

# **eFSAP Form 1 Amendment Instructions**

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## Amendment Requirements

These instructions are intended to provide a list of instructions for requesting the most frequent registration changes in the electronic Federal Select Agent Program (eFSAP) portal. Additional information can be found on the [Federal Select Agent Program - eFSAP Resource Center - User Tools](#) page of the Federal Select Agent Program (FSAP) website.

An amendment is defined as a request to update or change a registered entity's Certificate of Registration for Possession, Use and Transfer of Select Agents and Toxins (APHIS/CDC Form 1). An amendment is considered pending until final approval has officially been communicated to the entity via eFSAP. Approval is required before implementing the changes requested in the amendment.

In some cases, FSAP will send a *Request for Information* in order to obtain clarification and/or additional information for a pending amendment.

Amendment requests from a registered entity may or may not require FSAP review and approval. For example, the addition, removal, or modification of a laboratorian requires the Responsible Official (RO) or an Alternate Responsible Official (ARO) to log into eFSAP and perform the change. Other changes, such as the addition of a new work objective or changing a suite/room safety level designation, will require a request to modify sections of APHIS/CDC Form 1 in eFSAP, followed by FSAP review and approval. For amendments that require FSAP approval, an amendment number will be assigned. The amendment will initially be listed on the home page as pending. Once the amendment is approved, the status will be listed as approved. In some instances, supporting documentation, such as floor plans or decontamination records, may need to be uploaded in eFSAP prior to FSAP approval.

The Federal Select Agent Program will not approve an amendment request until it has been reviewed and provided that the request, and any required supporting documentation, is adequate.

## Federal Select Agent Program Concurrence

The Federal Select Agent Program (FSAP) is managed by the Centers for Disease Control and Prevention Division of Select Agents and Toxins (DSAT) and the Agriculture Select Agent Services (AgSAS) at the Animal and Plant Health Inspection Service (APHIS). An entity is registered with either DSAT or AgSAS. The agency that an entity is registered with is referred to as the "lead agency". The lead agency will provide a single point of contact (POC). The POC is responsible for coordinating all activities and communications with respect to your registration, including coordination with the non-lead agency.

An amendment to your registration involving a select agent or toxin not regulated by your lead agency will require concurrence from the non-lead agency. In these instances, you may be required to submit additional documentation. FSAP will initiate the concurrence process and all correspondence will be directed through your designated POC. Amendments requiring concurrence may require additional time for processing and review.

## Amendment Request Submission

The FSAP encourages entities to submit any amendments or amendment updates through the eFSAP portal.

Other personnel at the entity (e.g. administrative staff) may be granted read only access to eFSAP. Additionally, personnel at the entity may be granted super-admin access to eFSAP. These individuals can log into eFSAP and create drafts of Form 1 sections. However, all requests for changes to the registration or inspection finding responses must be submitted by the RO or an ARO with authorized permission to access the portal.

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 or FSAP review to make the change.

### To make an administrative change to the APHIS/CDC Form 1:

- Log into the eFSAP portal and click on the Form 1 tab.
- Select Amend. Choose the appropriate option from the drop-down menu. Click Ok.
- Fill out the new section or make changes to the current section.
- Click Save, Update, Add or Delete, depending on the request, to make the changes.
- Upon submission of the amendment, a notification will appear in the Notifications section on your Home page.

**If a notification does not appear, and you have confirmed that the change did not occur, contact your POC for help.**

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 reviewed by FSAP before approval. Requests that do not clearly explain the changes to be made to your registration or conflict with the information submitted may require the submission of additional documentation and result in delayed approval of your amendment request.

### To make a technical change to the APHIS/CDC Form 1:

- Log into the eFSAP portal and click on the Form 1 tab.
- Select Amend. Choose the appropriate option from the drop-down menu. Describe the requested change in the cover letter section that appears. Click Ok.
- Fill out the new section or make changes to the current section.
- Click Submit to send the amendment to FSAP for review and approval.
  - If you click Save Draft for a technical amendment, only a draft of the amendment will be

created. Drafts can be edited at a later time; however, FSAP will only review and process the amendment after it has been submitted.

- To edit or submit an amendment in draft form, click on Edit next to the amendment in the Amendments section of your home page.
- Submit required documentation by uploading it to the specific location within Form 1.
  - The documentation should be uploaded into the corresponding Form 1 section within eFSAP using the document upload area at the bottom of each section's page.
    - Select from the drop-down menu boxes the appropriate options to classify each document being uploaded. Multiple documents can be added then uploaded at once.
  - Do not upload or send multiple copies of a document. For example, if you upload your amendment documentation to eFSAP, you do not need to email a duplicate copy to your designated POC.

**Note:** A document cannot be larger than 25MB and the document name cannot contain any special characters. See the *eFSAP Document Upload guidance* available on the FSAP website for additional information.

- Upon submission of the amendment, a notification will appear in the Notifications section on your Home page. The amendment will also appear in the Amendments section of your Home page with a status of pending and an amendment identification number. Clicking on the Edit button in the Amendments section or the View button in the Notifications section will take you to the Amendment home page.

**If a notification does not appear, or a new amendment does not appear in the Amendments section, contact your POC for help.**

Entities should post any questions or additional information about submitted amendment requests in the General Discussion board of the amendment home page. The General Discussion boards on the entity Home page and each section of the Form 1 can also be used to communicate any general questions, concerns, or comments to FSAP.

If FSAP needs clarification or additional information regarding an amendment, a Request for Information will be submitted. To address the request from FSAP, click on the Edit button next to the amendment, make any necessary changes to the amendment or comments in the General Discussion, and click Return to Agency.

- The amendment will be processed for approval following the submission of sufficient information and, if applicable, pending satisfactory closure of an inspection. The entity will receive notification from eFSAP once the amendment has been approved.

## Some change requests may require the sequential submission of multiple amendments.

**Example:** A registered entity is adding two new laboratory rooms (Rooms A and B) to their registration for work currently approved for Principal Investigator (PI) Jones. The addition of these rooms has also resulted in 2 new staff being hired (Jane Doe and John Smith).

### Preferred order of submission of separate amendments:

- Amendment 1 (Section 4) – Add John Smith and Jane Doe-. See *Adding or Reapplying Personnel* for more details.
- Amendment 2 (Section 6) – Add Rooms A and B-. See *Addition of a New Building and/or Addition of a New Room/Suite to an Existing Building* for more details.
- Amendment 3 (Section 7A & 7C) – Modify all applicable work objectives for PI Jones to add the new rooms. Separate amendments must be submitted for each work objective you wish to modify. See *Modifying Work* for more details.

Some amendments require prior approval of another amendment before they can be submitted. For example, when changing a room from storage only to lab and storage, an amendment to modify the room in Section 6 to lab and storage must be approved before an amendment can be submitted to add a work objective associating the room with work.

## Examples of Amendment Request Language

Amendment request language should be as descriptive as possible and reference the sections of the APHIS/CDC Form 1 being updated. The examples below are intended to represent some of the most frequent amendment requests submitted by registered entities:

- “We would like to add PI Smith to our registration. He will be working with Highly Pathogenic Avian Influenza virus (HPAIV) in a new suite (3010) in building J. We have already added suite 3010 to Section 6 and HPAIV to Section 3. PI Smith has been added to Section 4 and he is unrestricted. Here we are adding a work objective to describe the HPAIV work PI Smith will be performing in suite 3010.”
- “We are removing rooms 101, 102, 103 and 104 from Principal Investigator (PI) Jones work objective WO001792.1. These rooms will continue to be used by other PIs and will not be removed from our overall registration. PI Jones’ inventory has been audited and has been relocated to laboratory room 105, currently approved for PI Jones.”
- “We are removing BSL3 rooms 205, 206, and 208 from our registration. Here we are modifying work objective WO001340.1 to remove these rooms. In a separate amendment, we will be removing WO001341.1, which only contains those rooms. All select agents have been reconciled and transferred to long-term storage in room 315. Rooms 205, 206, 208 have been decontaminated with vaporized hydrogen peroxide (VHP) performed by a contracted vendor. See uploaded decontamination procedures.”

**If you have any questions about the amendment process, these examples or any other types of amendments, contact your designated FSAP point of contact.**

## Personnel Amendments

### Changing a Responsible Official

An individual cannot self-appoint themselves as Responsible Official (RO) (i.e., a currently registered Alternate Responsible Official (ARO) cannot sign paperwork requesting to be the RO). When possible, the RO should send an amendment to appoint their successor. If the RO has already left the entity, the new RO must be appointed by an owner, controller or person of authority at the entity.

#### To add, change, or reapply a RO:

**Note:** A new RO must be assigned before the previous RO can be removed from the registration or their role updated. If the new RO is not currently approved on the registration (unrestricted in Section 4), then the individual must first be added to the registration under a different role before they can be assigned as the RO (see Adding or Reapplying Personnel).

