

Adding New Work Areas (New Spaces)

2022 Responsible Official (RO) Webinar Series

May 25, 2022



Session Outline

- What is “New Space”?
- Amendments and Supporting Documents
- New Space Inspections
- Special Scenarios



What is “New Space”?



Defining “New Space”

- **New space** – laboratory (lab) or storage areas not currently listed on the entity’s registration that the entity wishes to add to the registration for biological select agent or toxin (BSAT) work or storage

Buildings



Suites/Labs/Rooms

Labs/Rooms within Suites



Examples of New Space

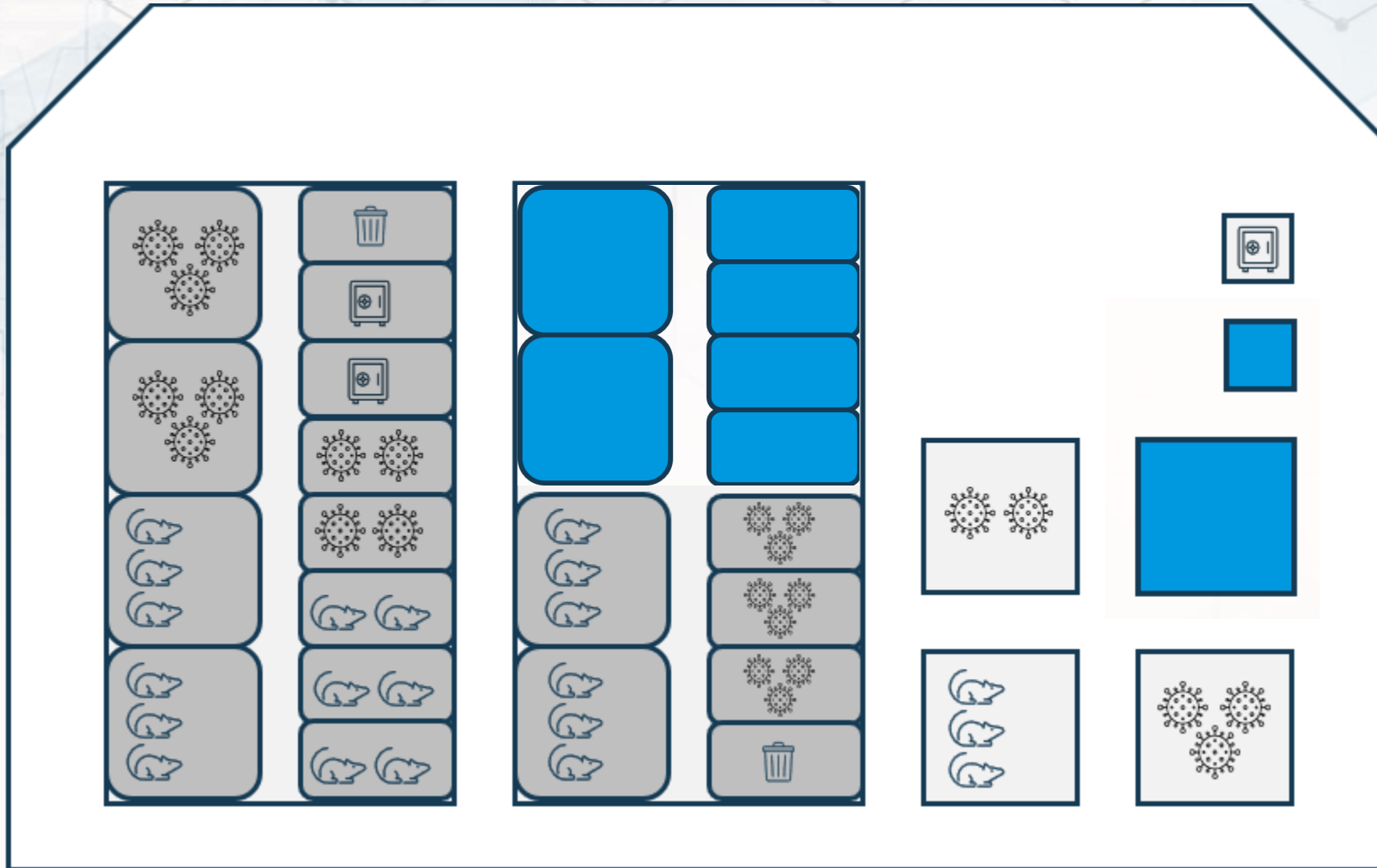
- Entity relocating – involves registering new building and deregistering old building
- Entity expanding –
 - Adding building to registration
 - Adding suite/lab to registration
 - Adding lab within suite to registration



Amendments and Supporting Documents



End Goal of Amendment Process



Grey spaces are registered with Federal Select Agent Program; Blue space is unregistered.

