7a/c. The agent(s)/toxin(s) will not be approved for use or storage until the Section 7a/c amendment is approved.*" After it is displayed, select "Proceed" and select "OK."

III. Removing a Select Agent/Toxin from the Entity Registration

Select agent/toxin is automatically moved into historical status (removed) when the following actions are performed:

1. All strains/serotypes have been removed from 7B.
2. There are no approved work objectives for the select agent/toxin.

IV. Adding/Removing/Modifying Select Agent/Toxin Strains and Serotypes

Section 7B information should be maintained on a real time basis. Section 3 is automatically updated based on Section 7B.

To add or modify select agent strain or toxin serotype information, the user must complete the following tasks:

1. Log into eFSAP and select the Form 1 tab.
2. Select "Amend."
3. Use the drop-down to select "Section 7B: Add/Remove/Modify Strains and Serotypes" click "OK."
   A. To add strains or serotypes, select the "Add" button at the top of the 7B table.
      1) Using the drop-down to select the agent or toxin, choose a select agent/toxin and strain or serotype. If strain or serotype is not known, select "unknown." If strain or serotype has known characteristics but is not listed in the drop-down list, select "other."
      2) Assign the strain/serotype to one or more PIs who are already approved for that agent or toxin.
      3) Click checkboxes to indicate if the strain is recombinant or synthetic or if these properties are not applicable.
      4) Select "Add agent/toxin & strain/serotype" button to add new strain/serotype to Section 7B.
      5) After a brief sync, the new information appears in the table.
   B. To delete strains or serotypes, select the row or rows, and click "Delete" at the bottom of the page. If deleting the last strain or serotype of any agent or toxin, a message appears to upload documentation of disposition. **Note:** PI users are not able to delete the last strain or serotype of any agent or toxin.
   C. To modify a single row, click the field that needs changing. When editing, the user cannot edit a header row, change the agent/toxin name, or edit a row that results in an exact duplicate.
      1) Change the data via drop-down list (strain or PI), free text (additional info) or checkbox (property).
      2) Click "Save" to execute change or "Undo" to revert to the original information.

D. To modify multiple rows, select the rows to modify and hit the "Edit" button at the bottom of the table. **Note:** When the initial row is selected, all sub-rows are selected automatically.
   1) When the window opens, the user can select which fields need to be edited and click the checkbox to activate the field(s) for modification.
   2) Use the drop-down list to select strain or PI or use the free text to add additional information or check the appropriate box (i.e., property). **Note:** If bulk editing strains and serotypes spanning multiple agents or toxins, the user is not able to change the strain/serotype or PI assignments.
   3) Select "Confirm" to proceed to the confirmation screen. Before saving the changes, review the changes on the confirmation. The user is notified on the confirmation page if their proposed changes results in exact duplicate entries. The user is given the option to proceed, delete the duplicates, or cancel the changes. Select "Proceed" to execute the bulk edit.

Chapter 5 – Facility Information

I. Changing Entity Name, Abstract, or Type

To change the entity name, abstract or entity type, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Change Entity Name, Abstract, or Type" and click "OK."
4. Make necessary changes to either entity name, type, or abstract. Other fields are "greyed out."
5. Once the required change is made, select "Save." When the dialog box appears, select "OK" to save.

II. Changing Entity Physical Address

To change the entity's address, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Change Entity Physical or Additional Address" and click "OK."
4. Type requested information into the cover letter and select "OK."
5. Make necessary changes to either the physical address or additional physical address(es). Other Section 1 fields are "greyed out."
6. Once the required change is made, select "Save and proceed."

III. Adding a New Building

To add a new building, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Section 6 – Add New Building" and click "OK."
4. When Section 6 A/B opens, provide the building name and answer questions 1-3.
5. When message box appears, select "Add Building" and "OK."

Note: The new building appears with no rooms assigned. Therefore, add room(s) and/or suite(s) to the building.

IV. Adding a New Room/Suite to an Existing Building

To add a new room/suite, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Section 6 – Add New Room or Suite" and click "OK."
4. Select whether the new space is a room or a suite. If a room, select whether the space is used for storage, laboratory, or both.
5. Select the building for the room/suite. If the space is a single room, enter the room number in the text box. If the space is a suite, enter the suite name in the text box.
6. Select the biosafety level(s) associated with the work to be performed in the room/suite. Click "Add Biosafety Level."

7. Enter the resources/references used to determine the biosafety level(s).
8. If adding a suite: add each room name/number; indicate if the room is "Lab Only", "Storage Only", "Lab and Storage", or "Other"; select the biosafety level(s) for the room, if applicable; and indicate if the air is HEPA filtered. Select "Add Suite Room." Add each room one at a time.
9. Answer the room/suite information questions 1-7 and the suite physical information questions 1–16 as described in the Form 1 Instructions.
10. Select "Add Room/Suite."
11. When the message box appears, select "OK."
12. Another message box will appear: "*[room or suite name] has been added. Don't forget to submit a 7A/C amendment for this room.*" Select "OK." **Note:** The new room/suite shows a status of "Unassigned" until an amendment is submitted and approved to add a work objective linked to the new space.

Note: Once a new room or suite has been added to the registration, it must be added to a work objective(s) by submitting amendments to modify a current work objective. The addition of a new room or suite may require an on-site inspection prior to approval.

V. Modifying an Existing Building

There are two methods to modifying an existing building depending on if it is currently unassigned or assigned to an approved work objective.

- **Unassigned**: A building that has not yet been assigned to an approved work objective can be modified administratively.
- **Assigned**: A building that is assigned to an approved work objective can be modified by submitting a technical amendment and requires approval by FSAP before work can begin.

To modify a building, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Section 6 – Modify Building" and select "OK."
4. Select the building from the drop-down menu and describe the changes that are being made.
5. Select "OK." When the message box appears, select "OK."
6. Make the appropriate changes in the Section 6 A/B and select "Save and Proceed."
7. When the message box appears, select "OK" and "Submit."

VI. Modifying an Existing Room or Suite

There are two methods to modifying an existing room or suite depending on if it is currently unassigned or assigned to an approved work objective.

- **Unassigned**: A room or suite that has not yet been assigned to an approved work objective can be modified administratively.
- **Assigned**: A room or suite that is assigned to an approved work objective can be modified by submitting a technical amendment and requires approval by FSAP.

