Department of Health Care Access and Information

Advisory Guide Series

A2

STERILE COMPOUNDING PHARMACIES

FOR HOSPITAL FACILITIES [OSHPD 1] BUILDINGS

Office of Statewide Hospital Planning and Development

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Department of Health Care Access and Information
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INTRODUCTION

The regulations and building standards for compounding pharmacies are varied and complex. This is because there are several enforcing agencies that have jurisdiction over their design and operations. The California State Board of Pharmacy (BoP) is responsible for the development and enforcement of regulations for pharmacies as prescribed in the California Code of Regulations (CCR), Title 16. Their website may be found at: California State Board of Pharmacy.

Title 16 regulations regarding compounding pharmacies may be found at: https://www.pharmacy.ca.gov/laws_regs/approved_regs.shtml.

The California Department of Public Health (CDPH) develops and enforces regulations in CCR Title 22, which also has regulations regarding pharmacies. The Licensing and Certification (L&C) Program of CDPH is responsible for regulatory oversight of licensed health care facilities and health care professionals to assess the safety, effectiveness, and quality of health care for all Californians. The L&C Program is comprised of three branches: Centralized Applications Branch, Field Operations Branch, and Professional Certification Branch. L&C licenses basic, supplemental, and special services in General Acute Care Hospitals, including pharmacies.

Title 22 regulations may be found at: California Code of Regulations - California Code of Regulations (westlaw.com).

The Department of Health Care Accessibility and Information's (HCAI's) Office of Statewide Hospital Planning and Development (OSHPD) develops and enforces building codes and standards for pharmacies, including those with compounding services. The codes and standards are found in CCR Title 24 at: https://www.dgs.ca.gov/en/BSC/Codes. Section 1224.19.3 of Title 24 requires sterile compounding areas of pharmacies to comply with Sections 1735 and 1751 of Title 16 Division 17 Article 4.5 (referred herein as CCR 16). It also requires compliance with the U.S. Pharmacopeia (USP) General Chapters <797> and <800>.

Access to these standards may be found at: USP General Chapter <797> and USP General Chapter <800>.

This Guide will cover the codes and standards in CCR Title 24, or those enforced by OSHPD. However, some information regarding regulations enforced by other jurisdictions is provided for reference only. The user of this Guide is responsible to know and apply all pertinent laws, regulations, codes, and standards that are applicable to the design and construction of a compounding pharmacy. OSHPD will only review and enforce the applicable standards found in Title 24.

Department of Health Care Access and Information (HCAI)
Office of Statewide Hospital Planning and Development (OSHPD)

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SECTION 1
STERILE COMPOUNDING ENVIRONMENT TYPES

The diagrams and checklists in this *Advisory Guide* will present information for the two types of sterile compounding environments, each having unique requirements:

Non-Hazardous Sterile Compounding regulations set standards for an appropriate sterile environment for mixing compounded sterile products that present no hazard to the compounding technician/pharmacy staff.

Hazardous Sterile Compounding regulations set standards for an appropriate sterile environment for mixing compounded sterile products that present a health hazard to the compounding technician/pharmacy staff and must also limit outside environmental exposure to adjoining rooms and at all ventilation discharge locations.

SECTION 2
CODE REFERENCES

References from several code sources enforced by others are included in the checklists. This guide is to be used for reference only. Whereas it presents code information regarding key elements of sterile compounding environments, this guide shall not be considered a complete representation of all requirements. Compliance with applicable laws, regulations and codes are the responsibility of the design professional in responsible charge, in accordance with Title 24, California Administrative Code, Section 7-115.

Access is provided to the codes promulgated by OSHPD through the California Building Standards Commission website (https://www.dgs.ca.gov/en/BSC/Codes) with active links to each publisher's website for read-only public access versions of the codes.

Part 1, California Administrative Code

Part 2, California Building Code, Volumes 1 and 2

Part 3, California Electrical Code (Note: Accessed through the National Fire Protection Association (NFPA), however, requires the creation of a user account to view the Free Access - NFPA 70: 2022 California Electrical Code - NFPA 70 (2020 NEC®)

Part 4, California Mechanical Code

Part 5, California Plumbing Code

Part 6, California Energy Code

Part 9, California Fire Code

Part 10, California Existing Building Code

SECTION 3
ACRONYMS AND DEFINITIONS

Acronyms and Definitions assist the user in recognizing and identifying various acronyms and terms generally used in OSHPD documents. Please refer to the Master Glossary of Acronyms and Definitions on the HCAI website at https://hcai.ca.gov/document/master-glossary-of-acronyms-and-definitions/.

Other definitions may also be found in Title 24, California Code of Regulations, California Building Standards Code.

Some of the terms and definitions below are not used in this *Advisory Guide,* however, they are provided here because of their relevance to the referenced standards.

Ante-area: an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room. [Section 1735.1(a), CCR 16]

Beyond use date (BUD): the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes). [Section 1735.1(b), CCR 16]

> Refer to *Section 1751.8, CCR 16. Beyond Use Dating for Sterile Compounded Drug Preparations* for further information regarding determination of allowable BUDs within various environments.

Biological Safety Cabinet (BSC): a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting (i.e. exhaust) should be dedicated to one BSC or Compounding Aseptic Containment Isolator (CACI). [Section 1735.1(c), CCR 16]

> These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2). See *Appendix 3* for details. [USP <800>]

Buffer Room or Buffer Area: is a term that is interchangeable with Cleanroom or Clean Area. See also definition for “Cleanroom or Clean Area”.

(1) As referenced in USP <797> an area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.

(2) As referenced in USP <800> for Hazardous Compounding: A type of secondary engineering control (C-SEC) under negative pressure that meets ISO Class 7 or better air quality where the primary engineering control (C-PEC) that generates and maintains an ISO Class 5 environment is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs.

Classified space: An area that maintains an air cleanliness classification based on the International Organization for Standardization (ISO). [USP <800>]

Cleanroom or Clean Area: a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located. [Section 1735.1(e), CCR 16] This term is interchangeable with Buffer Room or Buffer Area. See also definition for “Buffer Room or Buffer Area”.

(1) For nonhazardous compounding at least 30 air changes per hour of HEPA-filtered supply air [USP <797>] and a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

Compounded Sterile Preparations (CSP): A preparation intended to be sterile that is created by combining, diluting, pooling, or otherwise altering a drug product or bulk drug substance. A product produced by reconstituting a conventionally manufactured product for an individual patient strictly in accordance with the directions contained in the approved labeling provided by the product manufacturer is not considered a CSP for the purpose of this guide. [USP <797>]

Compounding Aseptic Containment Isolator (CACI): a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one Biological Safety Cabinet (BSC) or CACI. Air within the CACI shall not be recirculated nor turbulent. [Section 1735.1(f), CCR 16]

> Also referenced in USP <800> as a specific type of CAI that is designed for the compounding of sterile HDs. The CACI is designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment with unidirectional airflow for compounding sterile preparations.