APHIS/CDC Form 1 Focus Points for New Space

Section 6

- Describes the building, suite, and room physical information
- Defines the storage or lab status of rooms
- Defines the biosafety levels of labs

Section 7

- Ties work objectives to specific rooms
- Defines the way rooms and labs are being used




Amendment Process – New Building



- Section 6 – Add New Building
 - Name building
 - Answer questions about building's security and access

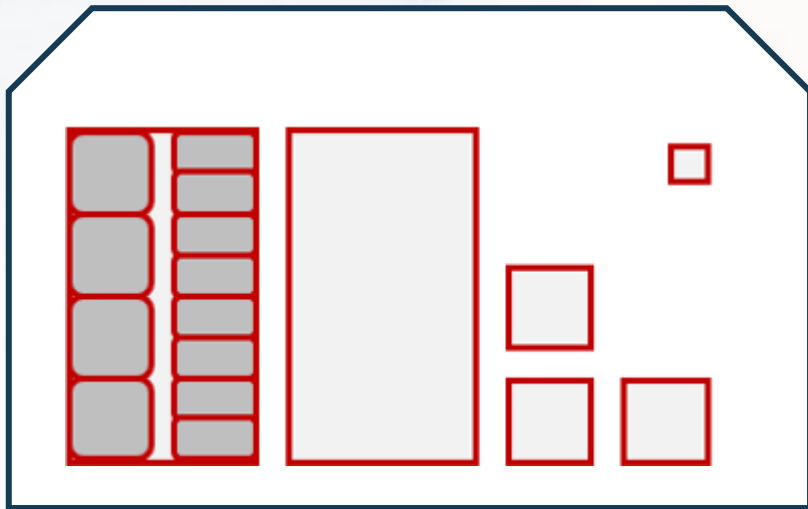


Building	Room/Suite	Status
 Regional Biocontainment Laboratory	No Rooms Assigned	Unassigned

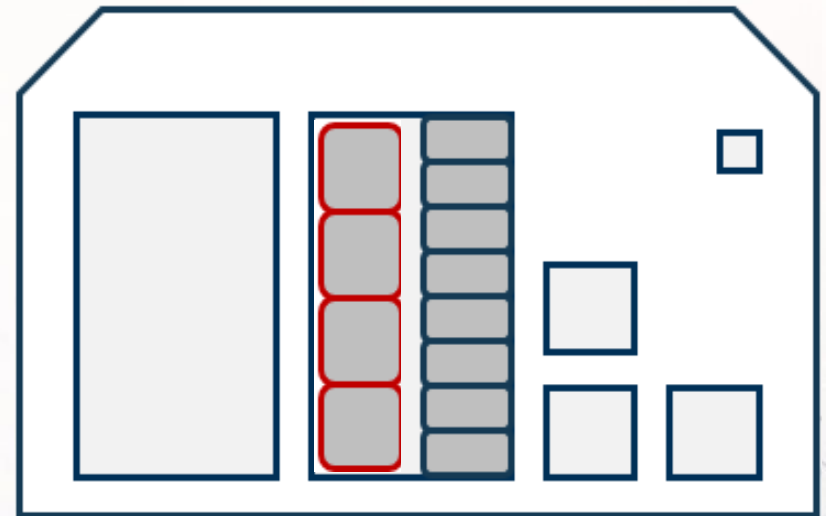


Amendment Process – New Suite/Room Options

- Section 6 - Add New Room or Suite. Select when:
 - Room or suite is not on registration, **and**
 - For rooms, the room is standalone



- Section 6 – Modify Room or Suite. Select when:
 - Suite is already on registration **and**
 - New room is within suite



Outlined in red is unregistered space. Outlined in blue is registered space.

