

NIH Division of Occupational Health and Safety

Primary Barrier Program

2024

Authored by the Division of Occupational Health and Safety (DOHS)

Summary: It is the policy of National Institutes of Health (NIH) that all primary barrier equipment receives periodic certification in accordance with applicable industry and NIH requirements. Covered primary barrier equipment certification, maintenance, and repair services are provided through the NIH Division of Occupational Health and Safety (DOHS) Primary Barrier Program (PBP). NIH laboratories and facilities are responsible for identifying primary barrier equipment located in their spaces and ensuring a service request is submitted for periodic (typically annual) equipment certifications. Requests for repairs of non-functional equipment should also be submitted, as necessary.

Purpose: The purpose of the NIH PBP is to ensure that engineering controls (biological safety cabinets (BSCs), chemical fume hoods (CFHs), animal care units (ACUs), local exhaust ventilation (LEV) devices, etc.) are properly maintained and certified to protect employees from potential exposure to biological agents and hazardous chemicals. The overall goal of the PBP is to provide a safe work environment that allows NIH employees and contractors to be confident that the engineering controls covered by this program are safe, effective, and appropriate for use.

References: The NIH PBP utilizes NSF/ANSI 49 standards applicable to the certification and maintenance of BSCs. The NIH also utilizes a modified version of the ANSI/AHRAE 110 standard for laboratory fume hood performance testing when commissioning new CFHs. Requirements for placement and installation of primary barrier equipment is found in the NIH Design Requirements Manual (NIH DRM). General PBP information can be found at the following website: https://ors.od.nih.gov/sr/dohs/safety/laboratory/Pages/primary_barrier.aspx

Scope/Applicability: The NIH PBP applies to all employees who use primary barrier engineering controls, and those responsible for the purchase, maintenance, or related administrative functions regarding such engineering controls. The equipment certifications and repairs are provided through a DOHS primary barrier services contract. Most services are offered at no cost to NIH researchers and facilities, including off-campus buildings, laboratories at biosafety levels up to and including BSL4 and the NIH Clinical Center Special Clinical Studies Unit (SCSU). Laboratories are responsible for the cost of High Efficiency Particulate Air (HEPA) filters replacement. Services that are beyond the scope of the contract can be pursued by the end user through a third-party vendor.

Acronyms:

- ACU Animal Care Unit
- ANSI American National Standards Institute
- ASHRAE The American Society of Heating, Refrigerating and Air-Conditioning Engineers
- BSC Biological Safety Cabinet
- DDCM Division of Design and Construction Management
- DOHS Division of Occupational Health and Safety
- CFH Chemical Fume Hood
- DRM Design Requirements Manual
- DTR Division of Technical Resources

- IC Institutes and Centers
- HEPA High Efficiency Particulate Air
- LEV Local Exhaust Ventilation
- NIOSH National Institute of Occupational Safety and Health
- NIH National Institutes of Health
- NSF National Sanitation Foundation
- ORF Office of Research Facilities
- ORS Office of Research Services
- PO Project Officer
- PI Principal Investigator
- PBP Primary Barrier Program
- TAB Technical Assistance Branch

Roles and Responsibilities:

An effective PBP is achieved when NIH management and employees work together to ensure that the primary barrier engineering controls are certified, maintained, and repaired in accordance with NIH requirements. The success of PBP implementation is supported by DOHS primary barrier services contract and PBP Manager's assistance to NIH laboratories and facilities.

The DOHS Division Director has the primary responsibility for overseeing all NIH DOHS programs, including the PBP.

The Division of Occupational Health and Safety (DOHS) monitors federal regulations and private industry standards and updates the PBP as necessary. DOHS also provides training resources to those responsible for carrying out the responsibilities of the PBP and ensures that periodic administrative reviews of the program are conducted. The DOHS also manages the primary barrier contracts.

The Chief of the Technical Assistance Branch (TAB) has the primary responsibility to designate the PBP Manager and to provide PBP guidance and direction, as needed. The Chief of the TAB also conducts the annual review of the PBP written document(s) and determines if the document(s) are ready to be published on the DOHS website.