Compounding Aseptic Isolator (CAI): a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent. [Section 1735.1(g), CCR 16]

> Also referenced in USP <800> as an isolator specifically designed for compounding sterile, non-hazardous pharmaceutical ingredients or preparations. The CAI is designed to maintain an aseptic compounding environment throughout the compounding and material transfer processes.

Compounding Workstation: is a term used to describe the Primary Engineering Control. Terms are interchangeable. See definition for “Primary Engineering Control (PEC)”.

Controlled room temperature: 20 degrees to 25 degrees C (68 degrees to 77 degrees F). [Section 1735.1(j), CCR 16]

Displacement airflow method: a concept which utilizes a low-pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds. [Section 1735.1(m), CCR 16]

Doff: to remove personal protective equipment (PPE). [USP <800>]

Don: to put on personal protective equipment (PPE). [USP <800>]

Equipment: items that must be calibrated, maintained or periodically certified. [CCR 16 1735.1(o)]

First air: the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free. [Section 1735.1(p), CCR 16]

Hazardous: see also “Hazardous Drug”. Means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge. [Section 1735.1(r), CCR 16] See also “Hazardous Drug”.

Hazardous Drug (HD): see also “Hazardous”. Any drug identified by at least one of the following criteria: [USP <800>]

- Carcinogenicity, teratogenicity, or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low dose in humans or animals

Laminar Airflow System (LAFS): a LAFS provides an ISO Class 5 or better environment for sterile compounding. The LAFS provides a unidirectional HEPA-filtered airflow that is designed to prevent contamination of a sterile compounding environment. If used to prepare only Category 1 CSPs, the ISO Class 5 PEC may be in an unclassified SCA. If used to prepare Category 2 CSPs, the LAFS must be located within a cleanroom suite with an ISO Class 7 or better buffer room and ISO Class 8 or better ante-room. [USP 797]

Laminar Airflow Workbench (LFW or LAFW): a Primary Engineering Control (PEC) that is a type of laminar airflow system that provided an ISO Class 5 or better environment for sterile compounding. The device provides unidirectional HEPA-fileted airflow. An LAFW shall not be used for the manipulation of hazardous drugs (HD’s). [USP 797 & USP 800]

Parenteral: a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration. [Section 1735.1(w), CCR 16]

Personal protective equipment (PPE): clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves. [Section 1735.1(x), CCR 16]

Preparation: a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile. [Section 1735.1(z), CCR 16]

Primary Engineering Control (PEC or C-PEC): a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators. [Section 1735.1(ab), CCR 16]

Also referenced in USP <800> as Containment Primary Engineering Control (C-PEC). A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through the following:

- The full or partial enclosure of a potential contaminant source
- The use of airflow capture velocities to trap and remove airborne contaminants near their point of generation
- The use of air pressure relationships that define the direction of airflow into the cabinet
- The use of HEPA filtration on all potentially contaminated exhaust streams

Product: a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA. [Section 1735.1(ad), CCR 16]

Secondary Engineering Control (SEC or C-SEC): also known as Containment Secondary Engineering Control (C-SEC)**.** The room with fixed walls in which the PEC is placed.

It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room. [USP <797>, USP<800>]

Segregated Sterile Compounding Area (SCA or S-SCA): a designated space for sterile- to-sterile compounding where a PEC is located within either a demarcated area (at least three- foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within one meter of a PEC. A visible perimeter must establish the boundaries of the SCA. The segregated sterile compounding area shall be restricted to preparation of Category 1 CSPs. Access to the SEC must be restricted to authorized personnel and required materials. [USP 797] USP

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by Section 1751.8(d), CCR 16.

(2)) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in Section 1751.4(f)(1)-(3), CCR 16, the assigned BUD shall comply with Section 1751.8(a-b) or (d), CCR 16.

Unclassified space: A space not required to meet any air cleanliness classification based on the International Organization for Standardization (ISO). [USP <800>]

SECTION 4
TITLE 24, PARTS 2, 3, 4, AND 5 CODE REFERENCES – SELECT EXCERPTS

The following list of Title 24 code sections have been determined to be the most relevant to users of this *Design Guide*. However, this is not intended to be all inclusive of codes, regulations, or laws related to the design and construction of compounding pharmacies. The user of this Guide is responsible to know and apply all pertinent laws, regulations, codes, and standards that are applicable to the design and construction of a compounding pharmacy. Refer to Section III *Acronyms and Definitions* for information regarding where access to these codes may be found.

PART 2: CALIFORNIA BUILDING CODE

1224.19 PHARMACEUTICAL SERVICE SPACE

PART 3: CALIFORNIA ELECTRICAL CODE

See the A8 Electrical Guide for Health Care Facilities

517.33 Critical Branch.

517.34 Equipment Branch Connection to Alternate Power Source.

PART 4: CALIFORNIA MECHANICAL CODE

321.4 All supply, return, and exhaust fans.

321.5 All control components and control systems

Design of the ventilation system

Environmental Air Ducts.

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505.1.1 Mechanical Ventilation.

505.6.1 (Fire Dampers) Prohibited.