Amendment Process – Section 6 - Add New Room or Suite

Section 6 A/B - Buildings and Suites/Rooms

Add Room

⚠ Important Information

Is this a Room or a Suite?

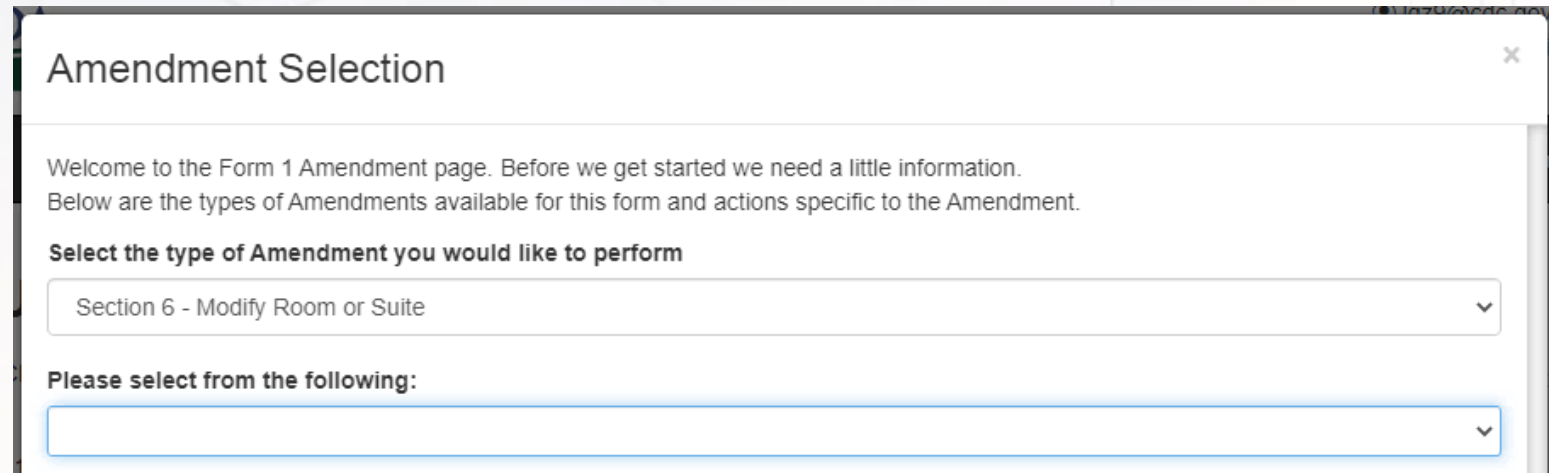
Room Suite

Assigned Building

- Choose the building housing new room or suite
- Define as room or suite
 - For suites, name all rooms within suite
- Define as lab, storage, or both
 - For labs, identify biosafety levels (BSLs)

Amendment Process – Section 6 – Modify Room or Suite

- Choose which existing room or suite to modify
- Modify as needed:
 - Room/suite name
 - Rooms within suite
 - Biosafety levels within suite
 - Questions about suite physical information



The screenshot shows a web form titled "Amendment Selection" with a close button (X) in the top right corner. The form contains the following text and elements:

Welcome to the Form 1 Amendment page. Before we get started we need a little information. Below are the types of Amendments available for this form and actions specific to the Amendment.

Select the type of Amendment you would like to perform

Section 6 - Modify Room or Suite

Please select from the following:

[Empty dropdown menu]

Amendment Process – New Suite/Room Tip #1

Is this a storage area, laboratory, or both?

Storage Laboratory Both

- If a lab area *may* be used to store BSAT, choose “Both”
- This selection is not directly amendable after the suite/room appears on the Section 6



Amendment Process – New Suite/Room Continued

- Section 6 – Add New Room or Suite
 - For rooms within suites, define biosafety levels, storage, or other
 - Answer questions about security of agents and biocontainment for room or suite

List All Rooms in Suite:

110	Lab & Storage	BSL2	NHBL2	<input checked="" type="checkbox"/> HEPA Filtered
120	Lab & Storage	ABSL2	NHBL2	<input checked="" type="checkbox"/> HEPA Filtered
130	Storage Only			<input checked="" type="checkbox"/> HEPA Filtered
140	Other - Equipment			<input checked="" type="checkbox"/> HEPA Filtered
150	Lab & Storage	BSL3	NHBL3	<input checked="" type="checkbox"/> HEPA Filtered
160	Lab & Storage	BSL3	NHBL3	<input checked="" type="checkbox"/> HEPA Filtered
170	Lab & Storage	BSL3	NHBL3	<input checked="" type="checkbox"/> HEPA Filtered
180	Lab & Storage	ABSL3	NHBL3	<input checked="" type="checkbox"/> HEPA Filtered
190	Lab & Storage	ABSL3	NHBL3	<input checked="" type="checkbox"/> HEPA Filtered



Amendment Process – New Suite/Room Tip #2

List All Rooms in Suite:

501

247 of 250 characters left

Room Type

Select room type

Select room type

Lab Only

Storage Only

1. Lab & Storage

Other

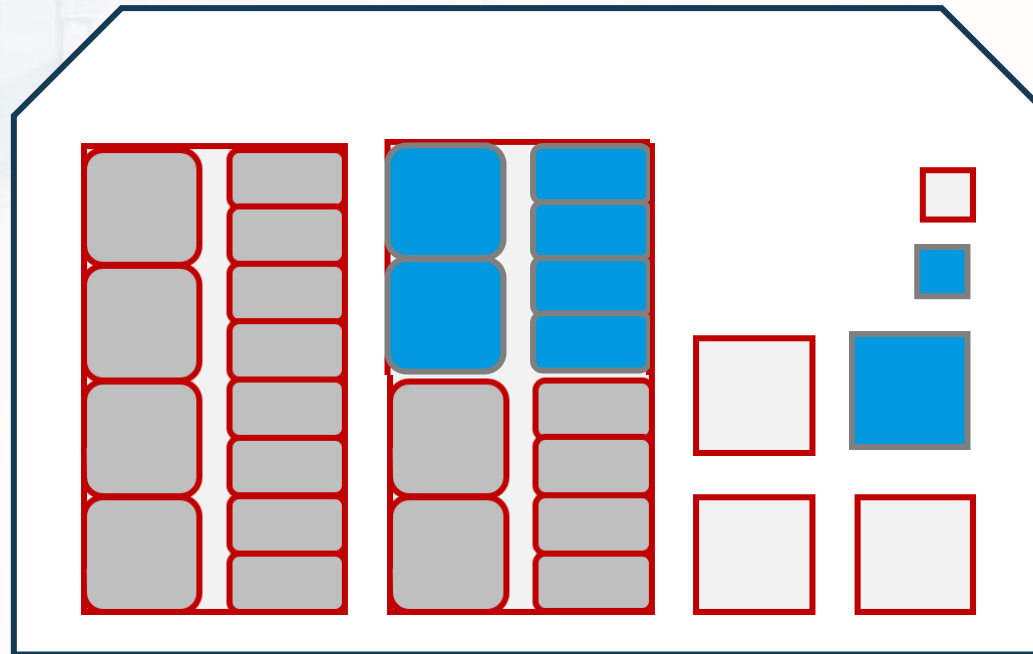
YES NO

- When to choose lab only:
 - No intent to store agent, toxin, or agent-infected animals
 - Space has short-term use (e.g., centrifuge room, procedure room)
- Selecting “Other” initiates additional selection options