PBP Manager, under the direction of the Chief of the TAB, has the primary responsibility to assist NIH Institutes and Centers (ICs), Clinical Center (CC), divisions and workgroups with implementing elements of the PBP, manage the primary barrier services contract, review and update the written PBP, maintain an inventory of all primary barrier equipment, and coordinate the efforts to ensure that primary barrier equipment units are tested, maintained and/or certified. The PBP Manager provides a guidance for selection of biological safety cabinets (BSCs) to be purchased for use at NIH laboratories and facilities.

Primary Barrier Services Contract Contracting Officer's Representative (COR) has the primary responsibility to oversee all business and technical functions of the DOHS primary barrier services contract on behalf of the company fulfilling the contract.

Principal Investigators (PIs) and Laboratory/Facility Supervisors have the responsibility to ensure that primary barrier engineering controls are maintained and certified on an annual or as needed basis (every six months for select areas). PIs and laboratory/facility supervisors can designate laboratory/facility personnel to submit DOHS service requests for new equipment certifications, periodic equipment re-certifications, repairs, and gaseous decontamination prior to BSC relocations. The online primary barrier service request form can be found on the following webpage:

https://ors.od.nih.gov/sr/dohs/safety/laboratory/Pages/primary_barrier.aspx.

Purchasing Agents have the responsibility to ensure proper clearance from DOHS has been obtained before a new BSC is purchased. Depending on the scope of the project, additional clearance from DTR will also be required.

Office of Research Facilities has the responsibility of maintaining mechanical systems that are essential to the function of primary barrier equipment. This includes systems such as exhaust fans, air handling units, and vacuum systems.

Employees are responsible for performing work in a safe manner; understanding and complying with all applicable provisions of the NIH PBP; following all standard operating procedures for their worksite, including procedures for performing work while using primary barrier equipment; reporting the problems with primary barrier equipment to their supervisors, and, if designated, submitting DOHS service requests for annual re-certifications or other types of services covered by the DOHS primary barrier contract.

Primary Barrier Program Elements:

This NIH PBP document details expectations for the following:

- DOHS Primary Barrier Services Contract
- Design Review Processes
- BSC Gaseous Decontamination Policy
- Obsolete BSCs and Replacement Planning

Primary Barrier Services Contract:

DOHS primary barrier services contract provides technical support for on-site preventive maintenance, inspection, certification, decontamination, and repair of NIH-owned primary barrier equipment that includes the following:

- Biological safety cabinets
- Chemical fume hoods
- Local Exhaust Ventilation systems (LEVs) such as downdraft tables/sinks and vertical/ horizontal clean benches
- Animal Care Units
 - Cage change stations
 - Animal racks
 - Animal isolators
 - HEPA Vacuum Cleaners

- HVAC HEPA filter banks
- Patient Isolators

Service requests can be submitted using an online form that can be found on the DOHS Primary Barrier website at:

https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/Pages/primary_barrier.aspx.

- The response time for routine equipment certification requests is typically ranges from one to two weeks. The laboratory/facility personnel should contact PBP Manager at **PrimaryBarrier@mail.nih.gov** or by calling **301-496-3457** if certification services have not been completed within two weeks from the request submission date.
- Animal Program Coordinators can submit a compiled list of animal care equipment due for certifications directly to DOHS PBP Manager. The list will be provided to the primary barrier services contract Project Manager for sharing with a technician servicing specific animal facility.
- NIH PBP has an established priority response for emergency calls. The order of priority for servicing primary barrier equipment is as follows:
 - a. BSC Emergency repairs (e.g., blower/motor outage, low airflow alarm, light bulb replacement, sash, electrical issues, etc.).
 - b. Equipment in patient care areas.
 - c. Critical research laboratories (e.g., pandemic response).
 - d. High-containment areas (BSL-4, BSL-3, SCSU).
 - e. Animal areas.
- Chemical fume hoods (CFHs), Local Exhaust Ventilation (LEV) units (e.g., downdraft tables), and Class II Type B ducted BSCs are connected to building exhaust ventilation systems. Therefore, any issues with the airflow must be resolved by the Office of Research Facilities (ORF) maintenance personnel. The following steps need to be followed to resolve the exhaust ventilation issues:
 1. Submit ORF [maintenance service request](#) (HVAC mechanical - laboratory utilities).
 - a. If there is no response from ORF within 3 days, the laboratory/facility personnel should use the maintenance service ticket number and call the ORF service desk at 301-435-8000 to ask for a status update on the ticket.
 - b. For further escalation, there is [ORF Escalation Process](#) that can be used referencing the maintenance service ticket number.
 2. The equipment shall not be used until the airflow issues are addressed by ORF maintenance since users will not be protected from exposure.
 3. Once ORF has adjusted the airflow, the laboratory/facility personnel need to submit a primary barrier [service request](#) ("Recertification after ORF adjusted building exhaust") for DOHS contractor to verify the airflow and recertify the equipment.
- CFH light bulb replacement is performed by ORF, and can be requested by submitting a [maintenance service request](#). The DOHS primary barrier services