To modify an existing room or suite, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Section 6 – Modify Room or Suite" and select "OK."
4. Choose the room or suite from the drop-down menu and describe the changes that are being made.
5. Select "OK." When the message box appears, select "OK."
6. Make the appropriate changes in the Section 6 A/B and select "Save and Proceed."
7. When the message box appears, select "OK" and "Submit."

VII. Removing a Room/Suite

Rooms automatically go to historical (removed) when the status changes from approved to unassigned. Suites automatically go to historical (removed) when the status of all the rooms with biosafety designation goes to unassigned. **Note:** Refer to Chapter 6 for instructions related to modifying or removing work objectives.

VIII. Modifying Section 5 Information

Section 5 is split into three sub-sections:

- 5A – Entity-Wide Security Assessment and Incident Response
- 5B – Entity-Wide Biosafety/Biocontainment
- 5C – Entry Requirements for FSAP Inspectors

In each sub-section, all questions unlock and are editable.

To modify Section 5 (entity-wide security and incident response), the RO must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select which Section 5 to update and select "OK."
4. Describe the changes being made. Click "OK." When the message box appears, select "OK."
5. Enter the updated information and select "Save and Proceed."
6. When the message box appears, select "OK" and "Submit."

Chapter 6 – Work with Select Agents and Toxins

In this amendment type, the user chooses the available options for their new work objective. First, the user chooses whether the work objective is "Work Only," "Work and Storage," and "Storage Only"; and then proceeds to choose primary and secondary biosafety levels, select agents/toxins, PI(s), buildings, and rooms. Users can choose multiple options with "Ctrl" and "click" functions.

Note: The user can modify any choices except for "Work Only," "Work and Storage," and "Storage Only" options, as well as the primary biosafety level. The section begins with a free text field for objective of work and ends with a string of "yes" or "no" questions that must be completed and may prompt the below attachments to be completed.

- Attachment A – Work with Toxins
- Attachment B – Work with Regulated Nucleic Acids, Genetic Modification of Select Agents or Toxins, Recombinant/Synthetic Nucleic Acids or Recombinant/Synthetic Organisms
- Attachment C – Work with Animals
- Attachment D – Work with Plants
- Attachment E – Work with Arthropods
- Attachment F – BSL3Ag Laboratories
- Attachment G – BSL4/ABSL4 Laboratories

When the attachment boxes open, the questions for the attachments are either gray (not required), red (required), or blue (completed). All of the required boxes must be blue in order to submit the amendment.

I. Adding New Work

To add new work to a registration, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."

3. Use the drop-down menu to select “Section 7AC – Add New Work Objective” and click “OK.” The request (cover letter) should specify the new work objective to be added, including the PI(s) name, the agents/toxins, and the registered spaces.
4. Select “OK.” When the message box appears, select "OK."
5. When Section 7C opens, select the type of work objective: “Add Work,” “Add Work and Storage,” or “Add Storage Only.”
    A. “Add Work” is selected for locations where procedures and manipulation of select agents or toxins are to be performed, but not storage. For example, necropsy rooms, injection/inoculation/exposure rooms, equipment rooms (e.g., flow cytometers, imagers, plethysmography).
    B. “Add Work and Storage” is selected for locations where select agents or toxins are to be manipulated and stored.
    C. “Add Storage” is selected for locations where no work is to be performed.
6. Select the biosafety level where the work is to be performed. If storage only is selected, designation of a biosafety level is not an option.
7. Select any additional biosafety levels of the same level, if applicable, from the “Designate Additional Biosafety Levels” box. For example, if the initial biosafety level chosen was BSL-3, then NIHBL-3 or NIHBL-3N can be added, if applicable.
8. Select the appropriate select agent(s)/toxin(s). To select multiple select agents/toxins, hold “Ctrl” key while selecting the appropriate select agent(s)/toxin(s).
9. Select the PI(s) who directs the work. To select multiple PIs, hold “Ctrl” key while selecting the appropriate PIs.
10. Select the building(s) and room(s) where the work is to be performed. To select multiple buildings or rooms, hold “Ctrl” key while selecting the desired buildings or rooms.
11. Select “Proceed.”
12. Enter the work objective. Answer questions 2-10.
    A. Storage-only work objectives have “Storage Only” prefilled in the text box. If storage only is selected, questions pertaining to work with the select agent/toxin are “greyed out” and do not need to be answered (questions 4, 9, and 10).
    B. Do not use symbols when entering maximum quantities. For example, cultures should be noted with concentrations listed as 1 x 10e7 cfu/ml, rather than 1x10^7 cfu/ml.
    C. If you answered “yes” to any portion of question 9 or 10, the corresponding attachment needs to be completed. An attachment library drop down will appear allowing users to select a previously completed attachment as a starting template. Select an attachment from the drop-down menu and click the “Use This Attachment” button to finalize the selection. Select “Save and Proceed.” The user can make any necessary modifications to the attachment on the following “Review and Discussion” page. Alternatively, the user can skip selecting an attachment from the drop-down list and complete a new attachment after saving and proceeding to the amendment “Review and Discussion” page.
13. Select “Save and Proceed” and “Submit.”

II. Modifying Work

To modify work to a registration, the RO must complete the following tasks:

1. Select Form 1 on entity’s landing page.
2. Select “Amend.”
3. Use the drop-down menu to select “Section 7AC – Modify Work Objective” and click “OK.”
4. Choose the work objective to be modified from the drop-down menu. The request should specify the modifications and the reason for the change. **Note:** Only approved and suspended work objectives are selectable.
5. Select “OK.” When the message box appears, select "OK."
6. When the work objective opens in Section 7C, click on the “Add” or “Remove” button next to the corresponding line for the secondary biosafety level(s), agents/toxins, PIs, or building/rooms. All available options (e.g., secondary biosafety levels, agents, buildings) show in a text box.
    A. Highlight the options to retain or add to the work objective. For example, if the work objective is

currently assigned to PIs Johnson and Smith and you wish to add PI Anderson, select all three names using the "Ctrl" button.

B. Select "Save Changes."
C. When the following message appears, "*If removing a room/suite or agent that is not associated with any other work objective, the item will be removed entirely fromthe registration, not just from the work objective"*, select "OK" to continue with removal.
D. **Note:** For all other changes, including the objective of work, go to the question and edit. Changinganswers in question 9 may open attachments. The corresponding attachment needs to be completed. An attachment library drop down will appear to allow the user to select a previously completed attachment as a template or the user may complete the attachment on the following "Review and Discussion Page."

