



Electronic Federal Select Agent Portal (eFSAP) January 2019 Updates

















Amendment Types

The eFSAP January 2019 release includes additional Administrative and Technical Amendments.

- Administrative Amendments Information is updated immediately in eFSAP without the Federal Select Agent Program review. These amendments do not require a cover letter.
- Technical Amendments Require review by the Federal Select Agent Program.
 Entity information is automatically updated in eFSAP upon approval. These amendments require a cover letter.





Amendment Types

The eFSAP January 2019 release includes additional amendments:

- □ Request to Change Lead Agency
- □ Section 3 Add a Select Agent or Toxin*
- □ Section 3 Deactivate Select Agent or Toxin*
- □ Section 3 Reactivate Select Agent or Toxin*
- Section 4 Change Responsible Official
- □ **Section 6** Add New Building*
- □ **Section 6** Add New Room or Suite*
- □ **Section 6** Modify Building
- □ **Section 6** Modify Room or Suite
- □ **Section 6** Remove Building*
- □ **Section 6** Remove Room or Suite
- □ **Section 7AC** Add New Work Objective
- □ **Section 7AC** Modify Work Objective
- □ **Section 7AC** − Remove Approved Work Objective



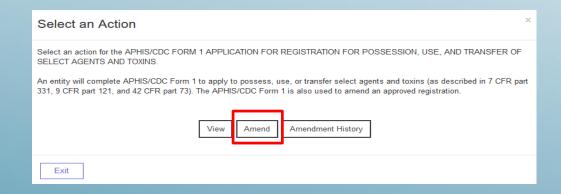


Amendment Submission

To submit an amendment, begin by selecting Form 1 on the home page.



Select Amend.







Amendment Types

Use the dropdown to view amendment types.

Select the type of Amendment you would like to perform

Request Change of Lead Agency

Section 1 - Change Entity Name, Abstract, or Type

Section 1 - Change Entity Physical or Additional Address

Section 2 - Sign Section 2

Section 3 - Add Select Agent or Toxin

Section 3 - Deactivate Select Agent or Toxin

Section 3 - Reactivate Select Agent or Toxin

Section 4 - Add/Remove/Modify/Reactivate Personnel

Section 4 - Change Responsible Official

Section 5A - Modify Entity-Wide Security Assessment and Incident Response

Section 5B - Modify Entity-Wide Biosafety/Biocontainment

Section 5C - Modify Entry Requirements for Federal Select Agent Programs Inspectors

Section 6 - Add New Building

Section 6 - Add New Room or Suite

Section 6 - Modify Building

Section 6 - Modify Room or Suite

Section 6 - Remove Building

Section 6 - Remove Room or Suite

Section 7AC - Add New Work Objective

Section 7AC - Modify Work Objective

Section 7AC - Remove Approved Work Objective

Section 7B - Add/Remove/Modify Strains and Serotypes

Request Registration Renewal

"All other amendments" is no longer an option as all amendments can be completed in eFSAP with the exception of a withdrawal request. To request withdrawal, send FSAP a message in the discussion section on the home page.





Request to Change Lead Agency (Technical Amendment)





Request to Change Lead Agency

Use the dropdown to select "Request Change of Lead Agency". Enter cover letter text and click Ok.







Request to Change Lead Agency

Review and/or edit the amendment cover letter, and click **Submit**.

Amendment	
Amendment Cover Letter	General Discussion
PI Smith will no longer work with CDC agents. 19955 of 20000 characters left	
	Type your message here
	Send Submit
▲ Withdraw Amendment	Save Submit

Once submitted a notification will display on the home page. The change will be reflected when the Federal Select Agent Program (FSAP) reviews and approves the amendment.





Section 3 – Add a Select Agent or Toxin (Administrative Amendment)





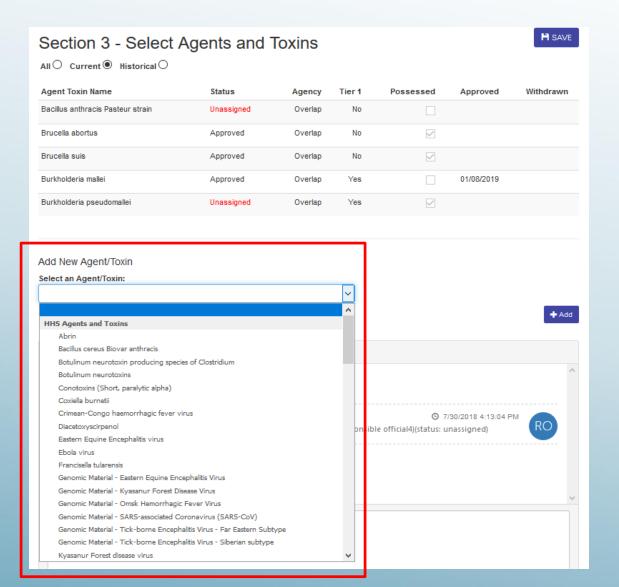
Use the dropdown to select "Section 3 – Add Select Agent or Toxin", and click Ok.

Select the type of An	nendment you would like to perform		
Section 3 - Add Sele	ct Agent or Toxin	~	
		Ok	





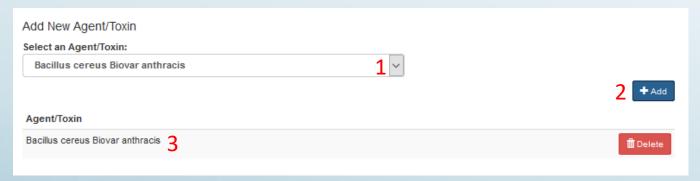
Use the dropdown to select the Agent/Toxin.







Use the dropdown to select the Agent/Toxin, and click **Add**. The Agent/Toxin will display below.



Click **Save** at the top of the page.







A message will display, click **Proceed**.



After clicking proceed, the agent/toxin will display on Section 3 as "unassigned". Submit a Section 7AC amendment to assign the agent/toxin to a work objective. The agent/toxin will be "approved" when the Section 7AC amendment is approved.





Section 3 – Deactivate Select Agent or Toxin (Administrative Amendment)





Use the dropdown to select "Section 3 – Deactivate Select Agent or Toxin", and click Ok.