- Log in to eFSAP and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 4 – Change Responsible Official.
- Select the new RO from the drop-down menu of unrestricted personnel at the entity.
- Complete a cover letter with the response.
- In the cover letter provide a request stating the name of the new RO.
  - The request should be made by the current, approved RO who will be replaced.
- Click Ok.
- A message box will appear. Click OK.
- Complete the Section 4 information (with the newly appointed RO information).
- Click Save and Proceed.
- A message box will appear. Click OK.
- Update the cover letter, if needed, and click Submit.
  - **Note:** If you click on Save Draft on the amendment page, you will save the amendment as a draft. You can return to a draft amendment at a later time. However, a draft amendment will not be reviewed by FSAP. In order to submit a draft amendment for review and approval by FSAP, open the amendment from your Home page and click Submit.
- Request a SAMS account for the new RO if they do not already have one (email [eFSAPsupport@cdc.gov](mailto:eFSAPsupport@cdc.gov)).
- After the amendment is approved and eFSAP access has been granted, the newly appointed RO should log in to eFSAP and either remove the former RO from the registration or modify their role. See *Removal of RO, ARO or Owner/Controller* or *Updating Information for Individuals Approved for*



Access for more details.

- Email [eFSAPsupport@cdc.gov](mailto:eFSAPsupport@cdc.gov) to request removal of SAMS account access for the prior RO or to change access to read-only, if appropriate.
- The new RO should review the information in eFSAP for accuracy and sign Section 2 of the Form 1. From the entity Home page, click on Form 1 and then Amend. From the drop-down menu select Sign Section 2.
- Click Ok.
- Review the Section 2 statements prior to electronically signing the form. Sign the form by typing your name in the text box.
- Click Save.

#### **Additional Information**

- By reviewing and signing Section 2, the RO is certifying that, as of the date indicated on the amendment submitted to FSAP, all information is current and accurate, and these requirements are met. This includes ensuring that plans are written and provisions and procedures described are in effect at the time of submission of the registration amendment, in accordance with the requirements of the Select Agent Regulations.
- Since all communication between a registering individual or entity and FSAP is through the RO or ARO, it is imperative that the RO and ARO contact information is kept up-to-date. If any Section 4 information changes, it must be immediately reported to FSAP. Verbal change requests cannot be accepted.

## Adding Individuals - General Information

When adding new individuals to your registration, use the eFSAP portal to add their information and generate the Department of Justice (DOJ) numbers.

- The first and last name for each individual must match what is entered in his/ her respective [FD-961 Form](#).
- DOJ Numbers, which will be entered into the FD-961 form, are generated within eFSAP for new individuals. Once assigned, an individual's DOJ number will not change, even if the person moves to another entity. If an individual being added already has a DOJ number, DO NOT generate a new DOJ number. Enter the previously provided number into eFSAP.
- When entering an individual's DOJ number, capitalize the letters as in XX123456.
- **FSAP approval must be granted for each individual before they access select agents/toxins. The eFSAP portal will be updated once approval is granted. Responsible Officials should review their pending staff regularly to determine when the status changes to unrestricted.**
- For individuals currently registered at another entity (valid SRA) who wish to be added to an

additional entity(s), the additional entity will enter the previously provided DOJ number into the DOJ box. The entity should NOT generate a new DOJ number. If you mistakenly generate a new DOJ number, notify your POC via eFSAP.

- Notify your POC that an individual with a valid SRA has been added to the registration using the General Discussion box at the bottom of Section 4.
- Do not submit an FD-961 form, fingerprints or photograph to the FBI/CJIS. Once the existing SRA is verified, the individual's status will be updated to unrestricted in eFSAP. The SRA expiration date will be the same at all entities. The date will be based on the current expiration date and not three years from the time of approval at the second entity.
  - For example, J. Doe is registered at Entity A with an SRA expiration date of May 15, 2019. When J. Doe registers at Entity B with access approval granted on October 17, 2018, his SRA expiration date for both entities will be May 15, 2019.
- Both ROs should coordinate actions so that only one renewal packet is submitted to CJIS for the individual. The portal will be updated for both entities upon renewal.

## Adding or Reapplying Personnel

**See the Definitions section for descriptions of the different types of personnel that can be added.**

The addition or reapplication of an individual to the registration is approved when their status in Section 4 changes from 'pending' to 'unrestricted'. An unrestricted individual may access select agents and toxins. However, approval of an individual's role as a PI does not occur until a request to assign them to a work objective has been approved. See *Addition of New Work* and *Modifying Work* for details on assigning work objectives.

- Following approval of a work objective assigned to the PI, the PI may acquire select agents and toxins (SAT) listed in the work objective. Once SAT is acquired, update Section 7B in eFSAP. See *Update Possession Status of Select Agents/Toxins* or *Modify Existing Strain or Serotype Information* for more details.
- If the PI will supervise staff, you must update supervisor information for affected laboratorians and animal care staff in Section 4. See *Updating Information for Individuals Approved for Access* for more details.

### To add personnel:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel. Click Ok.
- Section 4 – Entity Personnel will open. Click Add new personnel.

- Enter the name, and date of birth of the individual to be added.
  - For individuals who already have a DOJ number, enter the individual’s previously assigned DOJ number in the DOJ Number box.
  - For a new individual click the Generate new DOJ number button.
- Select the box for the role(s) the individual will have. If the individual is being added to become the future RO, select the most appropriate role (e.g., Administrative– Safety) since the RO role is not an option when an individual is initially added to the registration.
  - If ARO role is chosen, fill in the additional contact information boxes.
  - If Laboratorian or Animal Care Staff role is chosen, assign a supervising PI.
- Indicate whether the individual will have Tier 1 access or inventory responsibilities.
- Electronically sign the document.
- Click Add Personnel.
- Submit the completed FD-961 and supporting documents to CJIS.
  - For information on completing and submitting the complete FD-961 see the [Security Risk Assessment FAQ’s](#) and links available on the FSAP webpage.
- To request eFSAP access for the new individual, email [eFSAPsupport@cdc.gov](mailto:eFSAPsupport@cdc.gov) to request a SAMS account.

#### ***Additional Information***

- It is recommended that an entity have at least one ARO to ensure continuity of operations.
- An individual is withdrawn upon their removal from Section 4. In the event that an individual requires access approval in the future, the entity may request to reapply the individual. Reapplied individuals will use their previously assigned DOJ number.

#### **To reapply personnel:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel. Click Ok.
- Section 4 – Entity Personnel will open.
- Scroll down to the individual to be reapplied and click Edit.
  - **Note:** Clicking on the “withdrawn” radio button will show you only inactivated individuals.
- Click Reapply. A pop-up box will appear. Click OK.
- The individual will be listed as Pending without an assigned role. Click Edit.
- Select the box for the role(s) the individual will have. If the individual is being reapplied in order to become the RO, select the most appropriate role given the individual’s work (the RO role is not an option when initially being reapplied).
- Complete all information, including additional contact information or supervising PI, as appropriate.
- Indicate whether the individual will have Tier 1 access or inventory responsibilities.
- Electronically sign the document.

- Click Update.
- Submit the completed FD-961 and supporting documents to CJIS.
  - For information on completing and submitting the complete FD-961 see the [Security Risk Assessment FAQ's](#) and links available on the FSAP webpage.
- To request eFSAP access for the reapplied individual, email [eFSAPsupport@cdc.gov](mailto:eFSAPsupport@cdc.gov) to request a SAMS account.

## Updating Information for Individuals Approved for Access

In the event that an individual changes their name, role, or title, or is assigned to a new supervising PI, an update to Section 4 for that individual should be submitted in eFSAP. Additional changes that can be made are Tier 1 access status (see *Update to an Individual's Access to Tier 1 Select Agents/Toxins* for more detail), responsibility for inventory, and address and contact information for ROs and AROs. The date of birth and DOJ number cannot be modified once entered.

**Note:** Only laboratorians and animal care staff require a supervising PI.

### To Update/Modify personnel:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel. Click Ok.
- Select the individual to be modified and click Edit.
  - Update the information with the changes
- Click Update.

### *Additional Information*

- Since all communication between a registering individual or entity and the FSAP is through the RO or ARO, it is imperative that the RO and ARO contact information is kept current and accurate. If any Section 4 information changes, it must immediately be reported to FSAP. Verbal change requests cannot be accepted.
- A name change does not affect an individual's DOJ Number. Individuals who change their name should continue to use the same DOJ number for any future FD-961 or APHIS/CDC Form 1 submissions.

## Update to an Individual's Access to Tier 1 Select Agents/Toxins

Each individual who will have access to, or the ability to access, Tier 1 agents must be indicated by checking the Tier 1 access box in Section 4. Several circumstances may require updating an

individual's Tier 1 access status including, but not limited to, the following:

- Change in work assignment
- Addition or removal of a Tier 1 select agent/toxin
- Addition or removal of suite/room where Tier 1 select agents or toxins are used or stored
- Personnel pre-access suitability assessment or ongoing suitability monitoring decisions

**Note:** A change in Tier 1 access does not add or remove an individual from the entity's registration.

**To update Tier 1 access for an individual:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel. Click Ok.
- Find the individual to be modified and click Edit.
  - Select/deselect the box for Tier 1 access and click Update.