7. Select "Save and Proceed."
8. Review the attachments and make any necessary changes to those sections. After making the changes select "Save Changes." The questions for the attachments are either gray (not required), red (required), or blue (completed). All the required boxes must be blue in order to submit the amendment.
9. Select "Submit."

III. Removing Work

To remove work from a registration, the user must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Section 7AC – Remove Approved Work Objective" and click "OK."
4. Choose the work objective to remove and specify the following in the cover letter:
   A. If removing work objectives for the purpose of removing a room or suite from the registration, include a description of decontamination of the space. After submission of the amendment to remove the work objective, refer to Chapter 8 to upload documents if needed.
   B. If removing work objectives for the purpose of removing a select agent or toxin from a room/suite or from the entire registration, include a description of disposition of the select agent/toxin. After submission of the amendment to remove the work objective, refer to Chapter 8 to upload documents if needed.
5. Select "OK." When the message box appears, select "OK."
6. Choose which work objective from the drop-down to remove from approved or suspended work objectives. **Note:** Pending work objectives cannot be withdrawn by submitting a new amendment. Removing the work objectives must be submitted on the original amendment request. In addition, the only work objective for a select agent or toxin that is currently possessed is not an option on the drop-down list until the possession status of that agent/toxin changes (e.g., possession is added to a PI on another currently approved work objective or possession status is changed on Section 7B).
7. When the selected work objective opens, select "Save and Proceed."
8. Select "Submit."

Chapter 7 – Registration Renewal

I. Renewing the Entity Registration

Sixty days before the entity's registration expiration date, submit an amendment request to renew the registration and sign Section 2. To renew a registration, the RO or ARO must complete the following tasks:

1. Select Form 1 on entity's landing page.
2. Select "Amend."
3. Use the drop-down menu to select "Request Registration Renewal" and select "OK."
4. Upon selection, the user is taken to Section 2 and asked to certify the requirements from the select agent regulations are in effect at the entity by signing the RO name at the bottom of the screen. The signature

must match the username listed below the textbox. After signing, the user can navigate to the amendment and submit it.

II. Amendment Withdrawal

To withdraw an amendment, the RO must complete the following tasks:

1. From entity's landing page, scroll down to "Amendment Grid Table."
2. Select "Edit" next to the amendment you wish to withdraw.
3. At bottom of screen, select "Withdraw Amendment."
4. When the message box appears, select "OK." The amendment shows as "Deactivated."

III. Registration Withdrawal

To withdraw a registration, the RO must complete the following tasks:

1. In the General Discussion board on the entity landing page, provide a statement indicating the entity is requesting to withdraw its registration from FSAP. The request should state the wish to withdraw from FSAP, the reason for withdrawal, description of the disposition of agents/toxins, and the decontamination of registered space and equipment.
3. Remove all strains and serotypes (refer to the above instructions).
4. Remove all work objectives (refer to the above instructions).
5. Remove all personnel except the RO from Section 4 (refer to the above instructions).
6. Request registration withdrawal from entity landing page.

Chapter 8 – Additional System Features Available to Responsible Official

I. Entity Admin Center

From the entity landing page, RO/AROs have a link to the entity admin center. Upon opening the admin center, RO/AROs can view a list of all individuals with access to their entity's eFSAP data (i.e., all individuals with a SAMS account). Next to each individual's name, the admin center displays the current permission level of the individual (e.g., RO, super admin, read-only, or PI). **Note:** RO and AROs have the same system permissions, so AROs are displayed as RO in the admin center. The display table supports filtering to a specific person, sorting ascending versus descending, and the data can also be exported to a .csv file and downloaded.

In the admin center, RO/ARO users can switch individuals between read-only and super admin roles through a drop-down selector and saving. All other permission changes, or the addition or removal of users, requires the submission of a ticket to the eFSAP Help Desk. **Note:** The removal of an individual with a SAMS account from Form 1 Section 4 does not inactivate their SAMS account. An eFSAP Help Desk ticket is required to ensure their access to eFSAP is removed.

To change the user permission for an ARO, entity super admin or entity read-only user, the user must complete the following tasks:

1. Select the Admin Center tab.
2. Change the permission from the drop-down menu and click "Save."

II. Certificate of Registration

By clicking the download icon next to the entity's registration expiration date, users have instant access to the entity's Certificate of Registration and Letter of Registration. The documents contain up-to-date information for the current RO and AROs as well as the entity's demographic information.

III.Notifications

The entity landing page displays notifications informing entities of all actions that have been executed by the entity and FSAP staff (e.g., approval of amendments and transfer requests, closure of inspection findings, requests for additional information regarding report of release). The notification table displays the notification, who performed the task, the date and time the action was executed, and a description of the event.

Each column in the table can be filtered by keyword and sorted ascending/descending to aid in finding specific notifications. In addition, the table can be filtered using a drop-down selector enabling the user to only see notifications related to amendments, inspections, Forms 1-4, etc.

Entity RO/ARO and super admin users can flag a notification by pressing the "Flag" button on the right side of the notification table. These users can also archive unflagged notifications by selecting the corresponding checkbox and pressing the grey "Archive Selected" button.

Finally, all users can toggle the notification table to show only archived or flagged notifications.

IV. General Discussion

- General Discussions are messages sent between a regulated entity and FSAP within each section of Forms 1, 2, 3,and 4; amendments to Form 1; inspections; and the entity landing page. eFSAP automatically adds additional metadata to each message such as the date and time the message was sent, the user who sent the message, andwhat this message is regarding (e.g., 9/8/2020 9:23:09 AM, Responsible Official – Regarding: Form 3 Case ID TLR-F3-0000092). The users can search General Discussions by key words or metadata (date, time) using the search box. Users are also able to view general discussion messages in an optional "Conversation Mode" setting. By checking the "Conversation Mode" box in the discussion panel on the entity home page, users can reply directly to a message originating from a specific amendment, Form 1 Section, Form 2, 3, or 4 to reply. After hitting "reply", typing the message, and hitting "send", the new message becomes grouped with the previous message; users can continue to enter additional messages into that conversation thread if needed. The conversation generated from the home page will automatically mirror on the Form or amendment. Replies from the Form or amendment will likewise carry over to the home page. Users are also able to generate and reply to new conversations from the home page that may not be specific to any Form or amendment.

V. Amendments Grid Table

The Amendments Grid Table displays all technical amendments that have been created by the RO/ARO and super admin users. For each amendment, the grid table displays the Amendment Type and Number, shows the text of the cover letter, displays the date submitted and approved, the current amendment status, by whom the amendment was last modified, and who approved the amendment. The amendment table also contains an "edit" button which takes the users directly to the amendment review and discussion page to review the amendment or make additional changes.