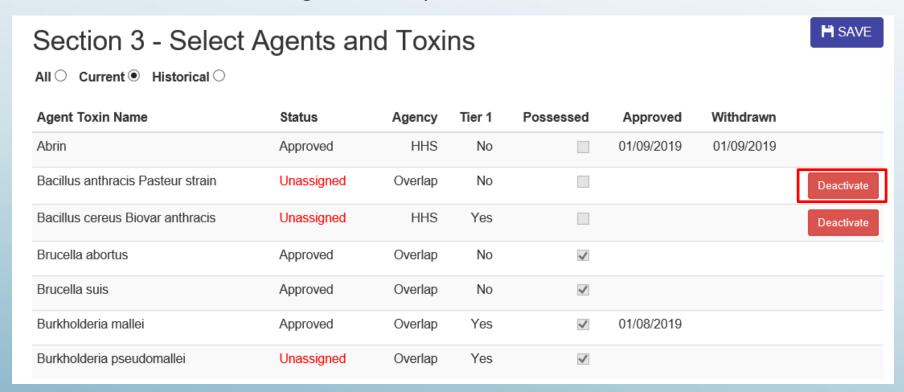


Deactivate – Removing an agent/toxin from the registration. Once deactivated, the agent/toxin will display on the "historical" tab in eFSAP.





Select **Deactivate** for the Agent/Toxin you would like to deactivate.

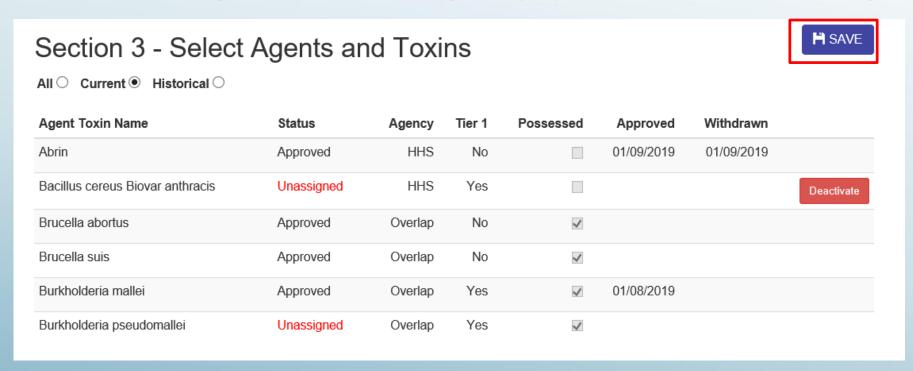


An agent/toxin can only be deactivated if it is not possessed and not a part of an approved work objective.





The deactivated Agent/Toxin will no longer display. Click **Save** to save the change.







Section 3 – Reactivate Select Agent or Toxin (Administrative Amendment)





Use the dropdown to select "Section 3 – Reactivate Select Agent or Toxin", and click Ok.

Select the type of Amendment you would like to perform		
Section 3 - Reactivate Select Agent or Toxin	~	
	Ok	

Reactivate – Adding a previously approved agent/toxin back to the registration. Once added, the agent/toxin will display on the "current" tab in eFSAP.





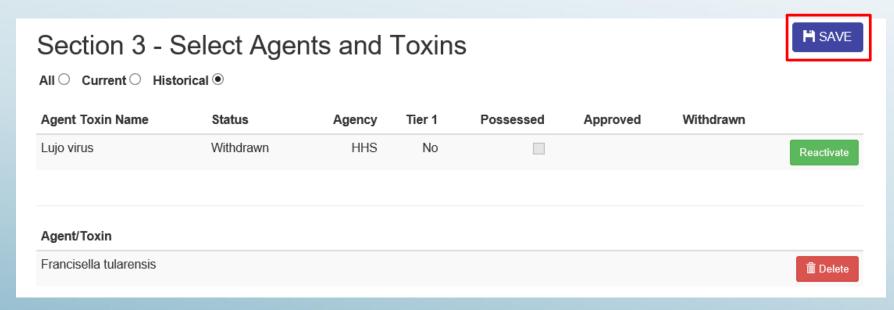
Historical agents/toxins will display. Click **Reactivate** next to the agent/toxin you wish to reactivate.







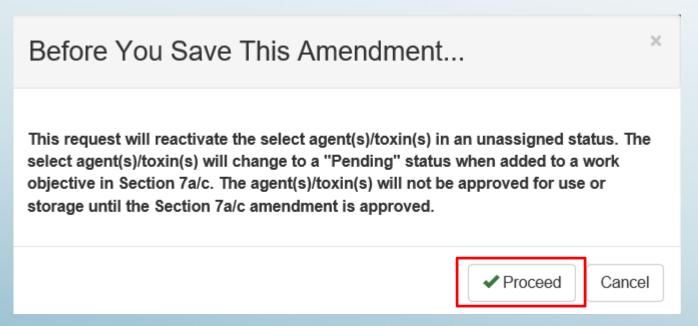
The reactivated agent/toxin will display below. Click **Save** to save the changes.







A message will display, click **Proceed**.



After clicking proceed, the agent/toxin will display on Section 3 as "unassigned". Submit a Section 7AC amendment to assign the agent/toxin to a work objective. The agent/toxin will be "approved" when the Section 7AC amendment is approved.





The reactivated Agent/Toxin will display on the current tab with an unassigned status.