contract is limited to completion of CFH initial and annual certifications only. All other services need to be procured through ORF or a third-party contactor.

BSC Gaseous Decontamination Policy:

The DOHS [decontamination policy](#) on gaseous decontaminations for routine certification of BSCs was updated in on September 1, 2022. The revised policy covers the following requirements:

- Applies to all BSCs housed in any laboratory which is not posted as BSL-3 or BSL-4.
- Applies equally to laboratories in clinical, animal, and laboratory research areas.
- Does not change the DOHS policy to conduct decontaminations prior to a BSC repair (such as a motor or HEPA filters change), move, or surplus.

Beginning September 1, 2022, DOHS has eliminated the requirement to perform a gaseous/vapor-based decontamination, regardless of agent, for all BSC units outside of BSL-3 or BSL-4.

1. Prior to BSC certification, the end users need to perform a full surface disinfection of the BSC with the appropriate EPA registered or validated disinfectant, including the lower work deck and catch tray under the grill.
2. Non-essential equipment is removed from BSC prior to certification to ensure manufacturer recommended airflows.
3. A BSC surface wipe will be performed by the DOHS technician with 70% ethyl alcohol for cleaning purposes prior to beginning the certification. This cleaning practice is not a substitution for end user-performed disinfection.
4. End users can contact their respective IC [Safety and Health Specialist](#) for guidance in selecting the appropriate disinfectant and conducting an appropriate BSC surface disinfection.

Design Review:

1. All BSC purchases for any reason and in any quantity, whether by NIH researchers or contractor supplied, require prior clearance from DOHS per [NIH Manual Chapter 6307-3/26307-3 Special Clearance and Other Acquisition Procedures](#). The clearance is required to determine that the selected BSC is appropriate for the research being conducted and can be supported at the location where it is to be installed. Additionally, BSCs must meet all clearance requirements outlined in the [NIH Design Requirements Manual](#) Appendix A.
2. Certain configurations are not permitted at the NIH, such as Class II Type C cabinets (thimble/canopy connection) and BSC with ultraviolet (UV) lights for disinfection purposes.
3. The PBP Manager advises on the following streamlined design review processes:
 - In-kind replacement for an existing Class II Type A2 BSC (see Attachment B)
 - Placement of a new Class II Type A2 BSC where no other renovations/alterations are taking place.
4. The construction project request ([Construction Projects](#)) must be submitted to install or replace a ducted Class II Type B BSC. This type of project requires a full design by an

architect/engineer and must be reviewed through the standard design and construction process. The project is assigned to ORF Division of Design and Construction Management (DDCM) Project Officer (PO) who would assist the laboratory/facility with the entire construction process.

5. New CFH placements and airflow testing standard are set by the NIH Office of Research (ORS) Division of Technical Resources (DTR). All criteria in the NIH DRM must be met, including a requirement for modified ASHRAE 110 testing. Once ASHRAE 110 testing is completed, the laboratory/facility personnel will submit a service request for initial CFH certification. These requirements apply to fume hood installations in renovated or existing spaces and cover placements of a brand new CFH or previously used equipment relocated from another space.