Each column in the table can be filtered by keyword and sorted ascending/descending to aid in finding specific amendments.

Entity RO/ARO and super admin users can flag an amendment by pressing the "Flag" button on the right side of the table. These users can also archive unflagged amendments by selecting the corresponding checkbox and pressing the grey "Archive Selected" button.

VI.Document Upload

eFSAP supports several hundred file types (e.g., .xls, .pdf, .rtf) and the maximum individual file size is limited to 25MB. After a file has been uploaded, an entity is able to track its review history (e.g., not reviewed, under review, or review complete), which is managed by FSAP. Each file has a unique file structure called metadata. However, eFSAP automatically generates a unique version of a file to prevent overwrite. File versioning occurs when a file has the same original name, category, and sub-category. In addition, the file must be of the same type. File versioning is indicated with a clock icon on the left side of the inspection grid table as a "down arrow" icon.

To open a file, click the arrow or icon, and a pop-up modal opens listing all versions. The document library indicates when a file was uploaded with date and time and who uploaded the file. The library is sortable, filterable, and searchable up to 500 files. From the current view, an entity can archive a file by selecting an individual file or files and clicking the "Send to Archive" button. From the archived files view, a file may be returned to current status by selecting a file or files and clicking the "Send Back to Current" button. The very bottom of the table lists the total number of files in the library, and the user can paginate and maximize the number of files viewable per page.

1. Landing Page
   Users can upload program documents, Form 5, policy, restricted experiments/exclusions, facilities, compliance, and other documents from the entity landing page. The user must select a subcategory and document type. If the user selects "Other," a description of the document is required.

2. Form 1
   Users need to navigate to the specific section of the Form 1 to access the category associated with the document. Users need to select the Form 1 tab and press the view key. From the Form 1 view landing page, select the section. Scroll down to the document grid table and select the "Upload" button. Choose the appropriate category and fill out all required information. Select the "Choose file" button to choose the document the user wants to upload from their computer.

3. Form 2
   Documents can be uploaded within the specific sections after the Form 2 is drafted or submitted. The user can upload supporting documentation, a response to a request for information, or other documents.

4. Form 3
   Documents can be uploaded within the specific sections after the Form 3 is drafted or submitted. The user can upload a response to a request for information or other documents.

5. Forms 4A and 4B
   Documents can be uploaded within the specific sections after the Form 4 is drafted or submitted. The user can upload a response to a request for information or other documents.

6. Inspection Module
   Inspection-related documents can be uploaded from the details page. The inspection number is pre-populated for the upload. The user must select a sub-category and document type. If the user selects "Other" as the document type, a description of the document is required.

   Documents pertaining to observation responses can be uploaded as part of the entity response within inspection resolution
   Page by clicking on the upload button within each observation. The inspection number, sub-category of "Post-Inspection Documents" and unique identifier (UID) number are pre-populated whenthe user uploads from the inspection details page. The post-inspection documents category defaults to "Other" but the user should select the appropriate category.

The Responsible Official and Entity Super Admin can reclassify uploaded files, changing the file's sub-category and description. Reclassification is performed from the locations listed above by pressing the green Reclassify button in the upload table. Reclassification does not affect the original upload date/time or the review status.

Chapter 9 – Inspection Module

When an announced inspection has been created and scheduled by FSAP, an entity receives notification, and the inspection populates on the entity's inspection grid table simultaneously with a unique inspection number and the type of inspection(s) being conducted. In contrast, for an unannounced inspection, an entity is notified through the notification table on the start date of the inspection.

In addition, hybrid inspections (remote plus follow-up visit) are also utilized by FSAP. The original (usually remote) inspection is denoted with a unique 4-digit number and the follow-up (usually on-site) visit has a ".1" appended to the original inspection number.

On the inspection grid table, an entity can track the progress of an inspection from the time it has been scheduled through closure. The inspection details page provides an entity with additional information about an inspection (e.g., identifying the inspectors). The details page duplicates the notification table found on the entity landing page, has a general discussion log to communicate with the FSAP point of contact (POC), and lead inspector, and a resource center for direct links to Forms 1-4 and amendments in read-only format. An entity can also upload pre-inspection documents.

After FSAP creates an inspection and assigns checklists to be used on an inspection, an entity can view the checklists, but only their CFR citations and corresponding descriptions. Clicking the inspection resolution button takes the user to the inspection cover page. The cover page details the authority, what the report means and how an entity should respond. After acknowledgement, the entity can view their inspection report (i.e., observations and corrective actions). An entity needs to provide a response to each departure or request for

information. General inspections concerns are read-only and do not need a response. An entity may dispute any departure and upload supporting document(s) to a dispute as a post-inspection document. Inspection reports are printable from the inspection resolution page.

I. Uploading Inspection Documents

An entity can upload files (or documents) from two locations. Pre-inspection documents or inspection documents may be uploaded from the inspection details page. Post-inspection documents may be uploaded from the inspection resolution page. eFSAP supports over several hundred file types (e.g., .xls, .pdf, .rtf) and the maximum individual file size is limited to 25MB.

After a file has been uploaded, an entity is able to track its review history (e.g., not reviewed, under review, or review complete), which is managed by FSAP. Each file has unique metadata automatically assigned to it upon upload and shown in the file library as its unique identifier. eFSAP also automatically generates a unique version of a file to prevent overwrite. File versioning occurs when a file has the same original name, category, and sub-category. In addition, the file must be of the same type. File versioning is indicated with a clock icon on the left side of inspection grid table.

To open a file, click the arrow or clock icon. A pop-up modal opens listing all versions. The document library indicates when a file was uploaded with date and time and who uploaded the file. The library is sortable, filterable, and searchable. From the "current" view, an entity can archive a file by selecting an individual file, multiple files, or all files and click the "Send to Archive" button. From the "archived" file view, a file may be returned to current status by selecting a file or files and click the "Send Back to Current" button. The bottom of the table lists the total number of files in the library. The user can paginate and maximize the number of files viewable per page, showing up to 500 files at a time.

The Responsible Official and Entity Super Admin can reclassify documents uploaded from within the inspection module on the Inspection Details or Inspection Resolution page by pressing the green Reclassify button in the upload table. For inspection files, users can correct the pre-inspection or inspection document and the description. For UID-specific uploads, only the description can be modified. Reclassification does not affect the original upload date/time or the review status.