506.3 Penetrations.

505.8 Product-Conveying Ducts Classification.

505.12 Pharmacies – Compounding Area of Parenteral Solutions

507.7 Pharmaceutical Compounding Exhaust Discharge

512.1 Dampers.

PART 5: CALIFORNIA PLUMBING CODE

416.0 Emergency Eyewash and Shower Equipment.

SECTION 5
OSHPD SUBMITTAL REQUIREMENTS

1. In addition to code citations listed in this document, pharmacy projects, as with all construction, remodeling, and alteration of hospital buildings and structures, are required to be designed in conformance with applicable codes as noted in OSHPD CAN-1 *Enforceable Codes*.
2. For those projects which are affected by local planning and zoning, evidence of approval is required as part of the submittal to OSHPD.
3. The *Pharmacy Checklist* portion of this guide in the following *Appendix A* is provided to assist the design professional in responsible charge [refer to CAC 7-115], in the preparation and submission of project documents. Inclusion of this checklist with all OSHPD submittals for sterile compounding projects will facilitate a more expeditious review.
4. *Appendix B - Pharmacy Summary Checklist* is required for all OSHPD submittals for sterile compounding projects. Provide as a separate document.
5. OSHPD projects that are created with an open project number via the eServices Portal must have a functional program, as described in *Pharmacy Checklist* item 3, and either a preliminary or final submittal received by the Office within 10 days.
6. Open OSHPD project numbers without an accompanying submittal within 10 days of the creation of that number will be cancelled. Facilities intending to use **mobile units** as an interim solution to maintain compounding operations during construction must submit:
    a. An application to the Board of Pharmacy (BoP) with an accompanying functional program, to confirm that the intended mobile unit has been assessed for conformance with applicable requirements for licensure, and that the mobile unit is acceptable for use at that facility in its proposed location.
    b. Construction documents to OSHPD per the guidelines listed in PIN 34 *Review of Mobile Units Used for Outpatient Hospital Services*, with an accompanying Alternate Method of Compliance (AMC) request for Program Flexibility (preliminary) for use of a mobile unit for inpatient sterile compounding. The AMC application shall be in accordance with the California Administrative Code (CAC) Section 7-104 and include a functional program.
        i. Chapter 11B, Section 206, CCR 24 (California Building Code) requires a ramp or lift to the trailer be provided for taking pharmaceutical products into and out of the trailer in a safe manner. Based on Title 24, Part 2, Section 1224.19 it is incumbent to require this as a condition of AMC approval.
        ii. A means for emergency power shall be available for the mobile unit for up to 72 hours of use due to loss of power. This may be integral to the unit, external or connected to Hospital system.
    c. Functional programs shall address the following specific items in addition to the general information required by CAC Section 7-119:

i. Make and model of the mobile cleanroom unit and a brochure showing the interior design of the mobile unit.

ii. A diagram of the intended site placement that includes path of travel from the mobile unit to the proposed destination of the compounded sterile products (CSP's) within the hospital. This could be either the hospital's Pharmacy Department, or the staff/service elevators intended for direct disbursement to the various patient care areas. Departmental boundaries along the CSP's interior path of travel must also be shown.

iii. A statement of reason regarding use of the mobile unit, and the intended duration. OSHPD may permit temporary use of the mobile unit for up to six months with the option of one six-month extension.

Please note that OSHPD approval is for construction identified in PIN 34. The Owner is to secure additional **separate** approvals as follows:

- The Board of Pharmacy for licensure of the mobile unit, based upon their initial application and subsequent onsite inspection and certification process at the end of construction.

- The California Department of Public Health for final Program Flexibility approval, which will be subject to prior approval processes by both OSHPD and the Board of Pharmacy. An onsite inspection by CDPH may be required prior to final approval for use. Program Flexibility may only be granted for a maximum of 12 months. CA Code of Regulations, Title 22, § 70267 (a)

7. Guideline for Mobile Units Used for Temporary Pharmacy Relocation:
   a. Trailer design shall comply with State and National design standards for highways.
   b. Trailer is assumed to consist of 8 wheels in the back of trailer, blocked to resist rolling, and two steel support legs in front connected to rubber or concrete pads capable of limiting punching shear of bearing surface when overturning loads are applied. Legs shall be braced and/or strengthened as necessary to resist forces as calculated in (c) below.
   c. Trailer tethered anchorage shall be designed to resist overturning and sliding forces from wind or seismic as follows:
      i. Trailer shall be parked on an engineered concrete or asphalt surface that is relatively flat for 10 feet around the trailer.
      ii. Utility connections are flexible allowing for 10 feet of movement.
      iii. Seismic horizontal and vertical demands may be based on ASCE 7-10 Chapter 13 at ASD force level using 50% Fp for temporary installations per CAN 2-108, page 4 of 8 Seismic Design (Long Term Temporary

iv. Permit – 180-day max*). *Extensions may be granted.

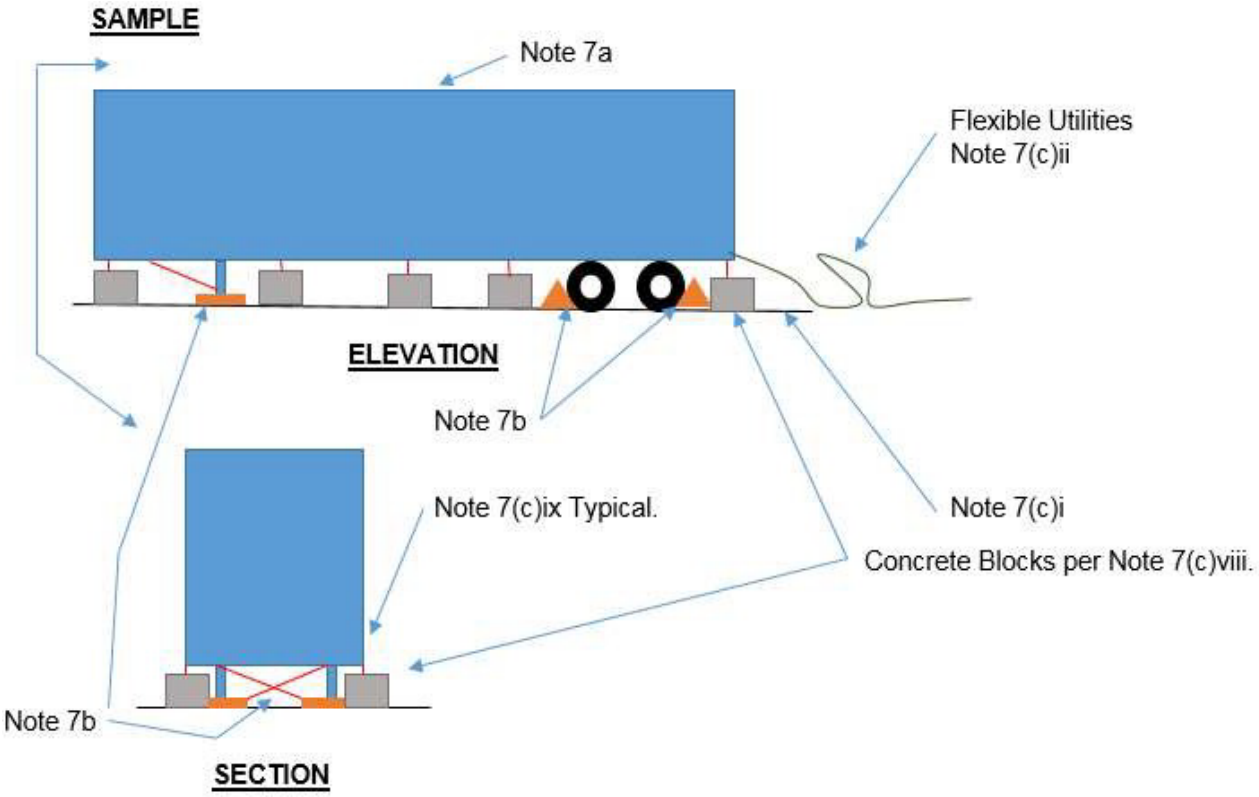
v. Wind Load horizontal and vertical demands may be based on ASCE 7-10 Chapter 29.5 (Other structure) at ASD force level using Risk Category II map. Demand/Capacity to be < = 1.0.