### Removal of RO, ARO, or Owner/Controller

**Note: A RO or a sole Owner/Controller cannot be removed without a replacement being appointed first.**

To add a new RO, see *Changing a Responsible Official* above. To add an Owner/Controller, see *Adding or Reapplying Personnel* above. Once the replacement RO or Owner/Controller has been added, you can remove the former RO or Owner/Controller. Removal of an ARO does not require a replacement.

**To remove a RO, ARO, or Owner/Controller:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 4 – Add/Remove/Modify/Reapply Personnel. Click Ok.
- Find the individual to be removed and click Edit.
  - Electronically sign the document.
  - If the individual will remain on the registration in a different role, remove the check on the RO, ARO, or Owner/Controller box, select the updated role and click Update.
  - If the individual is being removed from the registration entirely, click Remove and provide the reason for removal. Click Finalize.
  - If the individual is being removed, a pop-up box will appear that states the person will be inactive and not available for work packages. Click OK.
- Email [eFSAPsupport@cdc.gov](mailto:eFSAPsupport@cdc.gov) to request the inactivation of the SAMS account for the individual, if appropriate.
  - If the departing individual is also a PI, see *Removal of a PI*.

### ***Additional Information***

- In the event that an entity loses the services of its RO, it may continue to possess, use, or transfer select agents or toxins only if it appoints another individual as the RO, who meets the requirements of the regulations, and who has been approved by the APHIS Administrator or HHS Secretary following a security risk assessment by the Attorney General. Until a new RO is assigned, the ARO must assume the responsibilities of the RO position.
- In the event that an entity loses the services of its sole Owner/Controller, it may continue to possess, use, or transfer select agents or toxins only if it appoints another individual as the Owner/Controller, who meets the requirements of the regulations, and who has been approved by the APHIS Administrator or HHS Secretary following a security risk assessment by the Attorney General.

## Removal of Laboratorians, Animal Care Staff, and Support Staff

### **To remove Laboratorians, Animal Care Staff, and Support Staff:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel. Click Ok.
- Find the individual to be removed and click Edit.
  - Electronically sign the document.
  - If the individual will remain on the registration in a different role, remove the check on the Laboratorians/Animal Care Staff/Support Staff box, select the updated role and click Update.
  - If the individual is being removed from the registration entirely, click Remove and provide the reason for removal. Click Finalize.
  - If the individual is being removed, a pop-up box will appear that states the person will be inactive and not available for work packages. Click OK.
- If the individual was provided a read-only SAMS account, email [eFSAPsupport@cdc.gov](mailto:eFSAPsupport@cdc.gov) to request the inactivation of the SAMS account.

### ***Additional Information***

Once the individual is removed, he/she will be deactivated from the entity's registration. If the individual requires access approval in the future, the individual may be reapplied at that time. See *Adding or Reapplying Personnel* for more details.

## Removal of a PI

The removal of a PI requires additional documentation to account for the disposition of any inventory of select agents and/or toxins. It is important for entities to consider how the removal of a PI may affect other aspects of their registration (e.g., if the PI was the only PI assigned to a select agent/toxin, suite/room, laboratorian) and submit updates to appropriate sections of APHIS/CDC Form 1 as needed.

The removal of a PI must be completed in the following order:

- Remove the PI from Section 7B strains and serotypes, if necessary. No change is required if the strains/serotypes are registered as “Entity Wide”.
- Remove the PI from Section 7A & 7C work objectives (or remove the work objective) and provide a description or documentation of the disposition of assigned agents. Each work objective must be modified or removed as a separate amendment [e.g., If PI Smith is associated with three work objectives, in order to remove him from the registration, you must submit three separate amendment requests (one for each work objective)].
- Remove the role as supervising PI for affected staff. If the individual is not already assigned to another PI, assign one now.
- Remove the role of PI from the section 4 information.

### To remove a PI:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 7B: Add/Remove/Modify Strains and Serotypes. Click Ok.
- If the strain was transferred to another PI (intra-entity transfer), click Edit on each strain, update the assigned PI, and click Save. If the strain was destroyed or transferred to another registered entity, click Edit on each strain and click Delete. Click OK on the message box. Click Save after updating all strain(s)/serotype(s). See *Update Possession Status of Select Agents/Toxins or Modify Existing Strain or Serotype Information* for more details.
  - Note: If the strain/serotype was assigned as “Entity Wide” in Section 7B and it was kept by the entity, then no Section 7B update is required.
- Return to the Home page. Click on the Form 1 tab.
- Click Amend, and from the drop-down menu select 7A/C – Modify Work Objective and/or Attachment(s) to remove a single PI from a shared work objective or select 7A/C – Remove Approved Work Objective to remove the entire work objective from the registration.
- If modifying a current work objective, choose the work objective from the drop-down menu.
- Provide a cover letter with the request.
- The request should include the name of the PI to be removed, the reason for removal, and disposition of select agents/toxins under the control of the PI.
- For disposition of the PI’s select agent(s) and/or toxin(s) provide via statement or uploaded record:
  - Verification of inventory audit.

- If inventory is subsequently destroyed, provide documentation of destruction (e.g., autoclave records and statement signed by witness)
- If inventory is subsequently transferred to another registered entity, provide the APHIS/CDC Form 2 transfer number (e.g., CEA123456). For intra-entity transfers, provide chain of custody documentation.
- If the entity is removing a select toxin from its registration, but will continue to possess the select toxin under the regulated aggregate amount:
  - Include a statement and/or upload records showing that the amount of toxin possessed by the registered PI is under the regulated aggregate amount.
  - Include a statement of how the entity will ensure that each PI's select toxin inventory remains below the regulated aggregate amount.
- Click Ok. A message will appear. Click OK.
- If modifying a work objective, the one previously selected from the drop-down menu will open. Select Add/Remove on the Principal Investigator information line.
  - Select the PI(s) that are remaining associated with the work objective (Control + Click to highlight more than one at a time) and click Save.
  - Click Save and Proceed.
  - Update the cover letter, if necessary. Click Submit.
- If removing the work objective, the Section 7A & 7C will open. Scroll to the work objective and click Remove. Click OK. A message box will appear. Click OK.
- The work objective will open. Confirm that it is the correct work objective and click Save and Proceed.
- Update the cover letter, if necessary. Click Submit.

**Note:** If the work objective being removed is the only work objective assigned to a room/suite or select agent or toxin, then the room/suite, select agent, and/or toxin will be removed from the registration at the same time. See *Removal of Work* for more details.

- From the Home page, click on the Form 1 tab, then View/Edit, then click on the Section 7A & 7C tab.
- Scroll to the bottom of the page to the Upload Center and upload the supporting documentation.
  - For example, destruction records, amount of toxin possessed or intra-entity transfer documentation.
- If the departing PI has assigned staff, update all affected individuals. This can be done before or during the process of removing the PI from work objectives.
  - Return to the Home page. Click on the Form 1 tab.
  - Click Amend, and from the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel. Click Ok.
  - Select the PI to be removed and click Edit.
  - Click Remove as Supervisor from all Personnel button.
    - If the PI is the only supervising PI for certain individuals, you will receive a reminder message to update supervising PI information for those individuals.
    - Scroll to the affected individual and click Edit. Highlight the PIs you want assigned as supervisor (not including the exiting PI) and click Update.



- Once the amendments to update or remove the work objectives have been approved, section 7B has been updated (if necessary) and the PI has been removed as supervisor for staff in Section 4, the PI can be removed from Section 4.
  - From the Home page click on the Form 1 tab and then Amend. From the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel and click Ok.
- Select the PI to be removed and click Edit.
  - Electronically sign the document.
  - Click Remove and provide the reason for removal.
  - Click Finalize.
  - When the notification that the person will be inactive and not available for work packages appears, click OK.
  - **Note:** If the PI is also a RO, see *Changing a Responsible Official* for more details.

#### ***Additional Information***

- Each laboratorian, animal care staff, and unescorted visitor must be assigned to a designated PI. Additionally, each select agent/toxin and room (including each room within a suite listed as lab, storage, or lab and storage) must be associated with at least one PI in a work objective.
- An approved APHIS/CDC Form 2 is required prior to the transfer of select agents and/or toxins to another registered entity.
- Entities must conduct inventory audits of all affected select agents and toxins in long-term storage per section 11(e) of the [Select Agent Regulations](#) (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) when any of the following occur:
  - (1) Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;
  - (2) Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or
  - (3) In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.

### Swap One PI for Another (no change in work objectives)

Each PI must have at least one work objective in Section 7A & 7C. The work objective must include at least one select agent/toxin and at least one suite/room.

The replacing PI must be unrestricted in Section 4 and must be assigned to at least one work objective before a PI swap amendment can be performed.