II. Disputes

An entity can dispute a departure in their inspection report. Within 14 calendar days from receipt of the departure, the entity may email their dispute request to the DSAT Operations Branch Chief (lrsat@cdc.gov) or the DASAT Operations Unit Director (DASAT@usda.gov as appropriate. The request must specify the departure(s) that the entity is disputing. By 30 calendar days from receiving the departure(s), the entity must provide a written statement that clearly states why they consider the disputed departures(s) to be in error. The

entity may include documentation in support of the dispute. FSAP will attempt to resolve the dispute within 30 calendar days of the receipt of the written statement. The resolution of a dispute may include discussions with the entity or additional site visits. If the resolution of a dispute results in a change to an observation or required corrective action, FSAP updates the departure within eFSAP.

III. Inspection Resolution

For each status change described below, an entity receives a notification based on actions executed by FSAP.

• Scheduled – Inspection is scheduled but has not occurred.

• In Progress – Inspection is currently in progress based on inspection beginning and end dates.

• Inspection Closeout – Inspection has occurred and is under internal review.

• Inspection Resolution – FSAP has released at least one finding for entity review.

• Inspection Closed – A final determination has been made on inspection observations (i.e., no open observations).

• Closed Conditionally – One or more departure has been closed conditionally and there are no open observations.

• Canceled – Inspection has been canceled.

After at least one observation has been released, the inspection status changes from “Inspection Closeout Activities” to “Inspection Resolution”. Each observation is assigned a specific UID (e.g., XX-XX-XXXXX) that is associated with a specific regulation. When observations are released, the entity receives notification (e.g., “Inspection #XXXX UID-XX-XX-XXXX with Departure Type of XX has been released for entity review”). When FSAP has released all observations, the entity receives a notification (e.g., “All inspection findings have been released for Inspection #XXXX”).

If an inspection does not include any departures or any findings at all, a disclaimer appears at the top of the inspection resolution page indicating as such.

To view the inspection observations, the user must perform the following:

1. Select the inspection link on menu bar at entity home page to reach inspection grid table.

2. Click the details button for the corresponding inspection.

3. Click the inspection resolution button on the inspection details page. Note: Quicker access can be achieved by selecting the blue “View link” under the “Type” column in the notification table.

At the top of the inspection resolution page, an entity can toggle by the type of inspection observation (all, departure, general concern, amendment concern, request for information, or under review), departure type (all, immediate, or final), or departure status (all, open, or closed). The departure type, severity (if applicable), applicable work objective(s) (if applicable), response date (required for departures and request for information), repeat departure status, and open or closed status are presented. Each finding includes the inspector’s observation and the corrective action when applicable.

For departure observations and requests for information, an entity must return their response by entering their response in the “Entity Response” field. The response can be saved as a draft by clicking the “Save Draft” button. When the entity is ready to submit the response for FSAP review, the entity selects the “Send” button. Entities have the option of uploading supporting documentation with their typed response utilizing the upload

button adjacent to the "send" and "save" buttons. After submission, the entity receives a notification (e.g., "Inspection #XXXX UID:XX-XX-XXXXX has been responded to by the entity").

When FSAP determines the response addresses the observation, the entity receives a notification (e.g., "Inspection #XXXX UID:XX-XX-XXXXX has been resolved"), the status changes to closed, and the entity is unable to make edits. In certain situations, FSAP may close an observation conditionally (e.g., contingent on the entity submitting an amendment to modify a work objective). In this instance, the entity receives a notification (e.g., "Inspection #XXXX UID:XX-XX-XXXXX has been closed conditionally"). If FSAP recalls an observation, the entity receives a notification (e.g., "Inspection #XXX UID-XX-XX-XXXX has been recalled") and it no longer appears on the inspection resolution page. The observations and inspection report are printable from the top of the inspection resolution page.

IV. Closing an Inspection

When FSAP determines that entity responses have addressed all observations, the status of the inspection changes to "Closed." Closed inspections are read-only, but the information can be printed.

V. Conditionally Closing an Inspection

If one or more observations has been closed conditionally and there are no open observations, the status of the inspection changes to "Closed Conditionally." Closed Conditionally Inspections are read-only for the entity and can be printed. These inspections may be "Closed" at a later time by FSAP when the conditions have been met.

Chapter 10 – Submitting Request to Transfer

The APHIS/CDC Form 2, Request to Transfer Select Agents and Toxins, is used by entities to request prior authorization for a transfer of select agent(s) or toxin(s) from FSAP.

I. Section 1

To complete Section 1, the recipient must log into eFSAP. On the entity homepage, click "Form 2." Click "Create Form 2." Complete questions 1 through 14.

1. For question 1, use the drop-down menu to select the appropriate PI name.
2. For Section B, questions 2-12, complete the sender information. Ensure that the information is accurate.
3. For question 11, if "Yes" is selected, provide the APHIS/CDC Form 4 clinical ID (CID-F4-00XXXX).
4. For question 12, if "Yes" is selected, provide a description of the restricted experiment.
5. For question 13, select the select agent or toxin from the drop-down menu, then click "Add Agent/Toxin."
6. For question 14, enter both the carrier name and its DOT registration number**. Note**: If hand-delivered, provide the complete name of the FSAP-approved individual.
7. For Signature, type name and title in the appropriate fields. The name must be typed exactly as stated below box. The date auto-populates.
8. Click "Submit." **Note:** Clicking "Close" does not submit Section 1 or save the information. Clicking "Save Draft" does not submit Section 1 but saves the information. The user may return to a previously saved draft by going to the Form 2 grid table; locate the draft and click the "Edit Section 1" button.
9. When the message appears that the status of the transfer request changes to "Transfer in Review," click **"**OK**."**

II. Cancelling Transfer Request

Transfer requests can be cancelled from Section 1 during "Transfer in Review and Approved Section 2 Pending" status. The requests must be cancelled before Section 2 is completed by the recipient.

1. The recipient must log into eFSAP. On the entity homepage, click "Form 2." Locate the Transfer ID number from the list. Click "Edit Section 1."
2. Type name and title in the appropriate fields. The name must be typed exactly as stated below box. The date auto-populates.
3. Click the "Cancel Transfer" button located below the Signature**. Note:** Clicking the "Close" button does not cancel or save any changes made to the transfer request.