Obsolete BSCs and Replacement Planning:

Many BSCs have a long use life, sometimes up to 20-25 years. BSC manufacturers have been adjusting this timeframe and changing the availability for replacement parts and support, thus rendering cabinets obsolete.

1. The NIH laboratories/facilities PIs and supervisors need to identify whether the BSCs at their work locations have become obsolete. The table below includes the BSC models that are currently on NuAire, Baker, Labconco, and Thermo-Scientific obsolete equipment list:

NuAire Models	Baker Models	Labconco Models	Thermo-Scientific Models
407-400	B40A112	47720	1000 Series
407-600	B40AATS	47721	1100 Series
407-624D	B40ATS	70720	1200 Series
420-400	B60	70721	1400 Series
420-600	B60A112	36204	Herasafe KS Series
425-300	B60AATS	36205	
425-400	B60ATS	36208	
425-600	NCBC4	36209	
602-400	SG400	36212	
602-500	SG400M	36213	
602-600	SG401	36210	
806-600	SG600	36214	
	NCB-C4		
	VBM400		
	SG403		
	SG603		
	SG403A		

NuAire Models	Baker Models	Labconco Models	Thermo-Scientific Models
	SG603A		

2. ICs should begin budgeting for replacement of obsolete BSCs. In the event when an obsolete BSC breaks down or requires replacement parts, it may be difficult or not possible to repair the equipment. Proactive planning for replacement of BSCs will prevent unforeseen disruptions to laboratory research and/or animal care program activities.
3. PIs and laboratory/facility supervisors can contact the PBP Manager to request additional information on the BSC replacement process once ready to purchase a replacement BSC. Please feel free to reach out to PBP Manager, at **PrimaryBarrier@mail.nih.gov** or by calling **301-496-3457**.

NSF/ANSI Standard 49 “Biosafety Cabinetry: Design, Construction, Performance and Field Certification”

The PBP Manager serves as a voting member of the National Sanitation Foundation International Joint Committee on Biosafety Cabinetry. The Joint Committee is responsible for the [NSF/ANSI National Standard 49 “Biosafety Cabinetry: Design, Construction, Performance and Field Certification”](#). The purpose NSF/ANSI Standard 49 is to establish minimum requirements for materials, design, construction, and performance of Biosafety Cabinetry that are designed to protect personnel, product, and the environment. The standard details requirements for performance testing as well as field certification testing and decontamination procedures.

ATTACHMENT A

General References

[NIH Design Requirements Manual](#), Appendix A, Biological Safety Cabinet (BSC) Placement Requirements for New Buildings and Renovations

[NIH Design Requirements Manual](#), Chapter 6: Mechanical Design

[6307-3 - Special Clearance and Other Acquisition Procedures \(nih.gov\)](#)

[NSF/ANSI National Standard 49 "Biosafety Cabinetry: Design, Construction, Performance and Field" Certification](#)

ATTACHMENT B

Replacement-in-kind for an existing Class II Type A BSC

Important note:

New BSCs may be taller and wider than the older model you are replacing, and we need enough clearance to change filters and perform maintenance. Once you pick a model, please review the attached Clearance Attestation form to confirm that BSC meets NIH requirements. The completed form must be submitted to DOHS along with a quote for a new BSC at PrimaryBarrier@mail.nih.gov. If there are issues with any of the clearances, DOHS Primary Barrier Program Manager will help to work towards a solution.

Please note, your new BSC must be NSF 49 listed, have no UV light installed, and should not have a mechanical stand (unless authorized beforehand).

Class II Type A2 BSC replacement process:

1. BSC decontamination prior to removal:

- a. The existing BSC will need to be decontaminated prior to removal. You can submit a request for decontamination [here](#). Under normal circumstances, up to 2 weeks' notice is required to schedule a decontamination.
- b. Prior to decontamination, remove all equipment from inside the BSC and wipe it down with an appropriate disinfectant. The users of the BSC must clean and disinfect the catch tray under the grill.
- c. The decontamination process takes up to 48 hours to complete. Access to the lab during the initial decontamination process will be restricted for safety reasons.
- d. Once the decontamination is complete, you may not perform any further work in it.