If the replacing PI does not currently have any approved amendments assigned to him or her, and the only work objectives they will be assigned to are the ones where they are being swapped for an exiting PI, then you must first submit a request to modify one of the work objectives assigned to the exiting PI. In the request, remove the exiting PI and add the replacing PI. See *Modifying Work* for more details.

**Note:** This amendment type only replaces one PI name for another on work objectives, Section 7B strains and serotypes, and supervisor for personnel in Section 4. If swapping a PI also includes the addition of new agents/toxins, work objectives, or space, or additional modifications to current work objectives, see *Addition of Select Agent or Toxin*, *Addition of New Work*, *Addition of a New Building*, *Addition of a New Room/Suite to an Existing Building*, and/or *Modifying Work* for more details.

**To swap one PI for another:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu, select Replace Principal Investigator. Click Ok.
- Select the exiting PI from the drop-down menu on the left. Select the replacing PI(s) from the options that appear on the right. Click Next.
- A list of personnel currently assigned to the exiting PI will be listed. The current and revised assigned supervisors for each individual will also be listed. Verify that the information is correct. Click Next.
- Work objectives currently assigned to the exiting PI will be listed. The current and revised list of principal investigators assigned to each work objective will be listed. Verify that the information is correct. Click Next.
- A list of all assigned select agents and toxins that will be reassigned will be listed. Click on the arrow to open up a view of all the strains or serotypes affected for each select agent or toxin. Verify the information. Click Next.
- A confirmation statement will appear. If the information is correct, click Commit Changes.

Once you click Commit Changes, the changes will occur automatically. If at any point you cannot verify that the changes listed are correct, use the Back button to make changes to your initial request. Clicking Close will exit the amendment request without saving a draft.

## Select Agent/Toxin Amendments

### Addition or Reactivation of Select Agent/Toxin

Select agent or toxin should not be possessed at the time of the request.

**Note:** Addition or reactivation of a select agent or toxin to Section 3 does not constitute approval to use or store the select agent/toxin. The entity must receive approval of a work objective assigned to the select agent/toxin before the entity may acquire the select agent/toxin. An inspection may be required prior to approval of a work objective.

**Note:** If you are adding a Tier 1 agent or toxin and there is not currently a Tier 1 agent or toxin on the registration, additional updates may be required to Section 4 (Tier 1 access), Sections 5A and 6 (Tier 1 security requirements), and Section 5B (enrollment in an occupational health program).

#### **To add a select agent/toxin:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 3 – Add Select Agent and Toxin.
- Click Ok.
- Under Add New Agent/Toxin, choose the select agent or toxin you wish to add from the drop-down menu. Click Add. Repeat for any additional agents/toxins you wish to add.
- Click Save. The following notification will appear: *This request will add 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.*
- Click Proceed.
- A message box will appear. Click OK.

**Note:** If you are adding SARS-CoV or a Tier 1 agent/toxin to the registration, submission of the entity’s occupational health plan is required. From the Home page, click on the Form 1 tab and then View. Click on Section 3. Upload the document using the Upload Center at the bottom of the page.

- If applicable, amend the Section 1 Entity Abstract with any necessary changes. See *Modifying Section 1 Information, Change Entity Name, Abstract, or Type* for more details.
- If applicable, amend Section 5 with any updated information regarding entity-wide physical security, biosafety/biocontainment, and entry requirements for FSAP inspectors. See *Modifying Section 5 Information* for more details.
- If a room/suite will be added for the new select agents/toxins, see *Addition of a New Building* and *Addition of a New Room/Suite to an Existing Building* for more details.
- Submit a new amendment request to add a work objective or modify a current work objective to describe the work that will be performed with the new select agent or toxin. See *Addition of New Work or Modifying Work* for more details. Following approval of the work objective, the entity may acquire the select agent or toxin.
- Following internal transfer or receipt of a select agent or toxin by Form 2, the entity must update select agent or toxin possession status by logging in to eFSAP and updating Section 7B. See *Update Possession Status of Select Agents/Toxins or Modify Existing Strain or Serotype Information* for more details.

#### **To reactivate a select agent/toxin:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 3 – Reactivate Select Agent and Toxin.
- Click Ok.
- Click on the green Reactivate button for the select agent(s) and toxin(s) you wish to reactivate.
- Click Save.
- The following notification will appear: *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.*
  - Click Proceed.
- A message box will appear. Click OK.
- If applicable, amend the Section 1 Entity Abstract with any necessary changes. See *Modifying Section 1 Information, Change Entity Name, Abstract, or Type* for more details.
- If applicable, amend Section 5 with any updated information regarding entity-wide physical security, biosafety/biocontainment, and entry requirements for FSAP inspectors. See *Modifying Section 5 Information* for more details.
- If a room/suite will be added for the new select agents/toxins, see *Addition of a New Building* and *Addition of a New Room/Suite to an Existing Building* for more details.
- Submit a new amendment request to add a work objective or modify a current work objective to describe the work that will be performed with the new select agent or toxin. See *Addition of New Work* or *Modifying Work* for more details. Following approval of a work objective, the entity may acquire the select agent or toxin.
- Following internal transfer or receipt of a select agent or toxin by Form 2, the entity must update select agent or toxin possession status by logging in to eFSAP and updating Section 7B. See *Update Possession Status of Select Agents/Toxins* or *Modify Existing Strain or Serotype Information* for more details.

#### **Additional Information**

- The addition of a select agent or toxin requires that written plans, as applicable, are commensurate with the risk of the agent or toxin, given its intended use. This includes ensuring that plans are updated and provisions and procedures described are in effect as of the date that the amendment is submitted in accordance with the requirements of the Select Agent Regulations.
- For additional requirements for Tier 1 select agents and toxins, refer to sections 11(f), 12(d), 14(e), and 15(b) of the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).
- Reconstructed 1918 Influenza Virus requires special consideration and/or approval. Contact your designated FSAP representative prior to your amendment submission.

## Update Possession Status of Select Agents/ Toxins or Modify Existing Strain or Serotype Information

Section 7B information should be maintained on a real time basis. Whenever a strain or serotype is acquired, created, or destroyed, Section 7B must be updated.

Section 3 is automatically updated based on Section 7B. In order to accurately reflect the possession status of a select agent or toxin in Section 3, you must update Section 7B. If a strain or serotype is listed in Section 7B for a registered select agent or toxin, then Section 3 will show that the select agent or toxin is possessed. If there are no strains or serotypes listed in Section 7B for a registered select agent or toxin, then Section 3 will show that the select agent or toxin is not possessed. **Do not add a strain/serotype in Section 7B called “To Be Acquired”. This will result in your possession status changing to possessed for that agent.**

### To add, remove, or modify a select agent or toxin strain or serotype:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 7B: Add/Remove/Modify Strains and Serotypes.
- Click Ok.
- To add a strain or serotype, click Open, choose the select agent/toxin from the drop-down menu, enter one strain or serotype, select the assigned PI(s), and click Add Agent and Strain.
  - Only PIs that are unrestricted and have an approved work objective for that select agent or toxin will appear as options.
  - To assign the strain or serotype to all PIs at the entity, check the “Entity Wide” box.
- To modify a strain or serotype, scroll through the list of current strains and serotypes, Click Edit next to the one you wish to modify, make the change and click Save.
- To remove a strain or serotype, scroll through the list of current strains and serotypes, Click Edit next to the one you wish to remove, Click Delete. A message will appear. Click OK.
- Click Save at the top of Section 7B to save any additions or deletions.
  - Multiple strains can be entered or removed sequentially, prior to clicking Save.

## Removal of Select Agent/Toxin from the Entity

Prior to removal of a select agent/toxin from the entity registration, all strains or serotypes for that select agent/toxin must be removed from Section 7B. Additionally, the select agent/toxin must not be associated with any work objectives.

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 7B: Add/Remove/Modify Strains and Serotypes.

- Click Ok.
- Scroll to the strain or serotype you wish to remove and click on the Edit button for that line.
- The strain/serotype information will open in a separate pop up box. Verify that it is the correct strain/serotype and click Delete. A message box will appear. Click OK.
- After you have completed the step above for all strains/serotypes, click Save.
- Click on the Home button to return to your Home page.
- Remove the select agent/toxin from all work objectives it is associated with. See *Removal of Work and Modifying Work* for more details.
  - In the cover letter for the amendment to remove or modify the work objective, include the method of disposition of the select agent/toxin and verification of inventory audit.
  - To upload supporting documentation, such as record of destruction or inactivation, log in to the eFSAP portal, click on Form 1, View, and then Section 3. Scroll down to the Upload Center and upload the supporting documentation.
  - When the final work objective in Section 7A & 7C associated with a select agent or toxin is removed or modified to remove the select agent/toxin (See *Removal of Work and Modifying Work*), the select agent/toxin will be automatically removed from the registration. Previously registered strains and serotypes can be viewed in the Historical side of Section 7B and previously registered select agents and toxins can be viewed in the Historical side of Section 3.

#### **Additional Information**

An approved APHIS/CDC Form 2 is required prior to the transfer of select agents and/or toxins to another registered entity.