vi. Sliding may be resisted using friction between (1) trailer tires (rubber) and asphalt or concrete (parking lot surface), and (2) jack stands and asphalt or concrete.

vii. Friction between any combination of rubber, concrete and asphalt may be used to resist sliding using a static coefficient of friction equal to 0.5.

viii. Friction resisting force may be calculated by multiplying the static coefficient of friction by the operating weight of trailer plus the least weight of counterweights on one side of the trailer.

ix. Overturning may be resisted utilizing counterweights such as concrete blocks. Connections shall not be slack wires



8. Facilities intending to use modular unit(s) for either interim or final placement of sterile compounding must ensure that the modular units meet all the requirements listed in this *Advisory Guide* as well as all applicable codes related to construction, remodeling and alteration of hospital buildings and structures as noted in OSHPD CAN-1 *Enforceable Codes.*

9. Hospitals with less than 100 beds operating under a Hospital Pharmacy Permit Exemption shall provide all basic pharmaceutical services and be licensed by the Board of Pharmacy. Exempt hospitals shall have less than 100 licensed beds, and may not have a full-time pharmacist, nor be eligible for a sterile compounding license. See *Appendix C.*

APPENDIX A
[OSHPD 1] STERILE COMPOUNDING PHARMACY CHECKLIST

Compliance Guide for CBSC Requirements (Checklist items shown with an asterisk are Title 16 §1735 & §1751, and UPS <797> & <800> requirements that are included for reference only)

ARCHITECTURAL, MECHANICAL & ELECTRICAL COMMENTS

Texts in blue are requirements from other jurisdictions, such as CDPH and/or the State Board of Pharmacy and are not part of Title 24. The information is provided herein for reference only.

Facility Name:	Click or tap here to enter text.		
OSHPD Project Number:	Click or tap here to enter text.		
Facility Number:	Click or tap here to enter text.	Date:	Click or tap here to enter text.

PROJECT SCOPING		
Compliance		
	Sheet/Detail	
		1. Purpose: The project is required to achieve compliance with the BoP requirements.
		2. Basic Service: Pharmaceutical Service is a Basic Service for licensure of a General Acute Care Hospital; refer to CBC 1224.19.1. Sterile compounding must be located within a compliant licensed hospital building. This means, such service(s) shall be in a “Hospital Building” with a rating of SPC-2 or higher. Although it is preferred to locate the compounding facilities within the Pharmacy Department, existing hospitals may locate them elsewhere within the hospital when existing conditions make placement within the department infeasible. Remote placement will be subject to BoP and CDPH approval.
		3. Functional Program: Compounding projects associated with alterations to existing pharmacies and creation of new pharmaceutical service space must include a clear and thorough Functional Program per California Administrative Code (CAC) Section 7-119. The Functional Program must additionally include:

		a) Description of Interim Provisions for maintaining operations during construction, when applicable for renovation of existing compounding facilities in their present location. Interim placement must also meet required standards for that specific use as defined by code and noted in this advisory guide. Indicate if construction is required to prepare interim space prior to use.
		b) Project Timeline to include all phases of project implementation including all interim provisions and final scope of work. Timeline shall indicate for each phase: (i) Plan review and permitting (ii) Construction duration (iii) Licensing and Acceptance
		4. Pharmacy Summary Checklist: Projects associated with alterations to existing sterile compounding pharmacies and creation of new sterile compounding pharmaceutical service space must include a Pharmacy Summary Checklist *(see Appendix B)*. The Pharmacy Summary Checklist must be a standalone PDF and include:
		a) Overall floor plan identifying all department boundaries and the location of the project on the floor.
		b) Enlarged floor plan of the compounding spaces/areas and hazardous drug storage if provided. This plan shall identify all provided components in the Pharmacy Summary Checklist.
		Mechanical Systems: Mechanical support of these spaces must include intended International Standards Organization (ISO) air quality rating (e.g. ISO 5, ISO 7, and ISO 8), laminar airflow, pressure differential in relation to adjacent spaces, inches of water column, and air changes per hour. Identification of components must include any, and all, HEPA filtration, source of supply air, routing of return air, routing of required dedicated exhaust and roof termination at all impacted levels, duct material, etc. [CMC Table 4A]

GENERAL REQUIREMENTS – ALL ENVIRONMENT TYPES		
		5. Compounding Workstation *or* "Primary Engineering Control" (PEC):
		a) Coordinate with Pharmacist for specific type of PEC. All are to provide a minimum ISO Class 5 environment and provide ventilation/exhaust per the specific requirements of intended use. Type of PEC's to be identified later in the *Specific Environment Type* sections.
		b) Finishes – Subject to wet cleaning. [CBC 1224.19.3.2.2.2, CBC 1224.19.3.2.4.3, CBC 1224.19.3.3.2.3, CBC 1224.19.3.3.4.3]
		(i) If not built against the wall, all sides of the workstation must be accessible for cleaning and will require space to allow for reach behind the unit. If built against the wall, seal unit against wall to prevent intrusion of moisture, contaminants, and bacteria growth. [CBC 1224.19.3.2.1, 1224.19.3.3.1]
		c) Accessibility – Employee Workstation. [CBC 11B-203.9]
		d) Electrical Power - Provide critical branch power source for engineering controls such as hoods, laminar airflow workbenches, biological safety cabinets, barrier isolators. [CEC 517.33(A)(3) & (4)]
		e) Subject to certification and testing requirements.
		f) All PEC stands/bases are required to be anchored and braced per ASCE 7, Sections 13.1.4 and CBC Part 2, Section 1617A.1.18. Such anchorage and bracing shall be substantiated by engineering calculations and shall be submitted with the design/construction documents. Alternatively, OSHPD OPM(s) (see PIN 62) for the PEC stands/bases may be referenced on the design documents to satisfy this requirement.
		g) Equipment Anchorage – all roof mounted ventilation equipment must be anchored per ASCE 7, Sections 13.1.4, and CBC Part 2, Section 1617A.1.18.
		h) PEC shall have a visible pressure gauge for detection of filter leaks or defects. [CBC 1224.19.3.2.1 and 1224.19.3.3.1]