Section 3 - Select Agents and Toxins All © Current Historical ©					I SAVE		
Agent Toxin Name	Status	Agency	Tier 1	Possessed	Approved	Withdrawn	
Abrin	Approved	HHS	No		01/09/2019	01/09/2019	Reactivate
Bacillus anthracis Pasteur strain	Unassigned	Overlap	No				
Bacillus cereus Biovar anthracis	Unassigned	HHS	Yes				
Brucella abortus	Approved	Overlap	No	✓			
Brucella suis	Approved	Overlap	No	✓			
Burkholderia mallei	Approved	Overlap	Yes	✓	01/08/2019		
Burkholderia pseudomallei	Unassigned	Overlap	Yes	✓			
Francisella tularensis	Unassigned	HHS	Yes				



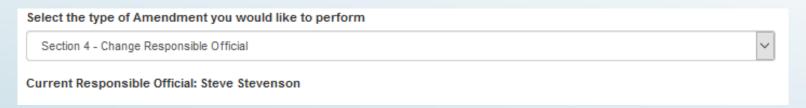


Section 4 – Change Responsible Official (Technical Amendment)

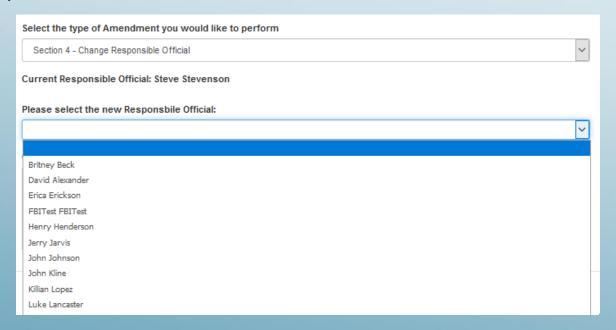




Use the dropdown to select "Section 4 - Change Responsible Official".



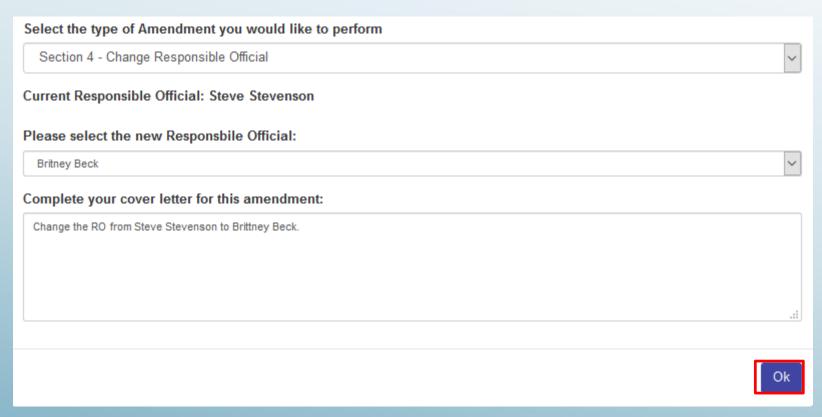
Use the dropdown to select the new Responsible Official (RO). The list shows all unrestricted personnel in Section 4.







Enter cover letter text, and click **Ok**.







Enter information for the new RO.

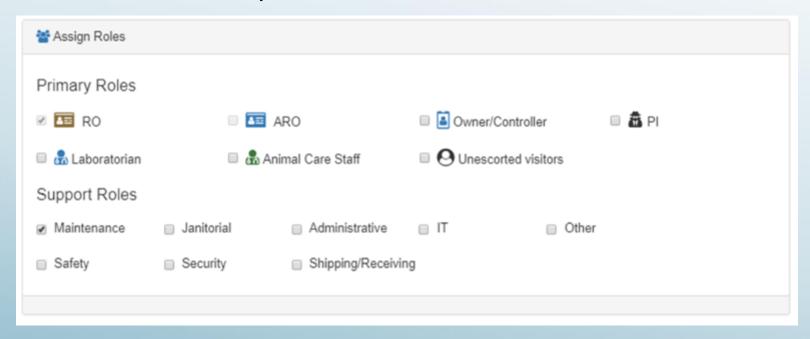
Last Name:	First Name:	
Beck	Britney	
96 of 100 characters left	93 of 100 characters left	
DOJ Number:		
BB070202		
Date of Birth:		
02/28/1982		
Business E-mail Address:	Title:	
e.g. user@website.com		☐ Tier 1 Access ☐ Inventory
Business Telephone #:	Business Fax #:	Emergency Telephone #:
()x	()x	()x
Mailing Address (NOT a post office box):	City:	State: Zip:
		Select an oı 🗸

The following information is required for an RO: business e-mail address, title, business telephone, business fax, emergency telephone, mailing address, city, state and zip code.





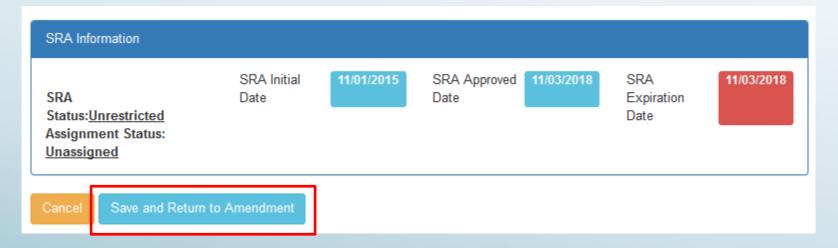
The RO role is automatically selected. Make additional selections if needed.







Click Save and Return to Amendment.







Review and/or edit the amendment cover letter, and click **submit**.

Amendment	
■Amendment Cover Letter	■ General Discussion
Change the RO from Steve Stevenson to Brittney Beck.	î
.di	
19948 of 20000 characters left	Type your message here
	.ii.
	Send
	Make Additional Changes Saw Submit
▲ Withdraw Amendment	wake Additional Changes

A notification will display on the entity home page once the amendment is approved. After the new RO is approved update or remove the former RO.





Section 6 – Add New Building (Administrative Amendment)





Section 6 – Add New Building

Use the dropdown to select "Section 6 – Add New Building", and click Ok.

Select the type of Amendment you would like to perform	
Section 6 - Add New Building	~
	Ok





Section 6 – Add New Building

Enter the building number and complete questions 1-3.

Add Building
Building Number:
Building 3
240 of 250 characters left
1. What security features are present outside of the building(s) where select agents and/or toxins are used or stored? (Check all that apply): Security lighting Bars/security film on windows Exterior intrusion detection system Perimeter fence Roving guards Video surveillance of all access points Vehicle screening Other
None

Click **Add Building** at the bottom of the page.