### Removal of Select Agent/Toxin from a PI (but not the Entity)

Each of the PI's work objectives that includes the select agent or toxin to be removed must be modified in individual amendments.

#### **To remove a select agent/toxin from a PI:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 7AC – Modify Work Objective and/or Attachment(s).
- Select the Work Objective number from the drop-down menu.
- Complete a cover letter with the request.
- The request should specify the select agent/toxin being removed and the name(s) of the PI(s) affected.
- The request should describe the disposition of the select agent/toxin.
  - Destroyed/Inactivated – Provide documentation (e.g. autoclave records and statement signed by witness).

- Transferred – Provide documentation consistent with your intra-entity transfer protocols (e.g., chain-of-custody) or APHIS/CDC Form 2 transfer number (ex. CEA 123456) for transfer outside the entity.
- Click Ok. A message box will appear. Click OK.
- The work objective will open.
- Click Add/Remove corresponding to the select agent/toxin line.
  - Select the agents/toxins to remain associated with the work objective (hold Ctrl key and Click to choose multiple agents) and click Save Changes. Scroll to the bottom of the work objective and click Save and Proceed.
- Update the cover letter, if needed, and click Submit.
- You will be returned to the Home page.
- Upload supporting documentation, such as destruction records or intra-entity transfer documentation in Section 3.
  - From the Home page, click on Form 1, click on View and then click on Section 3.
  - Upload the document using the Upload Center at the bottom of the page.
- Update Section 7B to reflect the removal of the select agent/toxin from the PI. See *Update Possession Status of Select Agents/Toxins or Modify Existing Strain or Serotype Information* for more details.
  - From the Home page Click on Form 1.
  - Click Amend, and from the drop-down menu select Section 7B: Add/Remove/Modify Strains and Serotypes.
  - Click Edit for each strain/serotype and update the assigned PI(s). If removing the strain/serotype entirely from the registration, click Delete and then OK when the pop-up box appears.
  - Once all applicable strains/serotypes have been updated, click Save.

**Note:** If Tier 1 status of entity personnel is affected by the removal of an agent or toxin, update Section 4. See *Update to an Individual's Access to Tier 1 Agents/Toxins* for more details.

## Facilities Amendments

### Addition of a New Building

#### To add a new building:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 6 – Add New Building. Click Ok.
- Section 6 A/B will open.
  - Provide the building name and answer questions 1-3.
- Click Add Building.

- A message box will appear.
- Click OK.
- Section 6 A/B will open. The new building will appear with no rooms assigned.

**Note:** You must add room(s) and/or suite(s) to the building. See *Addition of a New Room/Suite to an Existing Building* for more details.

## Addition of a New Room/Suite to an Existing Building

### To add a new room/suite to an existing building:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 6 – Add New Room or Suite. Click Ok.
- Select whether the new space is a room or a suite. See the Definitions section for a description of what constitutes a room versus a suite.
  - If a room, select whether the space will be used for storage, laboratory, or both.
- Select the building the room/suite is located in. 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.
- Select the Biosafety level(s) associated with the work to be performed in the room/suite. Click Add biosafety level.
  - Add every biosafety level that will be used in the room/suite, one at a time.
    - The biosafety level of the room/suite should be consistent with BMBL containment recommendations for the select agent/toxin listed and work described.
- Enter the resources/references used to determine the biosafety level(s).
- If adding a Suite, add each room name, 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. Click Add Suite Room.
  - Add each room one at a time. Rooms where work is performed, but no storage occurs, such as a necropsy room, should be listed as Lab Only and may need descriptors in the name, e.g., A101 – Necropsy. Rooms and corridors where waste that has not been decontaminated is stored should be listed as Storage Only and may need descriptors in the name, e.g., A102 – Corridor. If no work or storage occurs in a room (e.g. an anteroom), select “Other” and chose a room descriptor from the drop-down menu.
    - The room level settings (storage, lab, lab and storage) will affect the work objectives that can be assigned. For example, a suite that has three lab only rooms, two storage only rooms, and five lab and storage rooms will require at least three separate work objectives (one storage only, one lab only and one lab and storage) to describe the work performed in the suite. Work objectives cannot be assigned to rooms assigned Room Type: Other. Therefore, do not use this room type if any work or storage occurs in the space.



- Answer the room/suite information questions 1-7, and the suite physical information questions 1–16 as described in the Form 1 Instructions.
- Click Add Room/Suite.
- A message box will appear. Click OK.
- Another message box will appear that states, “[room or suite name] has been added. Don’t forget to submit a 7a/c amendment for this room.” Click OK.
- Section 6 A/B will open. The new room/suite will show a status of Unassigned until an amendment is submitted and approved to add a work objective linked to the new space.

**Note:** Floor plans and commissioning documents may be requested by FSAP. Refer to Section 6 of the Form 1 instructions for details on what information should be included in the documentation. To upload the supporting documentation, use the Upload Center at the bottom of Section 6.

- If a PI will be added to the entity registration to perform work in the suite/room(s), see *Adding or Reapplying Personnel* for more details.
- 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 (Section 7AC – Modify Work Objective) or add a new work objective (Section 7AC - Add New Work Objective). See *Addition of New Work* or *Modifying Work* for more details.

**Note:** FSAP will perform a Biosafety, Security, and Facilities review and, if necessary, will schedule an inspection of the new space prior to approving the Addition of New Work or Modification of Work Objective amendment.

- Amend Section 5 (as applicable) with any updated information regarding entity-wide physical security, biosafety/biocontainment, and entry requirements for FSAP inspectors. See *Modifying Section 5 Information* for more details.
- Amend Section 1 entity abstract, if applicable. See *Modifying Section 1 Information* for more details.
- If adding a new select agent/toxin, see *Addition of Select Agent/Toxin* for more details.

### ***Additional Information***

The addition of a new room or suite requires that written plans, as applicable, are site-specific to include the additional location. This includes ensuring that plans are updated and provisions and procedures described are in effect as of the date that the amendment is submitted, in accordance with the requirements of the Federal Select Agent Regulations.

## Modifying an Existing Building, Room, or Suite

### To Modify a Building:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 6 – Modify Building.
- Choose the building from the drop-down menu and provide a cover letter with the request.

- The request should describe the changes that are being made.
- Click Ok. A message box will appear. Click OK.
- Make the appropriate changes in the Section 6 A/B and click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.

### **To Modify a Room or Suite:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 6 – Modify Room or Suite.
- Choose the room or suite from the drop-down menu and provide a cover letter with the request.
  - The request should describe the changes that are being made.
  - For some changes, such as remodeling or updates to the HVAC system, FSAP may request additional documentation and perform a facilities or security review.
- Click Ok. A message box will appear. Click OK.
- Make the changes in the Section 6 A/B that appears.
  - To remove a room within a suite, click on Delete next to the room you wish to remove.
  - To add a room within a suite, type the room name in the blank text box and select the room type. Depending on the room type chosen, select the biosafety level or additional descriptor for the room. Check the “HEPA filtered” box, if appropriate. Click Add Suite/ Room. Click OK when a message box appears.
  - To modify a current room within a suite, see *To Modify a Room within a Suite* for more details.

**Note:** At the bottom of the Section 6 A/B, currently approved work objectives tied to the selected room/suite are listed.

- Click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.

### **To Modify a Room Within a Suite:**

The system currently does not allow for modifications to a room type or biosafety level for rooms within a suite. Therefore, you must first submit a request to remove the room from the registration and once that amendment is approved, submit a request to add the room back to the registration with the changes made. In order to remove a room within a suite from the registration, you must first remove it from all work objectives. Once the room has been added back to Section 6 with the changes made, you can add the room back to work objectives. See *Modifying Work* for details on how to remove the room within the suite from the work objective and how to add the room back.

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 6 – Modify Room or Suite.
- Choose the suite from the drop-down menu and provide a cover letter with the request.
  - The request should indicate which room(s) are to be modified and what the modification

will be.

- Click Ok. A message box will appear. Click OK.
- Scroll down to the list of rooms within the suite in Section 6 A/B. Click Delete next to the room you wish to modify.
- Click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.
- Once the request to remove the room has been approved, log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 6 – Modify Room or Suite.
- Choose the suite from the drop-down menu and provide a cover letter with the request.
  - The request should indicate that you are adding back a room to the suite and should also describe the modifications made to the room information.
- Click Ok. A message box will appear. Click OK.
- Under List All Rooms in Suite, type the name of the room being modified in the blank text box. Select the Room Type.
  - If the room type is Lab Only or Lab and Storage, select the biosafety levels.
  - If the room type is Other, select the descriptor from the drop-down menu.
- Check the “HEPA filtered” box, if appropriate.
- Click Add Suite Room.
- Click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.

#### *Additional Information*

The modification of a room or suite requires that written plans, as applicable, are site-specific to include the effect of the modification. This includes ensuring that plans (including floor plans) are updated and provisions and procedures described are in effect as of the date that the amendment is submitted, in accordance with the requirements of the Select Agent Regulations.