		6. Buffer Room/Cleanroom (Secondary Engineering Control - SEC):
		a) Mechanical Equipment and Ventilation - ISO Class, pressure differentials, and additional ventilation/exhaust per the requirements of the specific environment types, indicated later in this document.
		(i) Laminar Airflow - Designated area for the preparation of sterile products shall be ventilated in a manner not interfering with laminar airflow. [CMC 505.12]
		a. Air Supply - Air must be introduced through ceiling HEPA units. [CMC Table 4-A]
		b. Low Return/Exhaust – Return and exhaust grilles must be mounted low on the wall (unless a visual smoke study demonstrates dilution of particles and sweeping out of particles from the entire room), creating a top-down dilution of area air with HEPA-filtered make-up air. [CMC Table 4-A]
		i. One return/exhaust should be placed near the refrigerator's compressor. [CMC Table 4-A] (If a solid-state refrigerator is specified, external venting may not be needed.)
		(ii) Electrical Power – Provide equipment branch power source for delayed automatic or manual connection.
		a. Fans [CEC 517.34(B) (1.1), CMC 321.4 (Table 4-A for IV Prep, Pharmacy)]
		b. Controls [refer to CEC 517.34(B)(7), CMC 321.5]
		(iii) Equipment Anchorage – all roof mounted ventilation equipment must be anchored per ASCE 7, Sections 13.1.4 and CBC 1617A.1.18.
		b) Controlled room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or below and a relative humidity of 60% or below to be maintained for personnel. [CMC Table 4-A] (For continuous operation, essential power is necessary for cooling to operate compounding room during loss of power)
		c) Sealed-tight room with automatic/self-closing doors, like an Airborne infection isolation room [CBC 1224.4.4.1.3], except for Segregated Buffer Areas. [CBC 1224.19.3.2.2.4 and 1224.19.3.3.2.7]

		(i) Controlled door operators shall be readily openable in the egress direction without the use of a key or special knowledge or effort. [CBC 1010.2]
		a. Doors opening forces shall comply with the requirements of CBC 1010.1.3 and 11B-404.2.9.
		(ii) Power operated doors shall comply with the requirements of CBC 1010.3.2 and 11B-404.3.
		(iii) Special purpose horizontal sliding, accordion or folding doors shall comply with the requirements of CBC 1010.3.3 and 11B-404.2.9.
		d) Pass-throughs –If a pass-through is used, both doors shall not be capable of being open at the same time, and the doors should be interlocking. [CBC 1224.3.2.2.5, CBC 1224.19.3.3.2.8]
		e) Finishes – Nonporous and cleanable surfaces, ceilings, walls, and floors, subject to wet cleaning. The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the buffer area shall be smooth, seamless, impervious, free from cracks and crevices, and non- shedding. The surfaces shall be resistant to damage by cleaning agents, disinfectant, and tools used to clean. [CBC 1224.19.3.2.2.2, and CBC 1224.19.3.3.2.3.
		(i) [Floor finishes] Wet Cleaning – not affected by cleaning solutions. CBC 1224.4.11.1.3
		(ii) [Floors and Wall Bases] Wet Cleaning –monolithic without joints, coved wall base (like Operating Rooms). CBC 1224.4.11.2.2
		(iii) Wall finishes – washable, smooth, and able to withstand cleaning with chemicals (like Central Sterile Supply and Clean Corridors). CBC 1224.4.11.3
		(iv) Wall finish types – 2-coat epoxy-covered gypsum board, seamless vinyl or other impervious covering. [CBC 1224.19.3.2.2.2 and CBC 1224.19.3.3.2.3]
		(v) Ceiling finishes (restricted areas) – monolithic, scrubbable, and able to withstand cleaning and/or disinfecting chemicals; or utilize cleanroom style smooth and scrubbable panels, able to withstand cleaning with chemicals. [CBC 1224.19.3.2.2.2, CBC 1224.19.3.3.2.3, and CBC 1224.4.11.4.1]

		(vi) Ceiling finishes – Surfaces should be resistant to damage by cleaning agents, disinfectants, sporicidal agents, and tools used to clean. Junctures between the ceiling and the walls and between the walls and the floor must be coved or sealed to eliminate cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels must be caulked around each panel to seal them to the support frame. [CBC 1224.19.3.2.2.2, CBC and CBC 1224.19.3.3.2.3]
		(vii) Fire sprinklers – Recessed, covered, easily cleanable and of a type suitable for a cleanroom environment. [CBC 1224.19.3.2.2.2, and CBC 1224.19.3.3.2.3]
		(viii) Work surfaces, shelving and cabinets shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. Plastic laminate finish over a pervious substrate is not permitted. Organic material or plastic laminate over organic core not acceptable on counters, casework, doors, etc. [CBC 1224.19.3.2.2.2, and CBC 1224.19.3.3.2.3]
		(ix) Carts should be of stainless-steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.
		(x) Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection.
		(xi) The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed.
		f) Sources of water (sinks) or floor drains are not permitted in the Buffer Room/Area. [CBC 1224.19.3.2.2.3, CBC 1224.19.3.3.2.4]
		g) Eyewash station - Required wherever there is drug compounding and mixing. The eyewash station should be placed in the Anteroom but could be located in the Buffer Room provided it does not have a drain. When placed in the Buffer Room, it should be located just inside the door from the anteroom and at least one meter from the rim of the sink to the PEC. [CBC 1224.19.3.2.2.3, and CBC 1224.19.3.3.2.4]. [CPC 416.0]

		(i) When considering placement of eyewash within the Buffer Room, consideration should be given to weekly testing requirements.
		(ii) Water temperature to be tepid. [CPC 416.1]
		(iii) Eyewash location to be in an accessible location that requires no more than 10 seconds to reach – [CPC 416.1 - refer to ISEA Z358.1]
		h) Refrigerator on Essential Power required within the HD Buffer Room or Ante-area. Clearance around the refrigerator shall be accessible for cleaning. [CBC 1224.19.2.3.3 and 1224.19.3.3.2.5]
		(i) Provide critical branch power source. [refer to CEC 517(A)(9)]
		(ii) If used for hazardous drug storage, refrigerator must be in negative pressure room. [CBC 1224.19.3.3.2.5 and CBC 1224.19.2.3.7]
		(iii) Pass-through refrigerators are not permitted between a hazardous drug Buffer Room and any adjacent space. [CBC 1224.19.3.3.2.8]
		i) Dedicated environmental services, cleaning materials & supplies (for Buffer Room & Anteroom) - All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic microfibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. [CBC 1224.19.3.2.3.5, and CBC 1224.19.3.3.2.9]
		j) Accessibility – Employee Workstation [refer to CBC 11B-203.9] – Provide common use circulation, turning area & door clearance.
		k) Egress through intervening spaces [CBC 1016.2] - Sterile compounding pharmaceutical spaces located within “I-2” Occupancies are not considered “habitable rooms” and not subject to the requirements of CBC Section 407.4.1 regarding direct corridor access. [OSHPD CAN 2-407.4.1 *Direct Corridor Access*]