Amendment Process – New Suite/Room Results

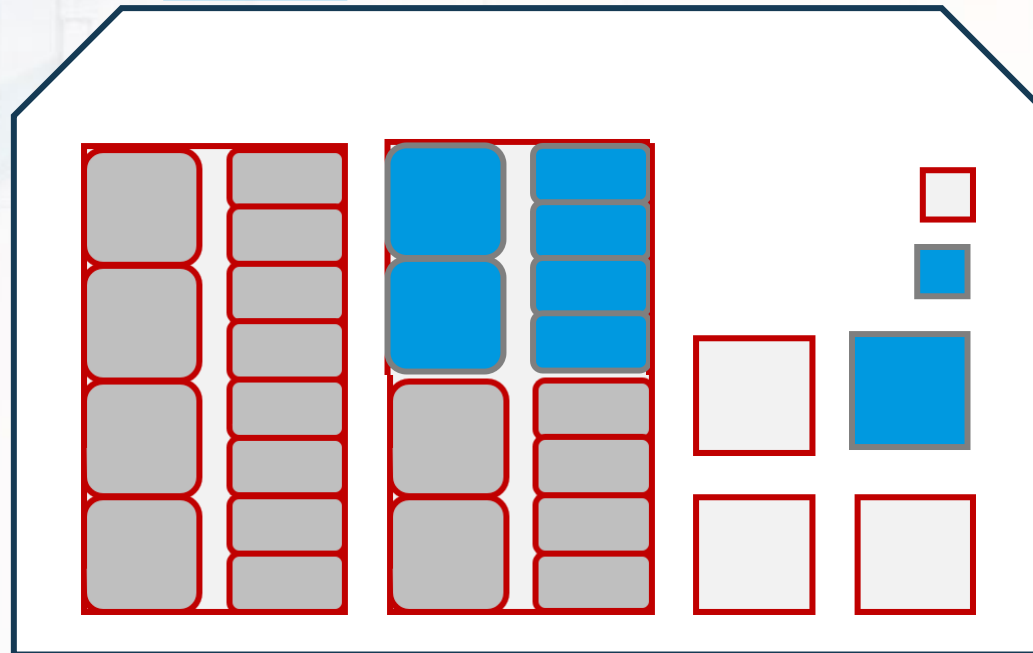
Building	Room/Suite	Status	Tier 1	Suite	#Rooms	Storage	BSLevels	Approved	Withdrawn
Regional Biocontainment Laboratory	100	Unassigned	<input checked="" type="checkbox"/> Tier 1	<input checked="" type="checkbox"/> Suite	9	<input checked="" type="checkbox"/> Storage	ABSL2 ABSL3 BSL2 BSL3		
	156	Unassigned	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input checked="" type="checkbox"/> Storage	No BSLs Assigned		
	201	Unassigned	<input type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input checked="" type="checkbox"/> Storage	BSL3		



Outlined in red is unregistered space. Outlined in blue in registered space.

Amendment Process – New Suite/Room Results Continued

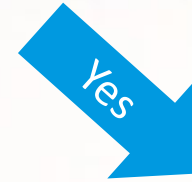
Building	Room/Suite	Status	Tier 1	Suite	#Rooms	Storage	BSLevels	Approved	Withdrawn
Regional Biocontainment Laboratory	100	Unassigned	<input checked="" type="checkbox"/> Tier 1	<input checked="" type="checkbox"/> Suite	9	<input checked="" type="checkbox"/> Storage	ABSL2 ABSL3 BSL2 BSL3		
	156	Unassigned	<input checked="" type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input checked="" type="checkbox"/> Storage	No BSLs Assigned		
	201	Unassigned	<input type="checkbox"/> Tier 1	<input type="checkbox"/> Suite	1	<input checked="" type="checkbox"/> Storage	BSL3		



Outlined in red is unregistered space. Outlined in blue in registered space.

Amendment Process – Work Objective Assignments

Does a current work objective capture the work and/or storage planned in the new space?
Considerations: BSL, Principal Investigator, agents, etc.



Section 7AC - Add New
Work Objective

Section 7AC – Modify
Work Objective and/or
Attachments



Amendment Process –Tying Work Objectives to Spaces

- Section 7 work and storage selections must coordinate with the lab and storage choices made in Section 6
- Biosafety levels
 - 2/3/4 must be separate, even if present in the same suite
 - Animal BSLs (ABSLs) must be separate from BSLs

		Section 6		
		Lab	Storage	Lab and Storage
Section 7	Work Only	✓	--	✓
	Storage Only	--	✓	✓
	Work and Storage	--	--	✓



Amendment Process – Work Objective Builder

Section 7C - Add Work/Storage

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

Add Work

Add Work and Storage

Add Storage Only

Designate BioSafetyLevel ⓘ

Designate Additional Biosafety Levels (if applicable)

Designate Select Agent(s) and Toxin(s)

Designate Principal Investigator

Designate Building and Room

Cancel

Reset

Proceed

Amendment Process – Add Work and/or Storage

Section 7C - Add Work/Storage

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

Add Work

Add Work and Storage

Add Storage Only

Designate Selected Agent(s) and Toxic(s)

Designate Principal Investigator

- First selection is whether the work objective will be for work only, work and storage, or storage only.