### Removal of a Room/Suite

It is important for entities to consider how the removal of a room/suite may affect other aspects of their registration (e.g., the room to be removed is the only registered location for a select agent/toxin or a PI). Removal of a room or suite is automatic when the last work objective associated with the room or suite is removed from the registration. This includes storage only work objectives.

**Note: A room or suite not associated with a work objective cannot be removed from the registration.**

### To remove a room or suite:

Submit amendment requests to remove the room or suite from all work objectives. See *Removal of Work* and *Modifying Work* for more details.

- In the cover letter for the amendment(s) to remove or modify the work objective, include the method used to decontaminate the room/suite and equipment in the space and a description of disposition of any agents that were stored in the space.
  - To upload supporting documentation, log in to the eFSAP portal, click on Form 1 and then Section 6. Scroll down to the Upload Center and upload the supporting documentation.
  - If you believe decontamination is not necessary, provide a risk assessment and/or contact your designated POC via the General Discussion board within the amendment.
  - For disposition of agents or toxins, include whether the material was transferred or destroyed. If transferred, indicate if it was an intra-entity or inter-entity transfer and provide documentation (e.g., chain-of-custody document) or the Form 2 transfer number.
- When the final work objective associated with the room or suite has been altered (either by complete removal of the work objective or modification) the room or suite will be automatically removed from the registration. Previously registered rooms and suites can be viewed in the Historical side of Section 6.

## Work Objective Amendments

### Addition of New Work

The addition of new work may require an inspection prior to approval. Prior to requesting new work, any new buildings/rooms, PIs, or agents must already have been added to the registration. See *Addition of a New Building*, *Addition of a New Room/Suite to an Existing Building*, *Adding or Reapplying Personnel*, *Addition of Select Agent/Toxin*, and *Reactivation of Select Agent/Toxin* for more information.

### To add new work:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 7AC – Add New Work Objective.
- Provide a cover letter with the request.
  - The request should specify the new work objective to be added, including the PI(s) name, the agents/toxins that will be used, and the registered spaces where the work will occur.
- Click Ok. A message box will appear. Click OK.
- The section 7C will open.
- Select the type of work objective: Add Work, Add Work and Storage, or Add Storage Only.
  - A Work objective should be selected for locations where procedures and manipulation of

select agent or toxins will be performed, but not storage of select agent materials (including waste). For example, necropsy rooms, injection/inoculation/exposure rooms, equipment rooms (Flow cytometers, IVIS imagers, plethysmography).

- A Work and Storage objective should be selected for locations where select agents or toxins will be manipulated and stored, including material contaminated with select agent or toxin.
- A Storage Only objective should be selected for locations where no work (e.g. opening of a vial of select agent or toxin) will be performed. The location may be used for inventory purposes and storage only.
- Select the Biosafety level that the work will be performed at.
- If Storage Only is selected, designation of a biosafety level is not an option.
- 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 BSL3, then NIHBL3 or NIHBL3N can be added, if applicable

**Note:** Work at BSL cannot be combined with ABSL or ACL levels; each level must have its own work objectives.

- Select the appropriate select agent(s)/toxin(s).
  - To select multiple select agents/toxins hold Ctrl key and click.
- Select the PI(s) who will direct the work.
  - To select multiple PIs, hold Ctrl key and click.

**Note:** Only PIs designated in Section 4 as having Tier 1 access will be options if Tier 1 agents or toxins are chosen.

- Select the building(s) and room(s) where the work will be performed.
  - To select multiple buildings or rooms hold Ctrl key and click the desired buildings or rooms.

**Note:** Only rooms designated in section 6 with the selected biosafety level and type of work (storage and/or laboratory) will be listed as options. Likewise, only rooms designated as Tier 1 will be options if Tier 1 agents are chosen.

- Click Proceed.
- Enter the work objective. Answer questions 2-10 as required in the Form 1 Instructions.
  - Storage Only work objectives will have the words 'Storage Only' prefilled in the text box. Questions pertaining to work with the select agent/toxin (questions 4, 9, and 10) will not have an option for answering.
  - Do not use symbols when entering maximum quantities. For example, cultures should be noted with concentrations listed as  $1 \times 10^7$  cfu/ml, rather than  $1 \times 10^{*7}$  cfu/ml.
- Click Save and Proceed.
- If you answered yes to any portion of question 9 or 10, the corresponding Attachment will show as red below the cover letter. Click on the red box to open the Attachment. Fill in the answers as directed in the Form 1 instructions and click Save Changes.

- Update the cover letter, if needed, and click Submit.
  - Note: If you click Save Draft on the amendment page, you will save the amendment as a draft. You can return to a draft amendment at a later time. However, a draft amendment will not be reviewed by FSAP. In order to have a draft amendment reviewed and approved by FSAP, open the amendment from your Home page and click Submit.
- You will be returned to the Home page.
- Prepare supporting documentation. From the Home page click Form 1 and then View. Open Section 7A and 7C. Upload documentation in the Upload Center at the bottom of Section 7A and 7C. Include the amendment number in the file name. Possible supporting documents include:
  - Biosafety Plan sections including agent specific biosafety containment and decontamination considerations or SOPs, agent-specific Risk Assessments for procedures that involve aerosol production, animal infections, rDNA work, large scale production, etc.
  - Request for approval of any proposed restricted experiments (section 13 of the regulations) or exclusions (section 3(d) and 3(e) of the regulations). Attachment B will capture information about restricted experiments.
- If applicable, update staff roles. See *Updating Information for Individuals Approved for Access* for more details.
- If applicable, update the entity abstract. See *Modify Section 1 Information* for more details.

### ***Additional Information***

- The addition of new work with a select agent or toxin requires that written plans, as applicable, are commensurate with the risk of the agent or toxin given its intended use. This includes ensuring that plans are updated and provisions and procedures described are in effect as of the date that the amendment is submitted, in accordance with the requirements of the Select Agent Regulations.
- If a restricted experiment is included in Section 7C, Question 1 (objectives of work) and/or Attachment B, you may receive a request for additional information from the FSAP.
- Certain objectives of work need specific FSAP approval. Consult with your designated FSAP representative or contact the CDC at 404-718-2000 or APHIS at 301-851-3300 option 3 for further information. For example:
  - Reconstructed replication competent forms of the 1918 pandemic influenza virus.
  - Experiments that involve the deliberate transfer of, or selection for, a drug or chemical resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, even if the drug or chemical resistance is temporary. Please note that chemical resistance applies to plant pathogens.
  - Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD<sub>50</sub> < 100 ng/kg body weight.
- Work with a select agent or toxin at a biosafety level lower than that recommended by the current edition of the BMBL or other nationally recognized guidance requires special consideration.

## Modifying Work

**The type of work associated with an approved work objective (e.g. Storage Only, Work and Storage, or Work Only) cannot be modified.**

**To modify work:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 7AC – Modify Work Objective and/or Attachment(s).
- Choose the Work Objective you wish to modify from the drop-down menu.
- Provide a cover letter with the request.
  - The request should specify the modifications that are being made and the reason for the change.
- Click Ok. A message box will appear. Click OK.
- The work objective will open in Section 7C.
  - If changing the Biosafety Level(s), Agents/Toxins, Pls, or Building/Rooms, click on the Add/Remove button next to the corresponding line.

- All available options (biosafety levels, agents, buildings, etc.) will show in a text box.
- Highlight the options you wish to keep 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, highlight all three names using the Ctrl button.
- Click Save Changes.
- **If removing a room/suite or agent that is not associated with any other work objective, a message will appear warning that the item will be removed entirely from the registration, not just from the work objective, if you proceed.** Click OK.
  - For all other changes, including the objective of work, go to the question and make the change.
- Click Save and Proceed.
- Click on each Attachment to make any necessary changes to those sections. After making the changes click Save Changes.
- Make any necessary changes to the cover letter and click Submit.

## Removal of Work

### To remove work:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 7AC – Remove Approved Work Objective.
- Select the correct work objective from the drop-down menu. The PI(s), agent(s)/toxin(s), building/room(s), biosafety level, work objective, and room designation for the chosen work objective will appear. Verify that the correct work objective was selected. If so, proceed to the cover letter. If not, select a different work objective from the drop-down menu.
- Provide a cover letter with the request.
  - The request should specify the work objectives to be removed.
  - If removing work objectives for the purpose of removing a room or suite from the registration, include a description of decontamination of the space.
    - If documentation of decontamination requires uploading a document, then complete the following after submission of the amendment to remove the work objective: Click on Form 1, View, Section 6. Scroll to the bottom of Section 6 and upload the document in the Upload Center.
  - 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.
    - If documentation of disposition requires uploading a document, such as signed autoclave records, then complete the following after submission of the amendment to remove the work objective: click on Form 1, View, Section 3. Scroll to the bottom of Section 3 and upload the document in the Upload Center.
- Click Ok. A message box will appear. Click OK.
- 
- Update the cover letter, if necessary.