		l) Airlocks and interlocking doors can be used to facilitate better control of air balance between areas of differing ISO classification (e.g., between the buffer room and anteroom), or between a classified area and an unclassified area (e.g., between the anteroom and an unclassified area such as a hallway). If a pass-through is used, both doors should not be capable of being opened at the same time, and doors should be interlocking. [CBC 1224.19.3.2.2.4, CBC 1224.19.3.2.2.5, CBC 1224.19.3.3.2.7, and CBC 1224.19.3.3.2.8]
		m) When designing doors, consider the placement of door closures, door surfaces, and the movement of the doors, all of which can affect airflow. Seals and sweeps should not be installed at doors between buffer room and anteroom. Access doors should be hands-free. (Refer to CBC Sections in "k" above.)
		7) Hazardous Drug (HD) Storage Where hazardous drugs are stored outside of an HD buffer room or HD segregated compounding area, an HD storage room under negative pressure and externally ventilated per the California Mechanical Code shall be provided. Hazardous drugs must be stored in a manner that prevents spillage, breakage or falling from shelves. Hazardous drugs shall not be stored on the floor. Refrigerated hazardous drugs must be stored in a dedicated refrigerator located in the Hazardous buffer room, hazardous segregated compounding area or hazardous storage room. [CBC 1224.19.2.3.7]
		a) Mechanical Equipment and Ventilation – Room shall be exhausted at 12 ac/hr and shall be under negative pressure. [CMC Table 4-A]

		8. Ante-area:
		a) Mechanical Equipment and Ventilation – ISO Class, pressure differentials, and additional ventilation/exhaust per the requirements of the specific environment types, indicated later in this document.
		(i) Laminar Airflow - Designated area for the preparation of sterile products shall be ventilated in a manner not interfering with laminar airflow. [CMC 505.12]
		a. Air Supply - Air must be introduced through ceiling HEPA units. [CMC Table 4-A]
		b. Low Return/Exhaust – Return and exhaust grilles must be mounted low on the wall (unless a visual smoke study demonstrates dilution of particles and sweeping out of particles from the entire room), creating a top-down dilution of area air with HEPA-filtered make-up air. [CMC Table 4-A]
		i. One return/exhaust should be placed near the refrigerator's compressor. [CMC Table 4-A] (If a solid-state refrigerator is specified, external venting may not be needed.)
		(ii) Electrical Power – Provide equipment branch power source for delayed automatic or manual connection.
		a. Fans [refer to CEC 517.34(B) (1.1), CMC 321.4 (CMC Table 4-A for Pharmacy)]
		b. Controls [refer to CEC 517.34(B)(7), CMC 321.5]
		(iii) Equipment Anchorage – all roof mounted ventilation equipment must be anchored per ASCE 7-10, Sections 13.3, 13.4 and CBC Part 2, Section 1616A.
		b) Controlled room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or below and a relative humidity of 60% or below to be maintained for personnel. [CMC Table 4-A] (For continuous operation, essential power is necessary to operate compounding during loss of power)
		c) Donning and Doffing Area.
		(i) Nonhazardous sterile preparation environment for donning and doffing. [CBC 1224.19.3.2.3.1]
		(ii) Hazardous sterile preparation environment for donning and doffing. [CBC 1224.19.3.3.3.1]

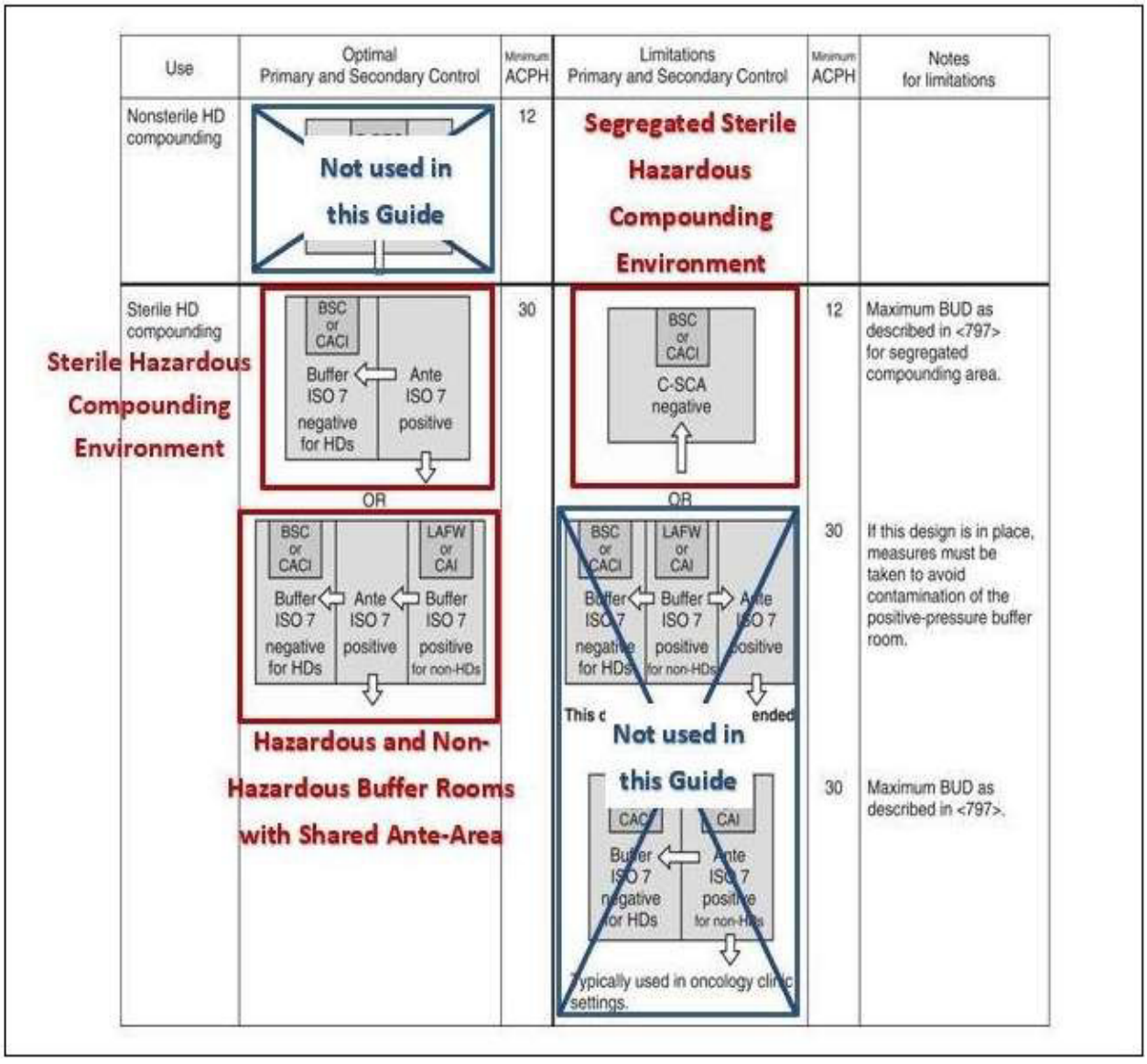
		a. Seating and/or other provisions for gowning at Demarcation Line to restricted area
		b. Storage for sterile gowns, gloves & booties
		c. Storage for contaminated gown, gloves & booties
		d) Finishes – Nonporous and cleanable surfaces, ceilings, walls, and floors, subject to wet cleaning. Organic material or plastic laminate over organic core not acceptable on counters, casework, doors, etc. Refer to CBC 1224.19.3.2.3.6.
		(i) Refer to CBC 1224.19 – Smooth, seamless, impervious, and non-shedding.
		(ii) [Floor finishes] Wet Cleaning – not affected by cleaning solutions. CBC 1224.4.11.1.3
		(iii) [Floors and Wall Bases] Wet Cleaning – coved. monolithic without joints (like Operating Room). CBC 1224.4.11.2.2
		(iv) Wall finishes (like Sterile Supply) – washable, smooth, and able to withstand cleaning with chemical. CBC 1224.4.11.3
		(v) Ceiling finishes (restricted area) – monolithic, scrubbable, and able to withstand cleaning and/or disinfecting chemicals. CBC 1224.4.11.4.1
		e) The anteroom shall not contain floor drains.
		f) Handwashing Station (capable for scrubbing to elbows, or scrub sink), with hands-free controls and nonrefillable closed soap dispensing system. [CBC 1224.19.3.2.3.3 and CBC 1224.19.3.3.3.3]
		i) In or adjacent to anteroom, with at least one meter clearance between the rim of the sink and the door opening to the hazardous buffer room. [CBC 1224.19.3.3.3.3]
		g) Eyewash Station – Required wherever there is hazardous drug compounding and mixing. It should be placed in the Anteroom but could be placed in Buffer Room with restrictions as noted. [refer to CBC 1224.19.3.2.3.4, CBC 1224.19.3.3.3.4, CPC 416.0]
		(i) Water temperature to be tepid. [CPC 416.1]
		(ii) Eyewash location to be in an accessible location that requires no more than 10 seconds to reach [CPC 416.1 refer to ISEA Z358.1.]