Designate Building and Room

Cancel Reset Proceed

Amendment Process – Designate Biosafety Level

Section 7C - Add Work/Storage

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

Add Work

Add Work and Storage

Add Storage Only

Designate Biosafety Level

Designate Additional Biosafety Levels (If applicable)

Designate Select Agent(s) and Toxin(s)

Designate Principal Investigator

- Selecting “Add Work” or “Add Work and Storage,” opens options under “Designate Biosafety Level.”
- These options come from all the buildings, rooms, and suites that are currently listed on our Section 6. Additional biosafety levels appear if applicable.

Cancel

Reset

Proceed

Amendment Process – Designate Select Agents and Toxins

Section 7C - Add Work/Storage

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

Add Work

Add Work and Storage

Add Storage Only

Designate BioSafetyLevel ⓘ

Designate Additional Biosafe

Designate Select Agent(s) and Toxin(s)

Designate Building and Room

- Next selection is which select agents and toxins are needed for this work objective.
- Options are based on the select agents and toxins listed on the entity's Section 3.
- The list is divided into non-Tier 1 Agents and Tier 1 Agents.

Cancel

Reset

Proceed

Amendment Process – Designate Principal Investigator

Section 7C - Add Work/Storage

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

Add Work

Add Work and Storage

Add Storage Only

- Next selection is the Principal Investigator (PI).
- PI names come from Section 4.
- Please note that if only Tier 1 agents selected in the previous box, the only PI names we will see listed are those that have the “Tier 1” box checked on their Section 4 information.

Designate Principal Investigator

Cancel

Reset

Proceed

Amendment Process – Designate Building and Room

Section 7C - Add Work/Storage

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

Add Work

Add Work and Storage

Add Storage Only

Designate BioSafetyLevel ⓘ

Designate Additional Biosafety Levels (if applicable)

Designate Select Agent(s) and Toxin(s)

Designate Building and Room

- Final selections are the building and room for the work objective.
- This information comes from the building and suite/room information on Section 6.
- This list may also be limited, depending on first selection of “work only” or “storage only” at the top of this page.

Amendment Process – Work Objective Builder Review

Section 7C - Add Work/Storage

FORM APPROVED
OMB: 0920-0576
EXP DATE: 01/31/2024

Add Work

Add Work and Storage

Add Storage Only

Designate BioSafetyLevel ⓘ

Designate Additional Biosafety Levels (if applicable)

Designate Select Agent(s) and Toxin(s)