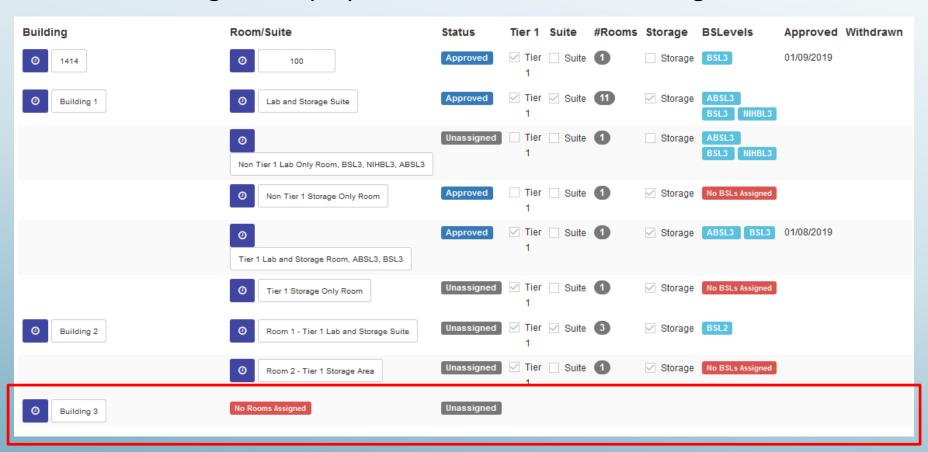






Section 6 – Add New Building

The new building will display in Section 6 with an "unassigned" status.



A notification will display indicating a new building was added.





Section 6 – Add New Room or Suite (Administrative Amendment)





Section 6 – Add New Room or Suite

Use the dropdown to select "Section 6 – Add a New Room or Suite", and click Ok.

Select the type of Amendment you would like to perform				
	Section 6 - Add New Room or Suite	~		
		Ok		

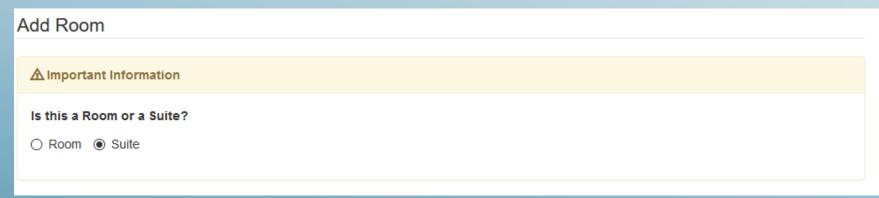




Identify the space as a room or suite. If room is selected, select storage, laboratory or both.



If suite is selected, the additional question will not display.







Use the dropdown to select the building. Enter the room number.

For each registered storage area, laboratory suite or room:

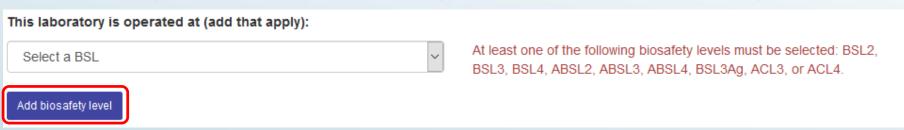
Include a floor plan for the suite or room where select agent and/or toxin is to be used or stored. Floor plan for each suite or room should include as applicable: points of entry and/or egress for personnel, locations of equipment [including but not limited to]: sink, eyewash, fume hood, freezer, refrigerator, floor drains, showers, incubator, centrifuge, animal caging, autoclave, Biological Safety Cabinet (BSC) including type (e.g., Class II, Type A2; Class III)], Heating Ventilation and Air Conditioning (HVAC) supply and exhaust vents, and cage washing area. A separate floor plan specifying airflow may also be requested.

Assigned Building Building 1 Room Number Non Tier 1 Lab Only Room, BSL3, NIHBSL3, ABSL3 204 of 250 characters left

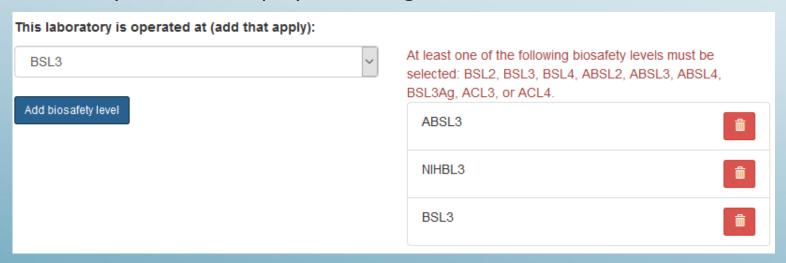




Use the dropdown to select a biosafety level and click Add biosafety level.



The biosafety level will display on the right.







After completing questions 1-16, and selecting **Add Room/Suite** the new room or suite will display in Section 6 as "unassigned".

Room/Suite	Status	Tier 1	Suite	#Rooms	Storage	BSLevels	Approved Withdrawn
0 100	Approved	✓ Tier	Suite	1	Storage	BSL3	01/09/2019
② Lab and Storage Suite	Approved	✓ Tier	✓ Suite	11	Storage	ABSL3 BSL3 NIHBL3	
Non Tier 1 Lab Only Room, BSL3, NIHBL3, ABSL3	Unassigned	Tier 1	Suite	0	Storage	ABSL3 BSL3 NIHBL3	

Submit a Section 7AC amendment to assign the new room or suite to a work objective. The room/suite will become approved when the Section 7AC amendment is approved.





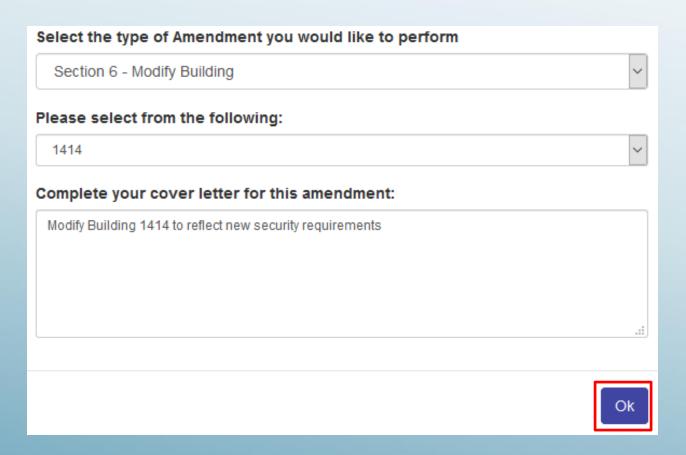
Section 6 – Modify Building (Technical Amendment)





Section 6 - Modify Building

Use the dropdown to select "Section 6 – Modify Building", and click Ok.