- Click Submit.
- If removing a PI, see *Removal of a PI* for more details.

## Other Amendments

### Renewing the Entity Registration

Sixty days before your entity's registration expiration date, submit an amendment request to renew your registration and sign Section 2.

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Request Registration Renewal.
- Provide a cover letter with the request and click Ok.
- A message box will appear. Click OK.
- Section 2 will open. Sign the form by typing your name in the text box and click Save.
- A message box will appear. Click OK.
- Click Navigate to Amendment. Update the cover letter, if needed. Click Submit.

To view and/or print your Certificate of Registration and Notification of Approval for Registration letter, click on the download icon next to the registration expiration date on your Home page.

### Modifying Section 1 Information

Entities should periodically review the information contained in Section 1 and notify the FSAP of any substantive changes. Updates to the Name and Abstract, including the Institutional Mission, Function and/or Size, should be verified at least with each registration renewal. A change of address, including a change of physical address, may be requested as an amendment and must include a detailed explanation.

#### **To change the entity name, abstract, or type:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 1: Change Entity Name, Abstract, or Type.
- Click Ok.
- Enter the updated information and click Save.
- A message box will appear. Click OK.

#### **To change the entity address:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 1: Change Entity Physical or Additional

Address.

- Type the requested change into the cover letter section.
  - Indicate whether the change is a physical change.
- Click Ok. A message box will appear. Click OK.
- Enter the updated information and click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.

**Note:** Section 1 denotes the physical location at which the entity is registered to possess select agents and/or toxins. The physical address will display on the entity's certificate of registration and is normally not changed unless there are extenuating circumstances, such as roads which are renamed, addresses being changed by the post office, or a change in physical location by the entity. Any change in the physical location of the entity will most likely require new Sections 5A, 5C, 6 and 7 as well as revision of entity-specific biosafety, security, and incident response plans, and an inspection. The entity's mailing address to which all official correspondence will be sent should be provided in the address field under *RO Information* in Section 4.

## Signing Section 2

**To sign Section 2 of the Form 1:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 2 – Sign Section 2. Click Ok.
- Sign your name and click Save.
- A message box will appear. Click OK.

## Modifying Section 5 Information

Entities should periodically review their Section 5 information and notify FSAP of any changes. Specifically, entities should review their entity-wide security, incident response, and biosafety/biocontainment information and their entry requirements for FSAP inspectors. Examples of types of changes that may require an update include:

- Addition of security lights or guards
- Addition of biometric system
- Addition of intrusion detection system
- Removal of locks
- Change to Tier 1 status prior to addition of a new Tier 1 select agent or toxin
- Changes in Personal Protection Equipment (PPE) requirements for visitors

**To update entity-wide security and incident response:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 5A: Modify Entity-Wide Security Assessment and Incident Response.
- Provide a cover letter with the request.
- The request should describe the changes being made.
- Click Ok. A message box will appear. Click OK.
- Enter the updated information and click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.

**To update entity-wide biosafety/biocontainment:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 5B – Modify Entity-Wide Biosafety/Biocontainment.
- Provide a cover letter with the request.
- The request should describe the changes being made.
- Click Ok. A message box will appear. Click OK.
- Enter the updated information and click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.

**To update entry requirements for FSAP inspectors:**

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Section 5C: Modify Entry Requirements for Federal Select Agent Program Inspectors.
- Provide a cover letter with the request. The request should describe the changes being made.
- Click Ok. A message box will appear. Click OK.
- Enter the updated information and click Save and Proceed.
- A message box will appear. Click OK.
- Make any necessary changes to the cover letter and click Submit.

***Additional Information***

Security and incident response plans should be site-specific and in accordance with the entity's risk assessments. Therefore, changes in entity-wide security and/or incident response may require that written plans be updated to ensure provisions and procedures described are in effect as of the date that the amendment is submitted, in accordance with the requirements of the Select Agent Regulations.

## Changing Lead Agency

### To request a change in your lead agency:

- Log in to the eFSAP portal and click on the Form 1 tab.
- Click Amend, and from the drop-down menu select Request Change of Lead Agency
- Provide a cover letter with the request.
- Click Ok. A message box will appear. Click OK.
- Click Submit.

## Withdrawal Requests

### Amendment Withdrawal

#### To withdraw an amendment:

- Log in to the eFSAP portal and scroll down on the Home page to Amendments.
- Click Edit next to the amendment you wish to withdraw.
- Click Withdraw Amendment.
- A message box will appear. Click OK.

The amendment will show as Deactivated.

### Registration Withdrawal

There is not an amendment option to request withdrawal of an entity from FSAP.

#### To withdraw from the Federal Select Agent Program:

- Log in to the eFSAP portal.
- In the General Discussion board on the Home page, provide a statement indicating the entity is requesting to withdraw its registration from the FSAP. The FSAP will reply and direct you through the withdrawal process.
  - The request should state the wish to withdraw from FSAP, the reason for withdrawal, the disposition of agents/toxins, and the decontamination of registered space and equipment.
  - Disposition of select agent/toxin
    - Verification of inventory audit, including verification that the laboratory and all storage units have been searched and confirmation that no select agents or toxins (unless maintaining excluded levels of toxin) remain at the entity.
    - Destroyed/Inactivated – Provide documentation (e.g., autoclave records and statement signed by witness)

- Transferred – Provide the APHIS/CDC Form 2 number(s) associated with the transfer of select agents to another registered entity(ies) (e.g., CEA123456).
- If the entity is withdrawing its registration, but will continue to possess select toxin(s) under the regulated aggregate amount, provide:
  - Statement and/or records showing that the amount of toxin possessed is under the regulated aggregate amount.
  - Statement of how the entity will ensure that each PI’s select toxin inventory remains below the regulated aggregate amount.
- Documentation that effective decontamination appropriate to the use of the suite(s)/room(s) must be provided.
  - If you believe decontamination is not necessary, provide a risk assessment and/or contact your designated FSAP representative.
- Scroll to the bottom of the page to the Upload Center and upload supporting documentation:
  - Select agent/toxin destruction/inactivation records.
  - Facility and equipment decontamination records.
- Remove all strains and serotypes from Section 7B.
  - From the Home page, Click on Form 1.
  - Click Amend, and from the drop-down menu select Section 7B: Add/Remove/Modify Strains and Serotypes.
  - Click Edit for each strain and click Delete.
  - Once all applicable strains have been removed click Save.
- Remove all personnel except the RO and PIs from Section 4.
  - From the Home page, Click on Form 1.
  - Click Amend, and from the drop-down menu select Section 4: Add/Remove/Modify/Reapply Personnel.
  - Click Edit for each individual (excluding the RO and those with a PI role) and select Remove. Provide a reason for removal and click Update. FSAP will remove RO’s and PI’s.
- On approval, FSAP will update the entity’s status to Withdrawn; perform the changes in Sections 3, 7A, and 7C; withdraw the RO and PIs; and request the inactivation of all entity SAMS accounts. The RO will receive an email from the FSAP POC confirming the finalization of the withdrawal request.

### ***Additional Information***

An approved APHIS/CDC Form 2 is required prior to the transfer of select agents and/or toxins to another registered entity.

## **Appendices**

If applicable, enter any additional attachments, tables, or forms here.

## Definitions

**Access** – An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

**Alternate Responsible Official (ARO)** – an individual designated by an entity with the authority and responsibility to ensure compliance with the Select Agent Regulations when acting as the RO.

**Animal and Plant Health Inspection Service (APHIS)** – A multi-faceted Agency with a broad mission area that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities. These efforts support the overall mission of USDA, which is to protect and promote food, agriculture, natural resources and related issues.

**Biosafety Cabinet (BSC)** – The primary means of containment developed for working safely with infectious microorganisms. BSCs are designed to provide personal, environmental and product protection when appropriate practices and procedures are followed.

**Biosafety in Microbiological and Biomedical Laboratories (BMBL)** – A publication by the Centers for Disease Control and Prevention and the National Institutes of Health that serves as a nationally and internationally recognized source for the standards and special microbiological practices, safety equipment, and facilities to work with a variety of infectious agents in various laboratory settings. The BMBL utilizes 4 biosafety levels (BSL 1 through 4) for work with pathogenic microorganisms based upon a risk assessment.

**Biosafety Level (BSL)** – The primary risk criteria used to define the four levels of containment, referred to as biosafety levels 1 through 4, are infectivity, severity of disease, transmissibility, and the nature of the work being conducted. Another important risk factor for agents that cause moderate to severe disease is the origin of the agent, whether indigenous or exotic. Each level of containment describes the microbiological practices, safety equipment, and facility safeguards for the corresponding level of risk associated with handling a particular agent. The basic practices and equipment are appropriate for protocols common to most research and clinical laboratories. The facility safeguards help protect non-laboratory occupants of the building, the public health and the environment.