Designate Principal Investigator

Designate Building and Room

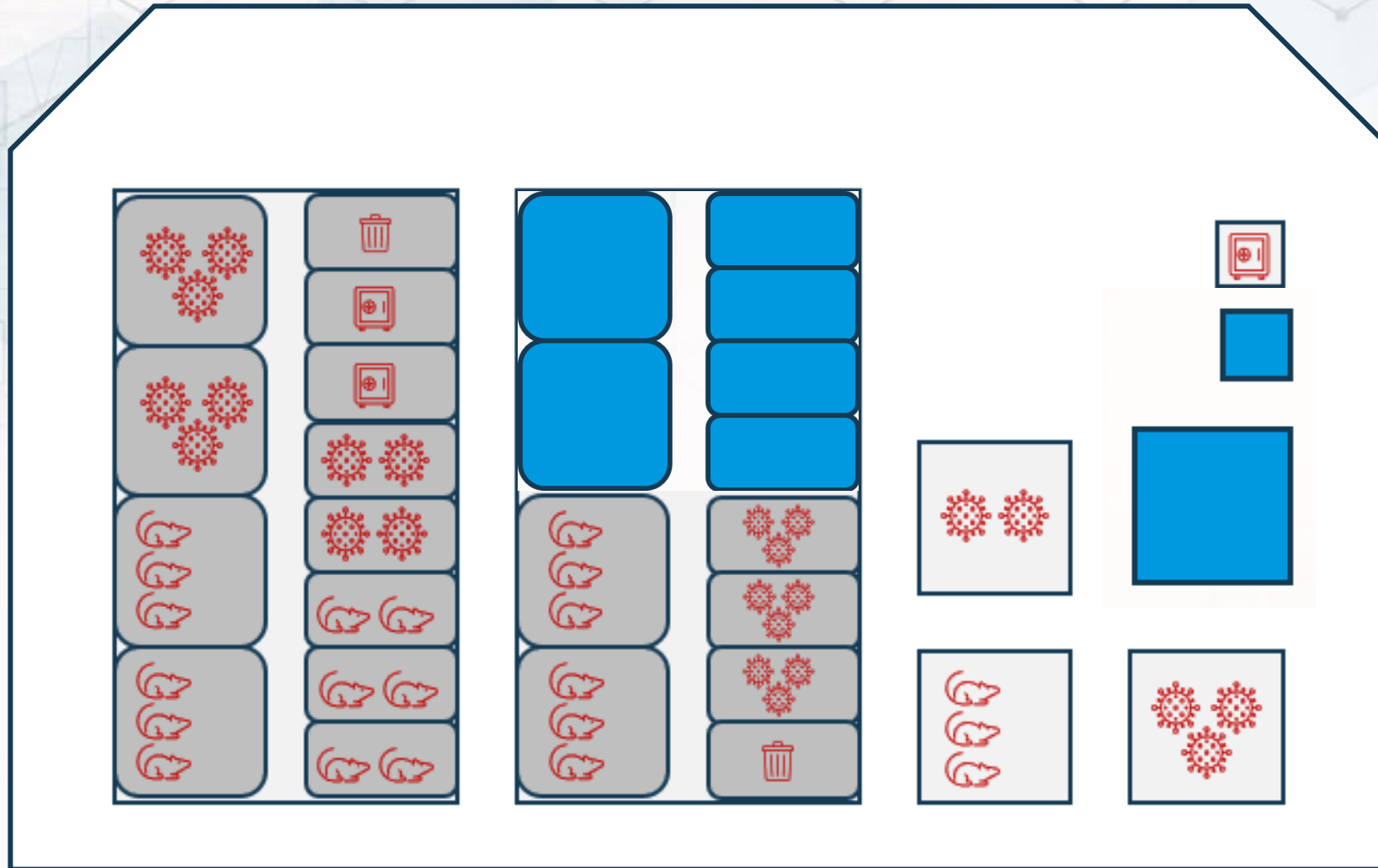
Cancel

Reset

Proceed

Fields read information from Form 1 Sections 3, 4, and 6

Amendment Process – Pending New Space Inspection

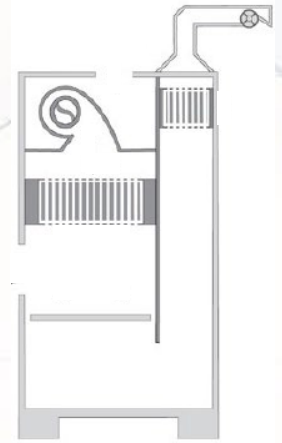


Icons in red symbolize pending work objectives. Rooms in blue symbolize unregistered space.

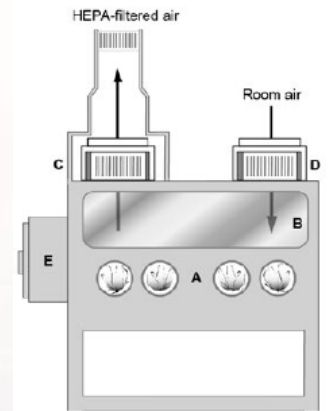
Documents to Support New Space Amendments (1-2)



- Updated floor plans, including notations of:
 - Containment boundaries
 - Security barriers (as applicable)
- (Re-)Commissioning report
 - BSL-3s and above – HVAC failure testing. See FSAP Policy Statement, *BSL-3/ABSL-3 Verification*, for more information.
 - Confirmation decontamination systems are present and operating as designed
 - Certifications of containment equipment in new space



BMBL, 6th Ed.