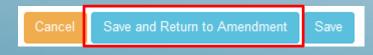


Section 6 – Modify Building

Enter the changes you would like to make.

Building Number:	
1414	
246 of 250 characters left	
1. What security features are present outside of the building(s) where select agents and/or toxins are used or stored? (Check all that apply):	
☑ Security lighting	
☐ Bars/security film on windows	
☐ Exterior intrusion detection system	
☐ Perimeter fence	
☐ Roving guards	
☐ Video surveillance of all access points	
☐ Vehicle screening	

Click Save and Return to Amendment.







Section 6 – Modify Building

Review and/or edit the amendment cover letter, and click **Submit**.

≜ Amendment Cover Letter	General Discussion
Modify Duilding 4444 to reflect new sequety requirements	y General Discussion
Modify Building 1414 to reflect new security requirements 19943 of 20000 characters left	Type your message here
▲ Withdraw Amendment	Make Additional Changes Save Submit

Once submitted a notification will display on the home page.





Section 6 – Modify Room or Suite (Technical Amendment)





Use the dropdown to select "Section 6 - Modify Room or Suite".

Section 6 - Modify Room or Suite	~
Please select from the following:	
Building 1 / Lab and Storage Suite / Long Term Storage Only	~
complete your cover letter for this amendment:	
Add a lab to the suite.	
	Ok

Use the dropdown to select the building. Enter your cover letter and click **ok**.





The "Section 6 - Modify Room or Suite" amendment allows you to add or remove biosafety levels.

This laboratory is operated at (add that apply):					
Select a BSL	ABSL3	ì			
Add a biosafety level	BSL3				
	NIHBL3				

To add a biosafety level (BSL), select the BSL using the dropdown and click **Add a biosafety level**.

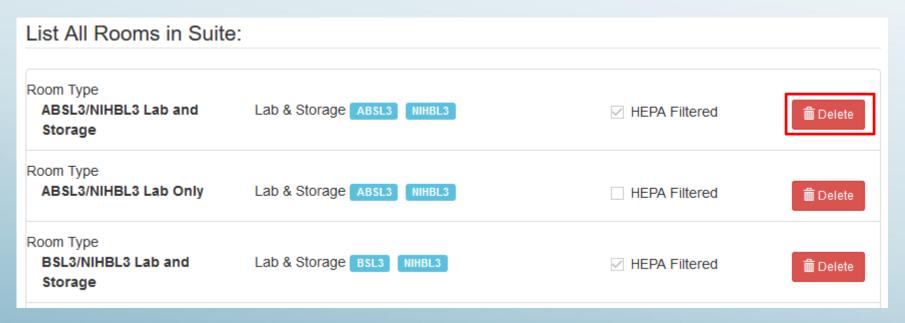
To remove a BSL, click the trash bin next to the BSL you would like to remove.

Click **Save and Return to Amendment**.





Rooms can be deleted from a suite using the "Section 6 - Modify Room or Suite" amendment.



Click **Delete** next to the room you would like to remove.

Click **Save and Return to Amendment**.





The "Section 6 - Modify Room or Suite" amendment allows you edit room/suite information.

1. Will this suite/room be used for Tier 1 select agent and/or toxin?				
● Yes ○ No				
2. Access to suite/room where select agent and/or toxin is stored or used is controlled by (check all that apply):				
☐ Lock and key				
☐ Card access system				
☑ Card access system with PIN				
☐ Biometric System				
☐ Other				
3. Access to the storage unit(s) where select agent and/or toxin are housed is controlled by (check all that apply):				
\square No access control on the storage unit(s)				
☐ Lock and Key				
☐ Card access system				
☑ Card access system with PIN				
☐ Biometric System				

Enter the changes you would like to make, and click Save and Return to Amendment.

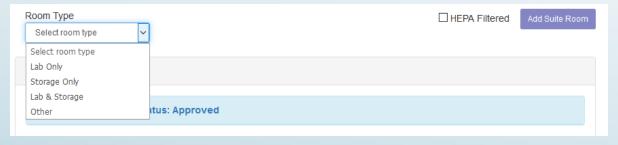




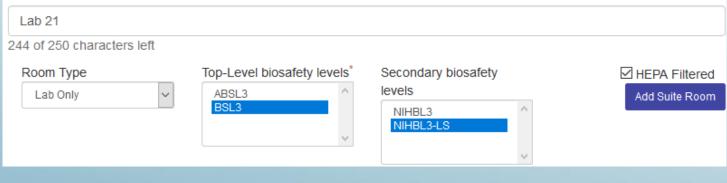
Section 6 – Modify Room or Suite (Add a Room to a Suite)

The "Section 6 - Modify Room or Suite" amendment allows you to add a room to a suite.

1. To begin, use the dropdown to select a room type.



2. Enter a room name, use the dropdown to make selections and click "Add Suite Room".



3. The added room will display.





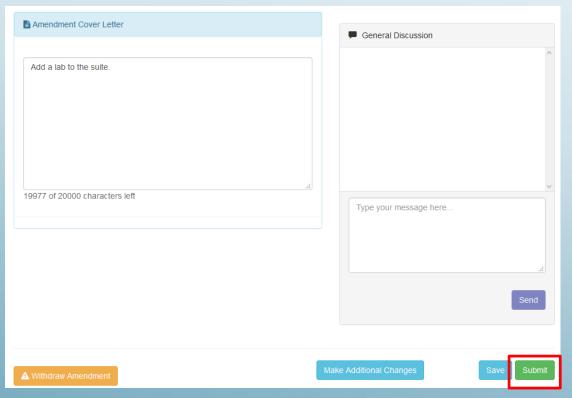


Section 6 – Modify Room or Suite (Add a Room to a Suite)

Click Save and Return to Amendment.



Review and/or edit the amendment cover letter, and click **Submit**.



Once submitted a notification will display on the home page.





Section 6 –Remove Building (Administrative Amendment)





Section 6 – Remove Building

Use the dropdown to select "Section 6 –Remove Building" and click Ok.