2. Once the decontamination is completed:

- a. Fill out and attach NIH form 2683, Certification that Equipment is Free from Hazards, to the BSC.
- b. Arrange for disconnection from utility services (vacuum) with Office of Research Facilities (ORF), if needed. We recommend submitting this request early, as it can take a month or more for this to be completed. Here is the link to request disconnection of BSC to utility services: [Construction Projects](#). Please note that you may need to email ORFBSB@mail.nih.gov to request authorization to enter design and construction work for your Institute & Center (IC).
- c. If the BSC is being removed for surplus, contact the IC Property Custodial Officer (PCO) to report excess property. The IC PCO will initiate the process in the NIH Business System (NBS) property system. NBS generates the Excess Receiving Form used to schedule the pick-up of excess property by the Property Reutilization and Disposal Section (PRDS). For additional details, please review chapter F, section 4 (Turn-in of Excess Property) of the NIH [Personal Property Management Guide \(PPMG\) - Disposal Phase](#).

- d. If BSC is being moved to another location, it will need to be recertified after the move is complete to protect BSC users, lab staff, and research work. Please submit a request for recertification using the following [Service Request](#) link. Submit a request to have your BSC reconnected to vacuum (if needed) using the following link: [Construction Projects](#). Please note that you may need to email ORFBSB@mail.nih.gov to request authorization to enter design and construction work for your IC.

3. For ordering a new BSC:

- a. Follow your IC's usual procurement process. Below are contacts for vendors that have representatives routinely on the NIH Campus and are also aware of NIH BSC requirements (NuAire and Thermo-Fisher). The contact information for Baker and Labconco sales representatives is also included.
- b. When you identify what BSC make and model you will order, NIH requires that DOHS review and approve the order before it is submitted. The review is simply a check that it meets NIH requirements. For that review, you can simply send the quote and model information along with the Clearance Attestation Form (attached) to NIH Primary Barrier Program Manager at PrimaryBarrier@mail.nih.gov.
- c. The [NIH Supply Center Catalog](#) offers several Class II, Type A2 BSC models for ordering by NIH laboratories and facilities (*search for "biosafety cabinet"*). Please note that some BSC models have a motorized base stand. A BSC with a motorized base stand should not be ordered unless a variance has been approved by DOHS to accommodate low ceiling clearance. DOHS approval is required prior to placing the order. Please email PrimaryBarrier@mail.nih.gov for additional guidance.

4. Once your new BSC is installed:

- a. Submit a request to have your BSC connected to vacuum (if needed) using the following link [Construction Projects](#). Please note that you may need to email ORFBSB@mail.nih.gov to request authorization to enter design and construction work for your IC.
- b. Gas/air are not allowed to be piped into new NIH BSCs.
- c. Submit a [service request](#) for initial certification of a new BSC. **Do not use the BSC until it has passed the initial certification.**

BSC vendors:

NUAIRE

Dana Lewandowski

LABREPCO

1-(800) 521-0754 ext 173

(410) 268-6685

dana.lewandowski@labrepco.com

THERMO-FISHER

Nicole Page

(+1) 301-514-1716

nicole.page@thermofisher.com

Customer Service (+1) 866-984-3766
Technical Support and Service: (+1) 800-438-4851

BAKER

Authorized Rep à Porter Creek Instruments
888-534-3128
sales@portercreekinstruments.com