**Bioterrorism Security Risk Assessment Form (FD-961 Form)** – The FBI's Application for Security Risk Assessment that assists the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS) to perform an electronic records check to determine if an individual who has been identified by a registered entity as having a legitimate need to access select agents or toxins exhibits one of the statutory restrictors which would either prohibit or restrict access.

**Centers for Disease Control and Prevention (CDC)** – One of the major operating components of the Department of Health and Human Services. Its mission is to collaborate to create the expertise, information, and tools that people and communities need to protect their health – through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.

**Chemical Hygiene Plan (CHP)** – Written program stating the policies, procedures and responsibilities that protect workers from the health hazards associated with the hazardous chemicals used in that

particular workplace.

**Containment** – Microbiological practices, safety equipment, and facility safeguards in place to protect laboratorians, the public, and the environment from exposure to infectious microorganisms or toxins that are handled or stored in the laboratory.

**Criminal Justice Information Services (CJIS)** – The Division of the Federal Bureau of Investigation that conducts security risk assessments of all individuals, Responsible Officials, Alternate Responsible Officials and non-governmental entities that request access to select agents and toxins.

**Department of Justice (DOJ) Number or Unique Identifying Number (UIN)** – Number provided to the Responsible Official through eFSAP for each individual listed on the APHIS/CDC Form 1. Each individual that completes the FD-961 Form must include the DOJ/UIN in Section II, item #11 of the form.

**Effluents** – Liquids such as those originating from laboratory sinks, floor drains, and other sources that are discharged into a sewer system. Where required<sup>1</sup>, these effluents are collected and decontaminated before disposal. A heat decontamination system holds contaminated liquid effluents to temperatures, pressures and times sufficient to inactivate biohazardous materials. A chemical decontamination system treats contaminated liquid effluents with an appropriate chemical disinfectant for a prescribed period of time to inactivate biohazardous materials.

**Electronic Federal Select Agent Program (eFSAP)** – secure information system portal used to communicate with FSAP and submit Forms 1, 2, 3, and 4.

**Entity** – Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity. See also “Facility”.

**Facility** – As used in this document, a “facility” is the physical structure where select agents or toxins are used, manipulated, and/or stored. An entity can be composed of multiple facilities, and a facility may contain multiple suites/rooms where work is performed and/or select agents or toxins are stored.

**Federal Select Agent Program (FSAP)** – The joint management of the Federal Select Agent Regulations by the Centers for Disease Control and Prevention’s Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service’s Agriculture Select Agent Services.

**High Efficiency Particulate Air (HEPA) filter** – An air filter composed of a mat of dense fibers arranged in folds, designed according to federal standards to trap at least 99.97% of airborne particles measuring 0.3 microns in diameter. HEPA filters remove bacteria, spores and viruses from the air with an efficiency of 99.97% or greater. HEPA filters and HEPA filter housings must be inspected annually.

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<sup>1</sup> Effluent decontamination is required for maximum containment facilities performing work at BSL4, ABSL4, and BSL3Ag. For propagative work performed at BSL3 with highly transmissible and pathogenic select agents, such as Avian influenza virus, Classical swine fever virus, and African Swine fever virus, liquid effluents must be decontaminated prior to release into a sewer system.

**Institutional Animal Care and Use Committee (IACUC)** – A self-regulating body that, according to U.S. federal law, must be established by institutions that use laboratory animals for research or instructional purposes to oversee and evaluate all aspects of the institution's animal welfare program.

**Institutional Biosafety Committee (IBC)** – An institutional committee created under the National Institutes of Health (NIH) Guidelines to review research involving recombinant DNA. The role of IBCs has evolved over time, and many committees also review other forms of research that entail biohazardous risks as part of their institutionally assigned responsibilities.

***In vitro*** – In glass, as in a test tube. An *in vitro* test is one done in the laboratory, usually involving isolated tissue, organ, or cell preparations.

***In vivo*** – In the living body or organism. An *in vivo* test is one performed on a living organism.

**Laboratorians and Animal Care Staff** – Individuals who perform any of the work listed in a Section 7A & 7C, Objective of Work and/or handle select agent infected animals, plant hosts or select agent contaminated hazardous waste (including animal bedding).

**N95 respirator** – A particulate filtering face piece respirator that filters at least 95% of airborne particles 0.3 microns and larger, but is not resistant to oil, and will not filter out volatile chemicals or other substances for which it is not designed to serve as a protective device. A N95 can be used to provide respiratory protection when working with biological agents. See also “N100”.

**N100 respirator** – A particulate filtering face piece respirator that filters at least 99.97% of airborne particles 0.3 microns and larger, but is not resistant to oil, and will not filter out volatile chemicals or other substances for which it is not designed to serve as a protective device. A N100 can be used to provide respiratory protection when working with biological agents.

**NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)** – A document that provides risk assessment, physical containment, and biological containment provisions relating to genetic elements, recombinant nucleic acids and recombinant organisms of select agents and toxins.

**Occupational Health** – Occupational health is a cross-disciplinary area concerned with protecting the safety, health and welfare of people engaged in work or employment. The goals of occupational health programs include fostering a safe and healthy work environment. They also seek to protect co-workers, family members, employers, customers, and many others who might be affected by the workplace environment. Occupational health may involve interactions among many subject areas, including occupational medicine, occupational hygiene, public health, safety engineering, industrial engineering, chemistry, health physics, ergonomics and occupational health psychology.

**Occupational Safety and Health Administration (OSHA) regulations** – 29 CFR Parts 1910.1200 and 1910.1450 provides specific requirements for handling toxins.

**Owner/Controller** – An individual is considered an Owner/Controller if the individual owns 50 percent or more of the entity, and/or is a holder or owner of 50 percent or more of the entity's voting stock, and/or is an individual who is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.



**Note:** An entity may have more than one Owner/Controller.

**Note:** Government-controlled entities, including public universities, will not have the option to assign an Owner/Controller.

**Personal Protective Equipment (PPE)** – Any protective clothing, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, goggles, or other garment or equipment designed to protect the wearer's body from injury by blunt or sharp impacts, electrical hazards, heat, chemicals, and infection, for job-related occupational safety and health purposes. PPE is used to reduce employee exposure to hazards when engineering and administrative controls are not feasible or effective to reduce these risks to acceptable levels. In these cases, PPE is often used in combination with BSCs and other devices that contain the agents, animals, or materials being handled to reduce risk of exposure or escape. In some situations, in which it is impractical to work in BSCs, personal protective equipment may form the primary barrier between personnel and the infectious materials. Examples include certain animal studies, animal necropsy, agent production activities, and activities relating to maintenance, service, or support of the laboratory facility.

**Point of Contact (POC)** – The individual who is the Federal Select Agent Program representative and point of contact for the entity.

**Powered Air Purifying Respirators (PAPR)** – PAPRs use a motorized air source to filter and clean ambient air before it is delivered to the user, usually through a full head covering (hood). PAPR systems can use many different filters such as HEPA, vapor protection, activated charcoal, or simple particulate filtration. A PAPR with HEPA filtration can be used to provide respiratory protection when working with biological agents.

**Principal Investigator (PI)** – The individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

**Responsible Official (RO)** – The individual designated by an entity with the authority and control to ensure compliance with the [Select Agent Regulations](#) (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331).

**Room** – As used in this document, a “room” is the physical location where select agents or toxins are used, manipulated, or stored. A facility may contain multiple rooms where work is performed and/or select agents/toxins are stored. Also see “Suite”.

**Security Risk Assessment (SRA)** – Electronic records check performed by CJIS to determine if an individual who has been identified by a registered entity as having a legitimate need to access select agents or toxins exhibits one of the statutory restrictors which would either prohibit or restrict access.

**Select Agent and Toxin** – The biological agents and toxins listed in 42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331 that have the potential to pose a severe threat to public health and safety, to animal health or products, or to plant health or products.

**Suite** – As used in this document, a “suite” is a collection of rooms with the same biosafety level (2, 3, or 4) that share a containment envelope or that are grouped together. A facility may have multiple suites where work is performed and/or select agents/toxins are stored. Also see “Room”.

**Support Staff** – Individuals who provide an indirect service in support of the direct work with select

agents or toxins. They do not work with select agents or toxins or select agent infected animals, bedding or plant hosts, but could potentially gain access to select agents/toxins.

**To be Determined (TBD)** – TBD is used in Section 7B if there are defined strains of the agent, but the entity does not have strain information for that isolate (e.g., diagnostic isolates that were not identified to the strain level).

**Tier 1 Select Agents and Toxins** – A subset of select agents and toxins designated in the Select Agent Regulations as “Tier 1” because these agents and toxins present the greatest risk of deliberate misuse with the most significant potential for mass casualties or deleterious effects on the economy, critical infrastructure, or public confidence. This list can be found in the Form 1 instructions for Section 3 and at [SelectAgents.gov](http://SelectAgents.gov).

**Unescorted Visitor** – An individual who also has access approval at a registered entity (the “home” entity) other than yours (the “host entity”) and will temporarily work with, or have access to, select agents or toxins, and receive site-specific training, at your registered entity.