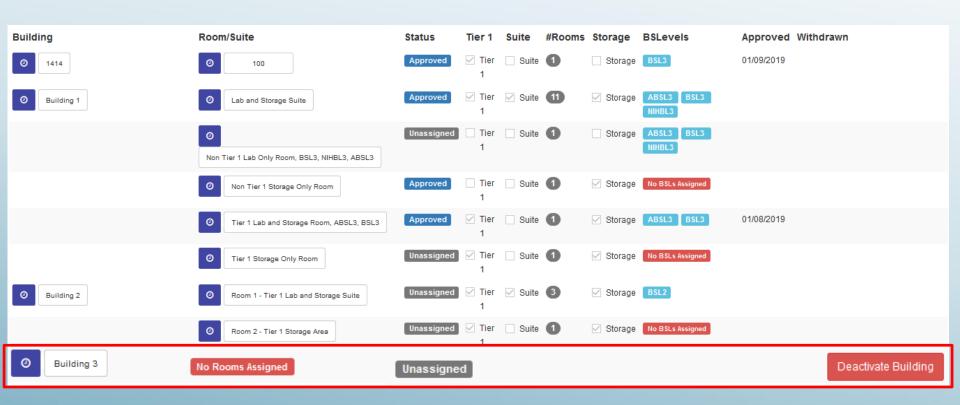






Section 6 –Remove Building

Select **Deactivate Building** next to the building you would like to remove.



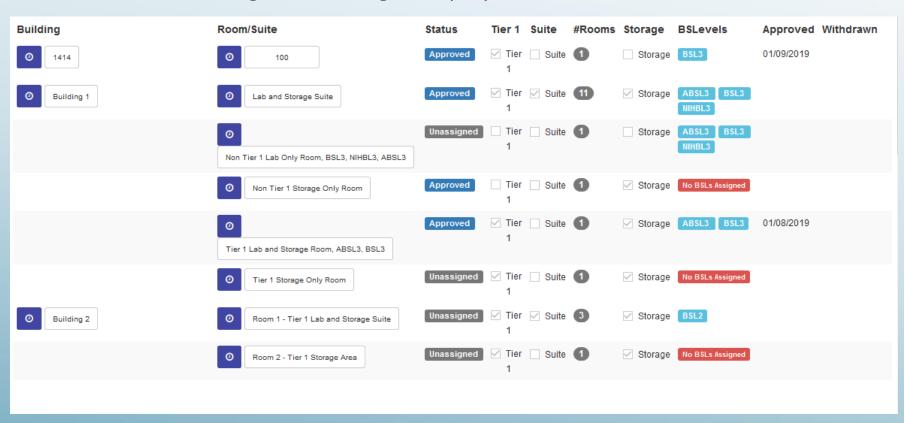
The deactivate button will only display for buildings that have no room/suites assigned.





Section 6 -Remove Building

The deactivated building will no longer display.







Section 6 – Remove Room or Suite (Technical Amendment)





Use the dropdown to select "Section 6 – Remove Room or Suite".

Select the type of Amendment you would like to perform	
Section 6 - Remove Room or Suite	~
Complete your cover letter for this amendment:	
Remove the Non Tier 1 Lab from Building 1	
	***)
	Ok

Complete your cover letter and click **Ok**.





Click **Remove** next to the room or suite you would like to remove.

0	Non Tier 1 Lab Only Room, BSL3, NIHBL3, ABSL3	Unassigned	Tier1	Suite	1	Storage	ABSL3;BSL3;NIHBL3	⊗ Remove
Ø	Tier 1 Storage Only Room	Unassigned	☑ Tier1	Suite	1	✓ Storage	No BSLs Assigned	⊗ Remove
0	Room 1 - Tier 1 Lab and Storage Suite	Unassigned	✓ Tier1	✓ Suite	3	✓ Storage	BSL2	⊗ Remove
②	Room 2 - Tier 1 Storage Area	Unassigned	✓ Tier1	Suite	1	✓ Storage	No BSLs Assigned	⊗ Remove

The list only shows rooms/suites with no assigned work.





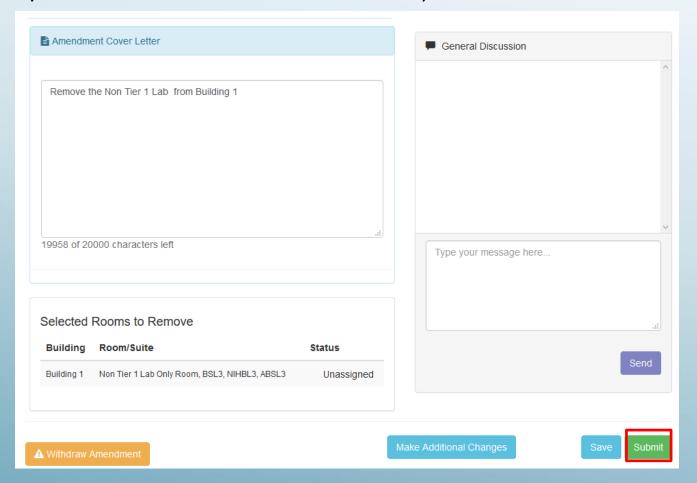
Select Remove Selected Room.







Review and/or edit the amendment cover letter, and click **Submit**.



Once submitted a notification will display on the home page.



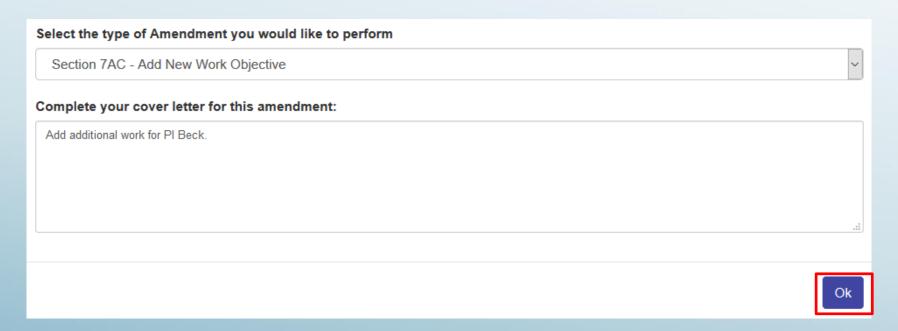


Section 7AC – Add New Work Objective (Technical Amendment)





Use the dropdown to select "Section 7AC – Add New Work Objective".



Complete your cover letter and click **Ok**.





Select Add Work, Add Work and Storage or Add Storage Only.