		h) Refrigerator on Essential Power required within the Buffer Room or Anteroom. Refrigerator to be in Ante area for Segregated environment. [CBC 1224.19.2.3.3 and 1224.19.3.3.2.5]
		(i) Provide critical branch power source. [refer to CEC 517(A)(9)]
		(ii) If used for hazardous drug storage, refrigerator must be in negative pressure room. Clearance around the refrigerator shall be accessible for cleaning. [CBC 1224.19.3.3.2.5]
		(iii) Pass-through refrigerators are not permitted between a hazardous drug Buffer Room and any adjacent space. [CBC 1224.19.3.3.2.8]
		i) Dedicated environmental services (cleaning materials & supplies for Buffer Room & Anteroom). All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding, preferably composed of synthetic microfibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. [CBC 1224.19.3.2.3.4 and CBC 1224.19.3.3.3.5]
		j) Accessibility – Employee Workstation [refer to CBC 11B-203.9] – Common use circulation, turning area & door clearance.
		k) Egress through intervening spaces [refer to CBC 1016.2] - Sterile compounding pharmaceutical spaces located within “I-2” Occupancies are not considered “habitable rooms” and not subject to the requirements of CBC Section 407.4.1 regarding direct corridor access. See OSHPD CAN 2-407.4.1 *Direct Corridor Access*.
		(i) Controlled door operators, if provided, shall be readily openable in the egress direction without the use of a key or special knowledge or effort. [refer to CBC 1010.1.9]
		(ii) Exit travel distance limitations shall apply. Travel distance shall follow CBC Section 1017.
		l) Automatic/self-closing doors, if provided, shall meet the requirements listed in *Checklist* item 6c).

		9. Buffer Area/Clean Area (Segregated Sterile Compounding Area - SCA):
		a) Mechanical Equipment and Ventilation – The ventilation requirements for the SCA is based on the room it is located in. Room should be evaluated for additional heat loads and comfort of the staff. [CMC table 4-A]
		b) Electrical Power – Provide equipment branch power source for delayed automatic or manual connection. a. Fans [CEC 517.34(B) (1.1), CMC 321.4 (Table 4-A for IV Prep, Pharmacy)] b. Controls [refer to CEC 517.34(B)(7), CMC 321.5]
		c) Finishes – Nonporous and cleanable surfaces, ceilings, walls, and floors, subject to wet cleaning. Organic material or plastic laminate over organic core not acceptable on counters, casework, doors, etc. [CBC 1224.19.3.2.4.3 and CBC 1224.19.3.3.4.3]
		d) Handwashing Station (capable for scrubbing to elbows, or scrub sink), with hands-free controls and nonrefillable closed soap dispensing system. The 1-meter perimeter around PEC shall not contain the sink. [CBC 1224.19.3.2.3.3 and CBC 1224.19.3.2.4.2]
		e) In or adjacent to SCA, with at least one meter clearance between the rim of the sink and the PEC. [CBC 1224.19.3.2.4.2 and CBC 1224.19.3.3.4.2]
		f) Eyewash station - Required wherever there is hazardous drug compounding and mixing. It shall be located at least one meter from the rim of the sink to the PEC. [CBC 1224.19.3.2.2.3, CBC 1224.19.3.2.3.4, CBC 1224.19.3.3.2.4, and CBC 1224.19.3.3.3.4] [CPC 416.0]
		g) Refrigerator on Essential Power required within the SCA. Clearance around the refrigerator shall be accessible for cleaning. [CBC 1224.19.2.3.3]