4. When the following message appears – "*Clicking OK, the form status will be changed to Transfer Cancelled. Do you wish to proceed?"* – click "OK."
   Note: Entity can provide a reason for cancelling the transfer in the General Discussion box. The recipient requesting the transfer can cancel the transfer request. The sender cannot cancel a transfer request.

III. Section 2

The sender must log into eFSAP. On the entity homepage, click "Form 2," locate the appropriate Transfer ID number and click "Edit Section 2." Complete questions 16-28.

1. For question 16, select the appropriate select agent or toxin from the drop-down menu.
2. For question 17, select the appropriate agent characterization from the drop-down list.
3. Complete questions 18-20, then click the "Add Shipped" button.
4. For Section E questions 21-23, ensure the information is accurate.
5. For Section F questions 24-28, shipping information must be completed. Name of individual packaging the select agent or toxin must be FSAP-approved. Include an accurate description of the package and tracking number.
6. For signature of sender, type your name and title in the appropriate fields. Name must be typed exactly as stated below box. The date auto-populates.
7. Click Submit. **Note:** Clicking "Close" does not submit Section 2 or save the information. Clicking "Save Draft" does not submit Section 2 but saves the information.
8. When the following message appears – "*Clicking OK, this form status will be changed to Section 3 Pending, do you wish to proceed?*" – click "OK."

Note: Click the "Print Form" button at the top of the form to print the Form 2 information.

IV. Section 3

The recipient must log into eFSAP, navigate to Form 2, and click "Edit Section 3" of the appropriate transfer request. Complete questions 29-32.

1. For questions 29-30, select the name of the individual who received the shipment from the drop-down list and add the date of receipt.
2. After verifying the amount described in Section 2, complete questions 31 and 32.
    1. If "No" is selected for 31, provide an explanation of any discrepancy for the amount shipped and received in the drop-down box.
    2. If "No" is selected for 32, provide a description of how the shipment was packaged and if the package was damaged to the extent that a release of the select agent or toxin may have occurred. **Note**: Contact FSAP and Complete APHIS/CDC Form 3 if "No" is selected for question 31 or 32.
3. For signature of Responsible Official, type your name and title in the appropriate fields. Name must be typed exactly as stated below box. The date auto-populates.
4. Click "Submit" to complete the transfer documentation. **Note:** Clicking "Close" does not submit Section 3 or save the information. Clicking "Save Draft" does not submit Section 3 but saves the information.
5. When the following message appears -- "*Clicking OK, this form status will be changed to Transfer Completed. Do you wish to proceed?*" – click "OK**."**

Note: If changes are needed to the form after transfer is completed, contact FSAP.

V. Expired Transfer Requests

Transfer Requests in "Approved Section 2 Pending" state for 30 days will auto-expire on the 31st calendar date after approval. This status will be reflected on the Form 2 grid table and in the transfer request history. Transfer requests set to expire within 7 days will be bolded on the grid table.

VI. Reuse/Reapply Form 2 Transfer Requests

Transfer requests can be created from previously submitted transfer requests by using reuse/reapply. Transfer requests in approved section 2 pending, section 3 pending, completed and cancelled states can be reused and transfer requests in transfer approval expired can be reapplied. Once reuse/reapply is selected, a new transfer

request is generated.

1. For section A, question 1, use the drop-down menu to select the appropriate PI name.
2. Section B, questions 2-12 are pre-populated with information from the previous transfer request and can be modified if needed.
3. For section C, question 13, use the drop-down to select the select agent or toxin. If a toxin is selected, include the total toxin quantity. For question 14, enter both the carrier's name and its DOT registration number.
4. For signature, type the name and title in the appropriate fields.
5. Click "Submit." The status will update to transfer in review and a new transfer request has been created.

Chapter 11– Submitting Report of Theft, Loss, or Release

The APHIS/CDC Form 3, Incident Notification and Reporting is used by entities to report a theft, loss, or release of a select agent or toxin.

I. Immediate Notification of a Theft, Loss, or Release

To report the immediate notification of a theft, loss, or release, the user must log into eFSAP, click "Create Form 3"under the Form 3 tab, and complete the following required questions in Section B.

1. For questions 1-2, enter the date and time of the incident and date the entity made immediate notification to FSAP.
2. For question 4, select from the drop-down list the location where the incident occurred. If the location is not listed on drop-down, enter the location in the box provided.
3. For question 5, Use the drop-down to select the appropriate select agent or toxin and the strain designation for question 6. Select the Recombinant Agent or PPQ Agent box if appropriate; otherwise, leave blank.
4. For question 7, enter the quantity and provide the unit of measure for each agent or toxin (e.g., vial, plate, ampoule) . Information must be provided for each strain and serotype. **Note:** Click "Add Row" for each additional select agent and toxin that needs to be reported and repeat questions 5-7.
5. For question 8, select "Theft**," "**Loss," or "Release." Select all that apply. The corresponding section appears based on the selection.

Section C (Release):

1. If "Yes" is selected for question 2, select the appropriate environment into which the release occurred (e.g., outside primary containment, outside secondary containment, outside the facility). Select all that apply.
2. If "Yes" is selected for question 4, provide the number of individuals/animals/plants exposed and the number of laboratory staff.
   Note: The number for 4a should be the total number that includes the number entered for 4b.
3. For question 6, select all that apply for the medical surveillance and/or treatment provided to individuals involved in the release incident.

Section D (Loss):

1. If "Yes" is selected for question 2, complete questions 3-5 for the local law enforcement agency contacted.
2. If "Yes" is selected for question 6, complete questions 7-8 for the FBI Agent contacted.
3. If "Yes" is selected for question 9, complete question 10 with the date recovered and duration of loss.
4. If "Yes/Unknown at this time" is selected for question 12, complete Section C.

Section E (Theft):

1. If "Yes" is selected for question 2, complete questions 3-5 for the local law enforcement agency contacted.

2. If “Yes” is selected for question 6, complete questions 7-8 for the FBI Agent contacted.
3. If “Yes” is selected for question 9, enter the date recovered.
4. If “Yes/Unknown at this time” is selected for question 10, complete Section C.

APPENDIX 1 (Incident Details): Provide a detailed description of the incident.

1. Describe decontamination of equipment, clothing, areas, individuals, etc.
2. Describe any other hazards posed by the theft, loss, or release.
3. Describe any other action taken to respond to the theft, loss, or release.
4. Include the duration of the release for a leak, spill, aerosolization, etc., as applicable to the incident.

Note: The form may be edited after submission prior to selecting the submission button.