LABCONCO

<https://www.labconco.com/sales-and-support/us-and-canada-sales>

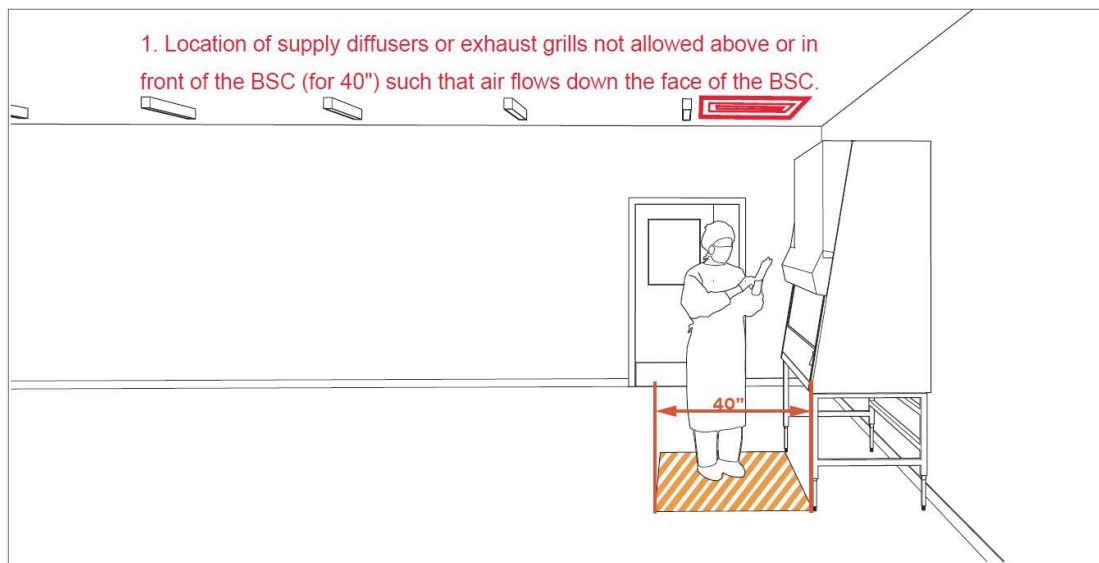
ATTACHMENT C
Replacement-in-kind Clearance Attestation Form

Laboratory Location (Building/Room):

Completed By:

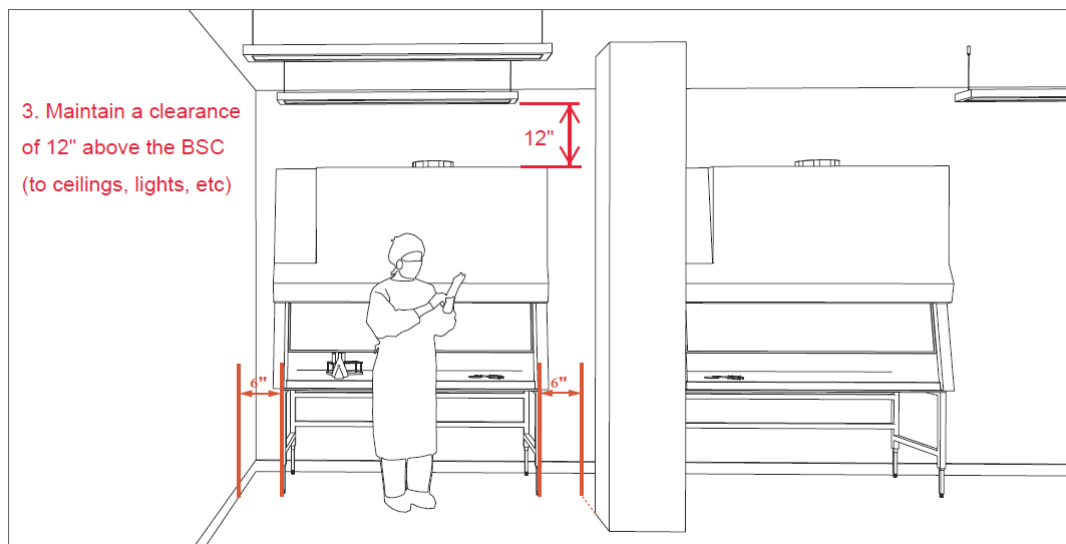
Date:

BSC Workspace:

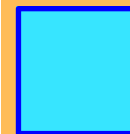


2. Maintain an undisturbed space of 40" around the BSC. *Undisturbed means free of both permanent (walls, cabinets, equipment) and temporary (door swings, people traffic, cabinet drawers/doors) encroachment.