Add Work	Add Work and Storage	Add Storage Only
Designate BioSafetyLevel 1	Designate Additional Biosafety Levels (if applicab	ole)
¥		
		V
Designate Select Agent(s) and Toxin(s)		Designate Principal Investigator
	^ 	^
Designate Building and Room		
	^ ~	^
		Cancel Reset Proceed

Additional fields will become available based on your selection.





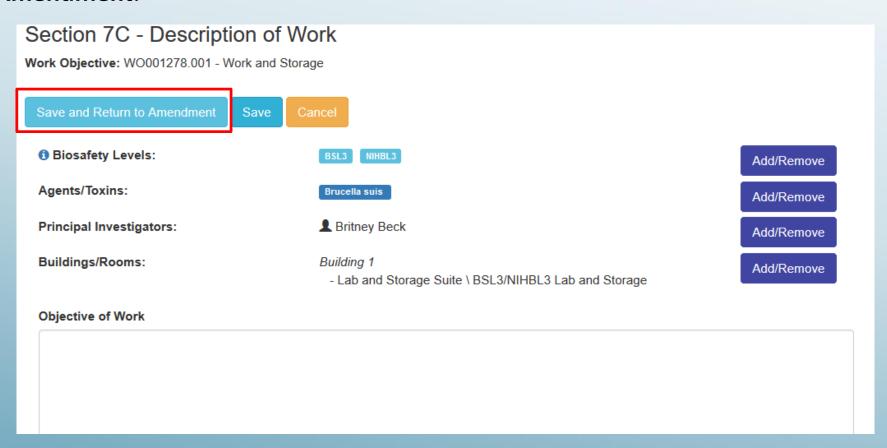
Select **Add Work and Storage**, use the dropdown to designate a biosafety Level, and additional biosafety levels if applicable. Designate the Select Agent and Toxin.

Add Work	Add Work and Storag	e Add Stora	ige Only
Designate BioSafetyLevel 1	Designate Additional Biosafety Lo	evels (if applicable)	
BSL3 ~	NIHBL3-LS		^
Designate Select Agent(s) and Toxin(s)		Designate Principal Inve	ectigator
Non Tier 1 Bacillus anthracis Pasteur strain Brucella abortus Brucella suis Tier 1 Bacillus cereus Biovar anthracis Burkholderia mallei Burkholderia pseudomallei Francisella tularensis		Non Tier 1 Britney Beck David Howard Tier 1 James Johnson Killian Lopez Sam Samuelson	A
Designate Building and Room 1414 Building 1 Building 2	La	b and Storage Suite / BSL3/NIHBL3 Lab bb and Storage Suite / BSL3/NIHBL3 Lab bb and Storage Suite / BSL3/NIHBL3 Lab cr 1 Lab and Storage Room, ABSL3, BSL	Only only (2)
		Cancel	Reset





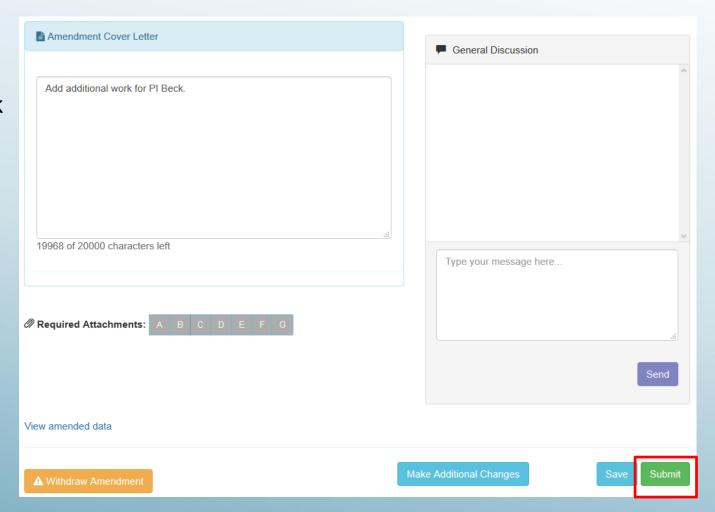
Enter an objective of work and respond to the questions. Click **Save and Return to Amendment**.







Review and/or edit the amendment cover letter, and click **Submit**.



Once submitted a notification will display on the home page.



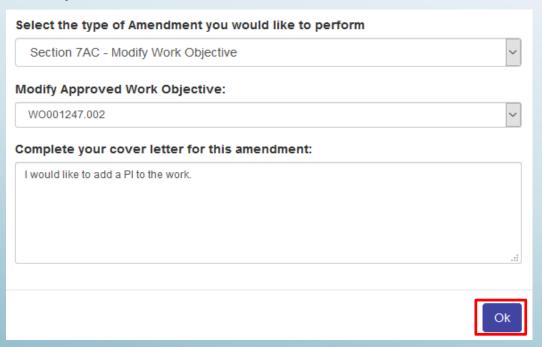


Section 7AC – Modify Work Objective (Technical Amendment)





Use the dropdown to select "Section 7AC – Modify Work Objective". Select the work objective, enter your cover letter and click Ok.



The work objective number can be found in Section 7AC.

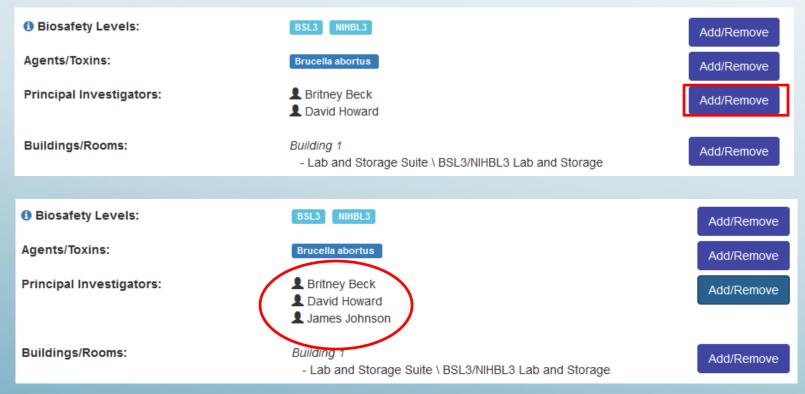
Work Objective: WO001247.002 Status: Approved Date Approved: 01/09/2019

Principal Work Only
Investigators: The Beck Lab studies how inner-membrane proteins affect LPS structure, and wI inner-membrane proteins attenuates Brucella abortus in animal models of infections.