Signature of Respondent and Submission:

1. Type name and title in the appropriate fields. Name must be typed exactly as stated below box. The date auto-populates.
2. Click “Immediate Notification” button to submit the form.

Note: Clicking “Close” does not submit or save the information. Clicking “Save Draft” does not submit but saves the information. To make edits to the submission, click “Save Update” button. If required questions are not completed, user receives a message indicating what questions need to be completed.

II. Complete Submission of an APHIS/CDC Form 3 for a Theft, Loss, or Release

To report a theft, loss, or release, the user must log into eFSAP and click “Create Form 3” under the Form 3 tab. The entity information auto-generates for Section A, except for question 7. Select the name(s) of PI from the drop-down list then click “Add” button. Complete the following questions for Section B.

1. Complete questions 1-2 by entering the date and time of the incident and date the entity made immediate notification to FSAP, if not already entered.
2. For question 3, select the Type of Immediate Notification. Select all that apply.
3. For question 4, select the location where the incident occurred from the drop-down list. If the location is not listed on drop-down, enter the location in the provided box.
4. For question 5, select the name of the select agent or toxin and the strain designation for question 6. **Note**: If the strain is not known, enter “Unknown.”
5. For question 7, enter the quantity and provide the unit of measure for each agent or toxin (vial, plate, ampoule, etc.). Information must be provided for each strain and serotype. **Note:** Click “Add Row” for each additional select agent and toxin that needs to be reported and repeat questions 5-7.
6. For question 8, select “Theft**,” “**Loss,” or “Release.” Select all that apply. The corresponding section appears based on the selection.
7. For question 9, use the drop-down list to select the severity that best fits this incident.
8. For question 10, the biosafety level(s) auto-populates where the incident occurred based on the location of the incident selected for question 4. If the biosafety level is not provided, select the biosafety level(s) where the incident occurred. Select all that apply. Select “Other” if the biosafety level is not listed or applicable to the space where the incident occurred then enter a description in the box provided.
9. If “Yes” is selected for questions 11 or 12, provide the appropriate APHIS/CDC Form 2 Transfer ID (T-F2-######) or APHIS/CDC Form 4 ID number (CID-F4-######) associated with this incident.

Complete Section C (Release), D (Loss), and/or E (Theft) according to the response to Section B, question 8.

Section C (Release/Potential Exposure):

1. For question 1, select the type of release/potential exposure. Select all that apply. If “Other” is selected, describe in the box provided.
2. If “Yes” is selected for question 2, select the appropriate environment into which the release occurred (e.g., outside primary containment, outside secondary containment, outside the facility). Select all that apply.
3. For question 3, select the type(s) of PPE worn at the time of the incident. Select all that apply.

a. Select “Other” if the type of PPE is not listed and describe in the box provided.
b. If respiratory protection is selected, describe the type (e.g., N95, PAPR) in the box provided.

4. If “Yes” is selected for question 4, provide the number of individuals/animals/plants exposed and the number of laboratory staff exposed. **Note:** The number for 4a should be the total number that includes the number entered for 4b.
5. For question 5, if not known at the time of the incident, select “not currently known.”
6. For question 6, select all that apply for the medical surveillance and/or treatment provided to individuals involved in the release incident.
7. If “Yes” is selected for 7a, describe the investigation in the box provided and check the corrective actions taken to lessen recurrences for 7b. Select all that apply. Select “Other” if the type of corrective action is not listed and describe in the box provided.

Section D (Loss):

1. For question 1, select the type of loss. Select all that apply. Select “Other” if the type of loss is not listed and describe in the box provided.
2. If “Yes” is selected for question 2, complete questions 3-5 for the local law enforcement agency contacted.
3. If “Yes” is selected for question 6, complete questions 7-8 for the FBI Agent contacted.
4. If “Yes” is selected for question 9, complete question 10 with the date recovered and duration of loss.
5. For question 11, enter the date of the last inventory/audit performed.
6. If “Yes/Unknown at this time” is selected for question 12, complete Section C.

Section E (Theft):

1. For question 1, select the type of theft. Select all that apply.
2. If “Yes” is selected for question 2, complete questions 3-5 for the local law enforcement agency contacted.
3. If “Yes” is selected for question 6, complete questions 7-8 for the FBI Agent contacted.
4. If “Yes” is selected for question 9, enter the date recovered.
5. If “Yes/Unknown at this time” is selected for question 10, complete Section C.

APPENDIX 1 (Incident Details): Provide a detailed description of the incident.

1. Describe decontamination of equipment, clothing, areas, individuals, etc.
2. Describe any other hazards posed by the theft, loss, or release.
3. Describe any other action taken to respond to the theft, loss, or release.
4. Include the duration of the release for a leak, spill, aerosolization, etc., as applicable to the incident.

Signature of Respondent and Submission:

1. Type name and title in the appropriate fields. Name must be typed exactly as stated below box. The date auto-populates.
2. Click “Initiate Submit” button to submit the form. The user receives a message indicating form has been submitted.

Note: Clicking “Close” does not submit or save the information. Clicking “Save Draft” does not submit but saves the information. To make edits to the submission, click “Save Update” button. If required questions are not completed, user receives a message indicating what questions need to be completed.

Once the Form 3 is submitted, information cannot be edited or added unless the status is changed to “Request for Information.” After the user provides the requested information or edits form, the user clicks “Return to Agency” button to submit information.

Chapter 12 – Reporting the Identification

The APHIS/CDC Form 4, Report of the Identification of a Select Agent or Toxin, is used by clinical or diagnostic laboratories and other entities to notify the Federal Select Agent Program of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.

I. Immediate Notification

To report the immediate notification of an identified, select agent or toxin, the user must log into eFSAP, click "Create Form 4A – Section A & B" under the Form 4 tab. For Section B, the user must complete the following steps:

1. For question 1, select the name of the select agent or toxin from the drop-down list.
2. For question 2, input the date identified.
3. For questions 3-4, input date of immediate notification and select type of notification.
4. For question 10, indicate whether there was a release outside of primary containment.
5. Scroll to the bottom of the page and click the "Immediate Notification" button.

Note: Clicking "Close" does not submit or save the information. Clicking "Save Draft" does not submit, but saves the information

II. Completing Sections A and B

To complete Sections A and B, the user must log into eFSAP, click "Create Form 4A – Section A & B" under the Form 4 tab. If completing the remainder of a Form 4A from an immediate notification, access the previously submitted Form 4A by clicking on the **"**View" button in line to the appropriate CID under Form 4A Section AB or in the Form 4 grid table. For Section A, answer questions 1-3. Questions 4-11 auto-populate.