Documents to Support New Space Amendments (2-2)



- New or updated biosafety, incident response, and security plans and/or associated standard operation procedures (SOPs)
 - Common findings during new space inspections are failures to update plans to account for new space

Personal Protective Equipment (PPE)

PPE Donning and Doffing

Tier 1 Security Barriers

BSAT Access Controls

Places of Refuge

Emergency Exits and Evacuation Routes

Decontamination Methods

Contact Information during Incidents

Alarms

Training Curricula



New Space Inspections



New Space Inspections - Timeline

Space Construction/
Preparation

Amendment and
Document Submission

New Space Inspection

Amendment
Resolution



New Space Inspections – Timeline Tips Amendment and Document Submission

Space Construction/
Preparation

Amendment and
Document Submission

New Space Inspection

Amendment
Resolution

- Begin submitting when construction/preparation of space is almost complete
- Consider number of amendments required, order of submission
- Work with FSAP Point of Contact (POC) for documents necessary for your specific situation



New Space Inspections – Timeline Tips

New Space Inspection

Space Construction/
Preparation

Amendment and
Document Submission

New Space Inspection

Amendment
Resolution

- Scheduled on “as-needed” basis
 - Fit into existing inspection schedule for all entities
 - Combined with standard inspection type if possible
- POC is preferred lead inspector



New Space Inspections – Timeline Tips

Amendment Resolution

Space Construction/
Preparation

Amendment and
Document Submission

New Space Inspection

Amendment
Resolution

- Requires adequate response to all relevant inspection findings
- May include updated documents, adjustments to pending amendments, updates to proposed procedures
- Once amendments approved, lab work may begin



New Space Inspections – Document Review

- Amendment supporting documents reviewed by Facilities, Security, and Emergency Response Specialists as applicable
 - Usually occurs prior to the new space inspection
 - May result in additional document requests/updates
- Inspectors will review additional documents required by 42 CFR 73, 9 CFR 121, 7 CFR 331



New Space Inspections – Physical Inspection

- Walkthrough of new space, including:
 - Proposed PPE donning/doffing procedures
 - Proposed lab and storage activities
 - Verification that containment equipment is in place
- Verification of security features described in pending amendments and updated security plan, such as:
 - Three security barriers for Tier 1 agents
 - Access control features



New Space Inspection Report

- **Amendment Concerns** - Concerns related to an entity's request to amend its registration. These concerns must be addressed prior to the approval of the amendment. Corrective actions are submitted as part of the amendment rather than as part of the inspection.



New Space Approval

- Requires adequately addressing all amendment concerns
- Once 7A/C amendment(s) approved, lab work may commence in new space
- Remember to perform inventory audit if relocating inventory into new space – Section 11(e)(1)



New Space Approved for Work or Storage

Building	Room/Suite	Status	Tier 1	Suite	#Rooms	Storage	BSLevels	Approved	Withdrawn
<input type="radio"/> Regional Biocontainment Laboratory	<input type="radio"/> 100	Approved	<input checked="" type="checkbox"/> Tier 1	<input checked="" type="checkbox"/> Suite	9	<input checked="" type="checkbox"/> Storage	ABSL2 ABSL3 BSL2 BSL3	03/29/2022	

The floor plan diagram shows a room layout with several distinct areas. On the left, there are four vertical columns of grey rectangular spaces. The top two columns contain icons of viruses, and the bottom two contain icons of mice. To the right of these is a central area with two vertical columns of blue rectangular spaces. Further right, there are two square grey spaces, each containing a virus icon, and two square blue spaces, each containing a mouse icon. On the far right, there are two small blue squares and one larger blue square, along with a small square containing a safe icon.

Grey spaces are registered with Federal Select Agent Program; Blue space is unregistered.

Special Scenarios



Entity Relocating

- After new space is approved and select agents and toxins moved, additional amendments are required
- Modify work objectives to remove old space
 - Requires proof of decontamination and verification all BSAT removed
 - Automatically moves old space to “historical” on Section 6
- Modify Section 1 (entity) and Section 4 (RO/ARO) addresses



Remodeling of Existing Registered Spaces

- Extent of remodeling affects options – moving agent to other registered space, storing agent in secured units, etc.
- May involve de-registering space and re-registering after remodel is complete
- May involve changing space from lab + storage to storage only



Key Points



- Amendment process is stepwise
 - Building → Suite → Room → Work
- Plan ahead with POC for amendments, documents, and new space inspection
- Do not move BSAT into new space, or begin lab work, until all amendments related to new space are approved



www.selectagents.gov

CDC Contact Information
Division of Select Agents and Toxins

Irsat@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins

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301-851-2070