You will be taken directly to the selected work to edit. In the example below, James Johnson was added as a Pl.



The Section 7AC – Modify Work Objective allows you to modify the secondary biosafety level(s), agents/toxins, principal investigator and buildings/rooms.





You can also edit the objective and questions related to the work.

	Objective of Work
Enter edits in	The Beck Lab studies how inner-membrane proteins affect LPS structure, and whether deletion of certain inner-membrane proteins attenuates Brucella abortus in animal models of infection and whether these animals are protected against later challenge with wild-type. In our non-Tier 1 BSL-3 lab, only in vitro work is performed. Methods include culture in broth and on agar plates. Centrifugation of cultures and re-suspension/concentration of cell mass. Standard genetic techniques such as electroporation, plating on selective media, colony isolation.
the text box to	re-suspensioniconcentration of cell mass. Standard genetic techniques such as electroporation, planing on selective media, colony isolation.
reflect desired	
change(s).	
	it.
	4449 of 5000 characters left

3. Provide an estimate of the maximum quantity of functional toxin held by the PI at any one time (e.g., 500 mg, 100 ml x 100 ug/ul).

Click or type
information
directly to edit
responses.

Abrin

2
249 of 250 characters left

4. Equipment that may produce infectious agent or toxin aerosols (e.g., ultracentrifuge, flow cytometer, cell sorter, plate washer) is contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory.

Yes
No

5. Inventory record is reconciled:

Annually

Other (specify frequency)

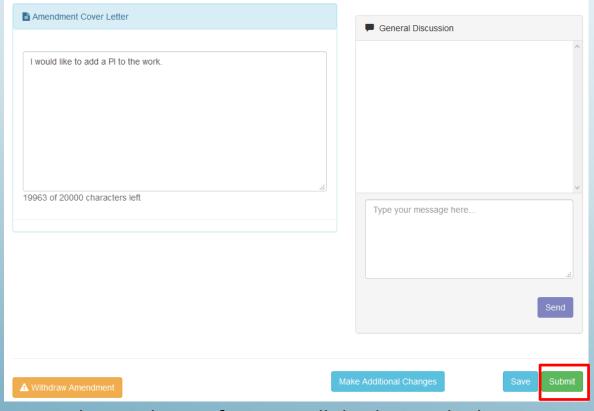




Enter changes, and click Save and Return to Amendment.



Review and/or edit the amendment cover letter, and click **Submit**.



Once submitted a notification will display on the home page.





Section 7AC - Remove Approved Work Objective (Technical Amendment)





Use the dropdown to select "Section 7AC – Remove Approved Work Objective". Select the work objective, enter your cover letter and click Ok.

Select the type of Amendment you would like to perform	
Section 7AC - Remove Approved Work Objective	~
Complete your cover letter for this amendment:	
Remove work PI Lopez and PI Howard are conducting with Brucella abortus.	
	.::
	Ok





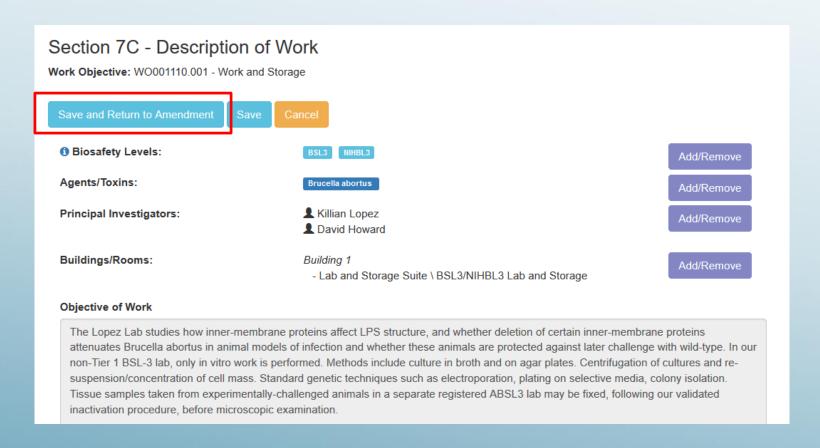
Select **Remove** to remove the work.

Work Objective: WO	001110.001	Status: Approved	Date Approved:		Active Work ✓
Principal	Work and Sto	orage			View
Investigators: Killian Lopez David Howard	The Lopez Lab studies how inner-membrane proteins affect LPS structure, and whether deletion of certain inner-membrane proteins attenuates Brucella abortus in animal models of infection and whether these animals are protected against later challenge with wild-type. In our non-Tier 1 BSL-3 lab, only in vitro work is performed. Methods include culture in broth and on agar plates. Centrifugation of cultures and resuspension/concentration of cell mass. Standard genetic techniques such as electroporation, plating on selective media, colony isolation. Tissue samples taken from experimentally-challenged animals in a separate registered ABSL3 lab may be fixed, following our validated inactivation procedure, before microscopic examination.				
Agents/Toxins:		Ø	Required Attachments: A	B C D E F G	
Brucella abortus		В	uildings/Rooms: uilding 1 - Lab and Storage Suite \ BSL3/ torage	NIHBL3 Lab and E	Giosafety Levels: 3SL3 NIHBL3





Click Save and Return to Amendment.







Review and/or edit the amendment cover letter, and click **Submit**.

Amendment	
Amendment Cover Letter	■ General Discussion
Remove work PI Lopez and PI Howard are conducting with Brucella abortus.	
19928 of 20000 characters left	Type your message here
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Once submitted a notification will display on the home page.





Additional Assistance

- ☐ The eFSAP Resource Center has resources to assist with the use of eFSAP.
- □ For technical assistance with eFSAP, or for assistance with the Secure Asset Management System (SAMS), please submit a help request ticket at <u>eFSAP</u>

 <u>Customer Support Request Form</u>, email <u>eFSAPSupport@cdc.gov</u>, or call 1 (877) 232-3322.
- □ For all other inquiries regarding your entity's registration, please contact your designated FSAP point of contact (POC).