Section B:

1. For question 1, select the name of the select agent or toxin from the drop-down list unless completed for immediate notification.
2. For question 2, input the date identified unless completed for immediate notification.
3. For questions 3-4, input date of immediate notification and select type of notification unless completed for immediate notification.
4. For question 5, enter the number of samples received.
5. For question 6, select the sample type received.
6. For question 7, enter the case/patient/sample origin (zip code); if the sample origin is international, leave this field blank or enter "00000".
7. Provide the international location in the question 22 Comments/Notes box.
8. For question 8, record the type of test(s) performed by selecting all that apply. If "Other" is selected, describe the test method in the box provided.
9. For question 9, select all that apply:
   A. **Transferred** – Provide the recipient facility name and the date of the transfer and the APHIS/CDC Form 2 number (T-F2-########) in question 22 (Comments box).
   B. **Destroyed** – Indicate method of destruction and date destroyed. If "Other" is selected, describe the destruction method.
   C. **Retained** – Provide the PI name from the drop-down menu.
10. If "Yes" is selected for question 10, complete an APHIS/CDC Form 3.
11. If "Yes" is selected for question 11, provide date of notification.
12. If "No" is selected for question 12, complete blocks 13-21 regarding sample provider information. If the answer to question 12 is "Yes," skip to question 22.
    A. If "Yes" is selected for question 13, provide the name of the country from the drop-down menu of countries.
    B. For questions 14-21, enter the name and contact information of the sample provider and point of

contact. Click “Add Row” to provide additional sample providers, as needed.

13. For question 22, provide additional comments and notes [e.g., sample identification number, animal species, human specimen sources (blood, sputum)].

Signature of Respondent and Submission:

1. Type name and title in the appropriate fields. Name must be typed exactly as stated below box. The date auto-populates.
2. Click “Submit” button to submit the form. The user receives a message indicating form has been submitted.

Note: Clicking “Close” does not submit or save the information. Clicking “Save Draft” does not submit but saves the information.

III. Completing Sections C and D

To complete Sections C and D, the user must log into eFSAP, click “Create Form 4A – Section C & D” under the Form 4 tab. For Section C, answer questions 1-3. Questions 4-11 auto-populate.

Section D

1. Question 1 auto-populates.
2. For question 2, provide the notification date from the Reference Laboratory.
3. For question 3, provide the number of samples provided to the Reference Laboratory.
4. For question 4, select the sample type sent to the reference laboratory from the drop-down list.
5. For question 5, enter the zip code for the sample origin, if known. If not known, enter the zip code.
6. For questions 6-7, provide the date sample(s) shipped to Reference Laboratory and the name of Reference Laboratory. To add additional Reference Laboratories, click “Add Row” button.
7. For question 8, select all that apply:
   D. **Transferred** – Provide the recipient facility name and the date of the transfer and the APHIS/CDC Form 2 number (T-F2-########) in question 22 (Comments box).
   E. **Destroyed** – Indicate method of destruction and date destroyed. If “Other” is selected, describe the destruction method.
   F. **Retained** – Provide the PI name from the drop-down menu.
8. If “Yes” is selected for question 9, complete an APHIS/CDC Form 3.
9. If “No” is selected for question 10, complete blocks 11-20 regarding sample provider information. If the answer to question 10 is “Yes,” skip to question 22.
   A. If “Yes” is selected for question 12, provide the name of the country from the drop-down menu of countries.
   B. For questions 13-21, enter the name and contact information of the sample provider and point of contact. Click “Add Row” to provide additional sample providers, as needed.

Signature of Respondent and Submission:

1. Type name and title in the appropriate fields. Name must be typed exactly as stated below box. The date auto-populates.
2. Click “Submit” button to submit the form. The user receives a message indicating form has been submitted.

Note: Clicking “Close” does not submit or save the information. Clicking “Save Draft” does not submit but saves the information.

Chapter 13 – Reporting the Identification for Proficiency Testing

To report the identification of a select agent or toxin identified from a proficiency sample, the user must log into eFSAP and click "Create Form 4B" under the Form 4 tab.

Section A:

1. For questions 1-3, provide the name and contact information for the person completing the form.
2. For questions 4-13, this information auto-populates for a registered entity.
3. For question 14, provide sponsor contact information.

Section B:

1. For question 1, select the select agent or toxin identified from the drop-down list.
2. For question 2, provide the date the proficiency sample was received.
3. For question 3, provide the date the proficiency sample was identified. Click "Add" to add additional samples and repeat questions 1-3 for each sample added
4. For question 8, select all that apply:
   A. **Transferred** – Provide the recipient facility name and the date of the transfer and the APHIS/CDC Form 2 number (T-F2-########) in question 22 (Comments box).
   B. **Destroyed** – Indicate method of destruction and date destroyed. If 'Other' is selected, describe the destruction method.
   C. **Retained** – Provide the PI name from the drop-down menu.

Signature of Respondent and Submission:

1. Type name and title in the appropriate fields. Name must be typed exactly as stated below box. The date auto-populates.
2. Click "Submit" button to submit the form. The user receives a message indicating form has been submitted.

Note: Clicking "Close" does not submit or save the information. Clicking "Save Draft" does not submit but saves the information.

Chapter 14 – Getting Help and Support

eFSAP users can contact the points of reference listed below for assistance or questions with the system.

1. For general questions regarding the select agent regulations and how to complete particular sections of the forms, please contact your assigned FSAP POC.
2. For eFSAP issues, please contact the eFSAP Help Desk weekdays from 7AM to 7PM (Eastern), excluding U.S. Federal Holidays:
   A. Submit an eFSAP Help Desk ticket at eFSAP Support Form.
   B. Email the eFSAP Service Desk at efsapsupport@cdc.gov.
3. For SAMS account-related issues (e.g., account creation, resetting your password, updating your profile), follow the self-service information provided below or contact the SAMS Helpdesk weekdays from 8 AM to 6 PM (Eastern), excluding U.S. Federal Holidays (telephone: 877-681-2901 or email: samshelp@cdc.gov).
   A. Online Password Reset: Forgot Your Password?

   B. Updating Profile Information for active SAMS accounts:
      1. Login to main SAMS account at https://sams.cdc.gov.
      2. On the left side menu, click on "My Profile" and the system allows changes based on "Tasks" options.