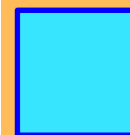
Distance to Adjacent Walls & Columns:



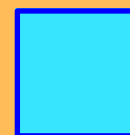
4. Maintain a clearance of 6" on sides and behind the BSC (to walls, columns, benchtops, equipment, etc)



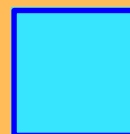
I confirm that this replacement has the appropriate clearances.



I confirm that this replacement does not have the appropriate clearances. I will discuss with DOHS.

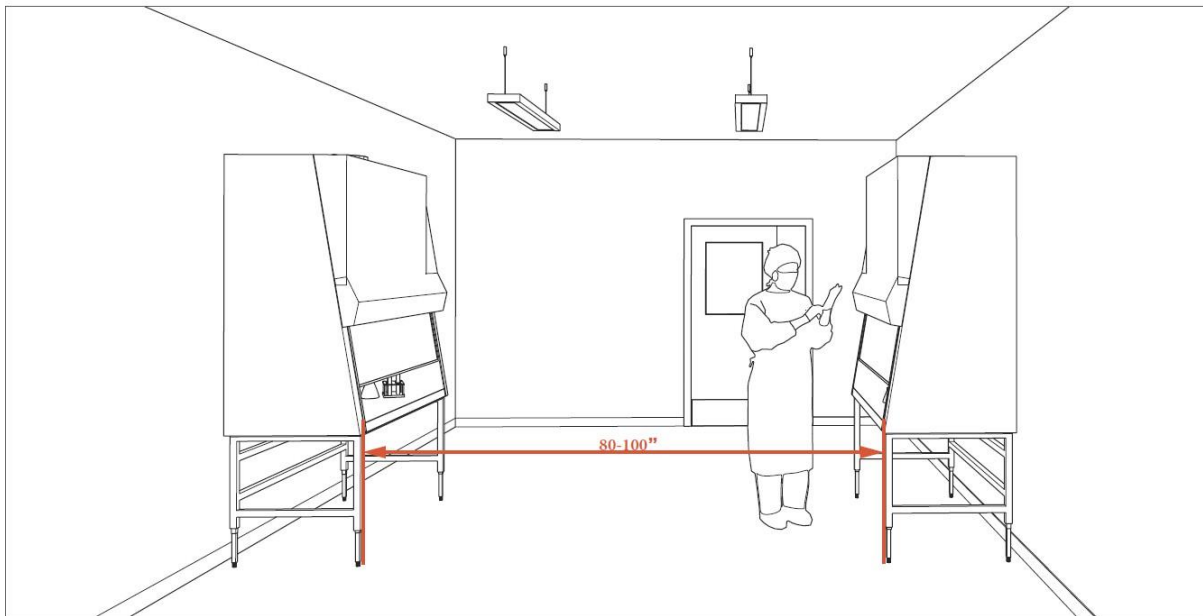


I confirm that this replacement has the appropriate clearances.



I confirm that this replacement does not have the appropriate clearances. I will discuss with DOHS.

BSC Placement Along Opposing Walls:

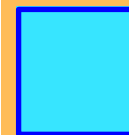


Maintain a distance of 80" between BSCs on opposing walls where there is no potential traffic between BSCs and 100" when there is potential traffic.

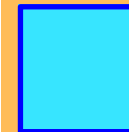
Distance to Opposing Bench Tops:



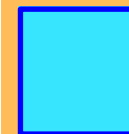
Maintain a clearance of 60" in front of the BSC if there is any possibility of traffic behind the occupant working at the BSC.



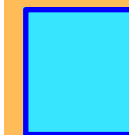
I confirm that this replacement has the appropriate clearances.



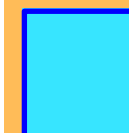
I confirm that this replacement does not have the appropriate clearances. I will discuss with DOHS.



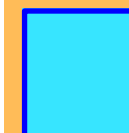
Not Applicable



I confirm that this replacement has the appropriate clearances.



I confirm that this replacement does not have the appropriate clearances. I will discuss with DOHS.



Not Applicable