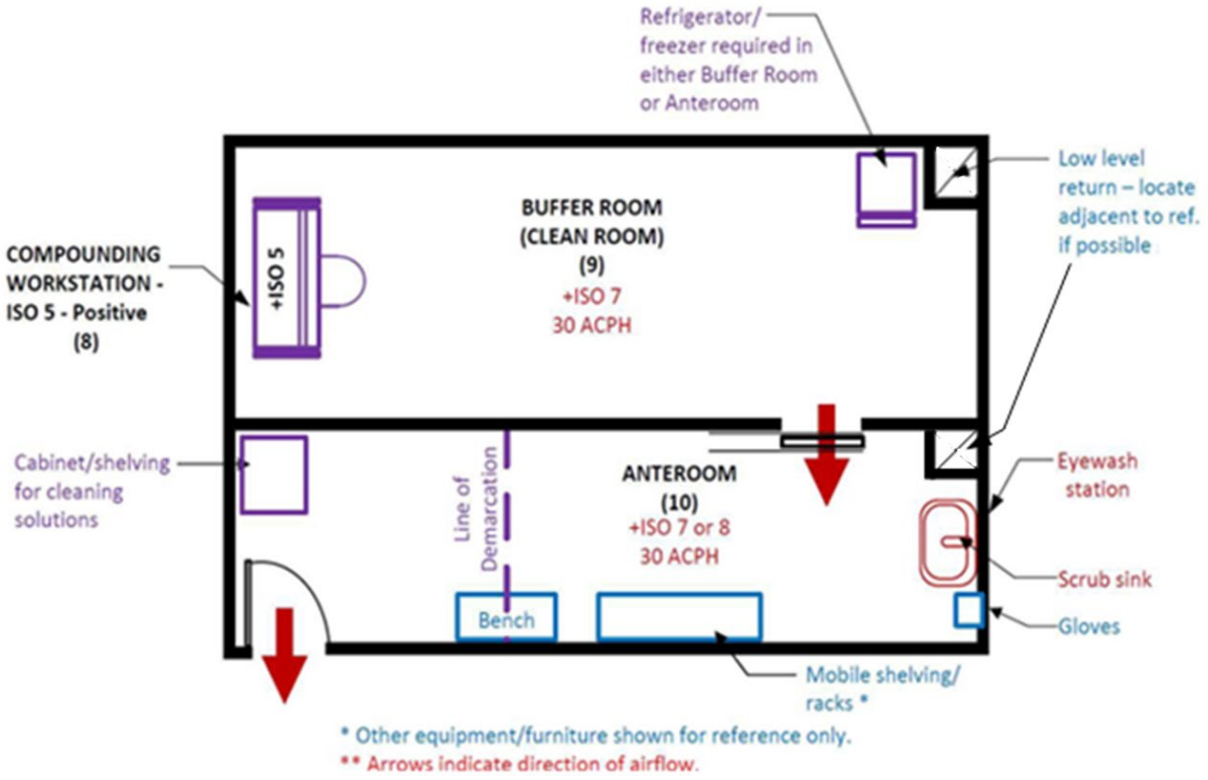
GENERAL ROOM RELATIONSHIPS – VARIOUS ENVIRONMENT TYPES

The following chart, provided for reference only from <USP 800> regulations, provides a high-level overview of the required relationships between the various environments, and their associated allowable Beyond Use Dates.



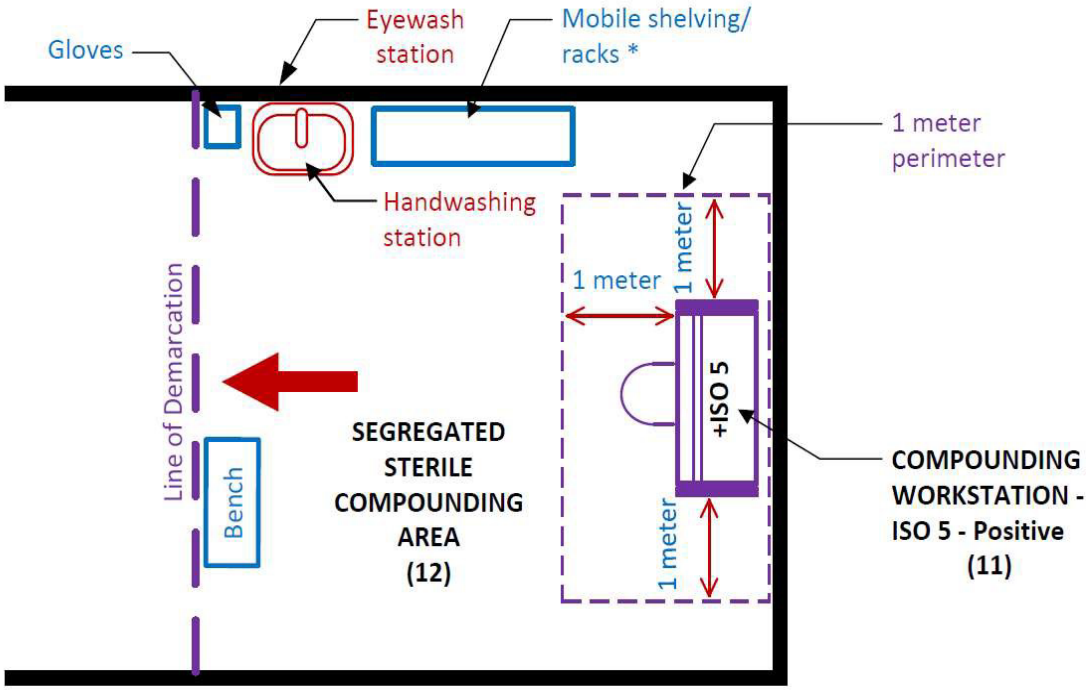
The illustrations on the following pages represent specific environment types to highlight unique requirements pertinent to each. Illustrations are diagrammatic and for reference purposes only. The actual design is the responsibility of the design professional in responsible charge, to be developed in coordination with their client under the advisement of pharmacy staff.

SPECIFIC ENVIRONMENT TYPE – STERILE NON-HAZARDOUS



PROJECT SCOPING		
Compliance		
	Sheet/Detail	
		10. Compounding Workstation (PEC): (Refer to CBC 1224.19.3.2.1)
		a) Meets the general requirements of *Checklist* Item 5, above.
		b) ISO Class 5 - Positive Pressure through non-turbulent, laminar- flow, HEPA-filtered "first air." Coordinate with Pharmacist for specific type of PEC.
		(i) Laminar Airflow Workbench (LAFW)
		(ii) Compounding Aseptic Isolator (CAI)
		11. Buffer Room/Cleanroom (SEC): (Refer to CBC 1224.19.3.2.2)
		a) Meets the general requirements of *Checklist* Item 6, above.
		b) ISO 7 - Positive Pressure HEPA-filtered. [CBC 1224.19.3.2.2.1]
		(i) Supply air to room to be minimum of 50% (i.e. 15 ACPH) HEPA-filtered air. Total ACPH may be augmented by the ISO Class 5 PEC not to exceed 50% (i.e. 15 ACPH). [CMC Table 4-A]
		(ii) 30 Air Changes Per Hour (ACPH) minimum. [CMC Table 4-A]
		(iii) Positive 0.02 to 0.05 inches water column (w.c.) in relation to adjacent anteroom. [CMC Table 4-A]
		(iv) Continuous monitoring. Pressure differential, temperature, humidity.
		12. Anteroom: (Refer to CBC 1224.19.3.2.3)
		a) Meets the requirements of *Checklist* Item 7 above.
		b) Access nonhazardous buffer rooms through an anteroom.
		c) ISO Class 8 or better - Positive Pressure HEPA-filtered. [CMC Table 4-A]
		(i) 30 ACPH minimum. [CMC Table 4-A]
		(ii) Positive 0.02 inches water column minimum in relation to the adjacent, non-compounding spaces. [CBC 1224.19.3.2.3.2, CMC Table 4-A]
		(ii) Continuous monitoring. Pressure differential, temperature, humidity.

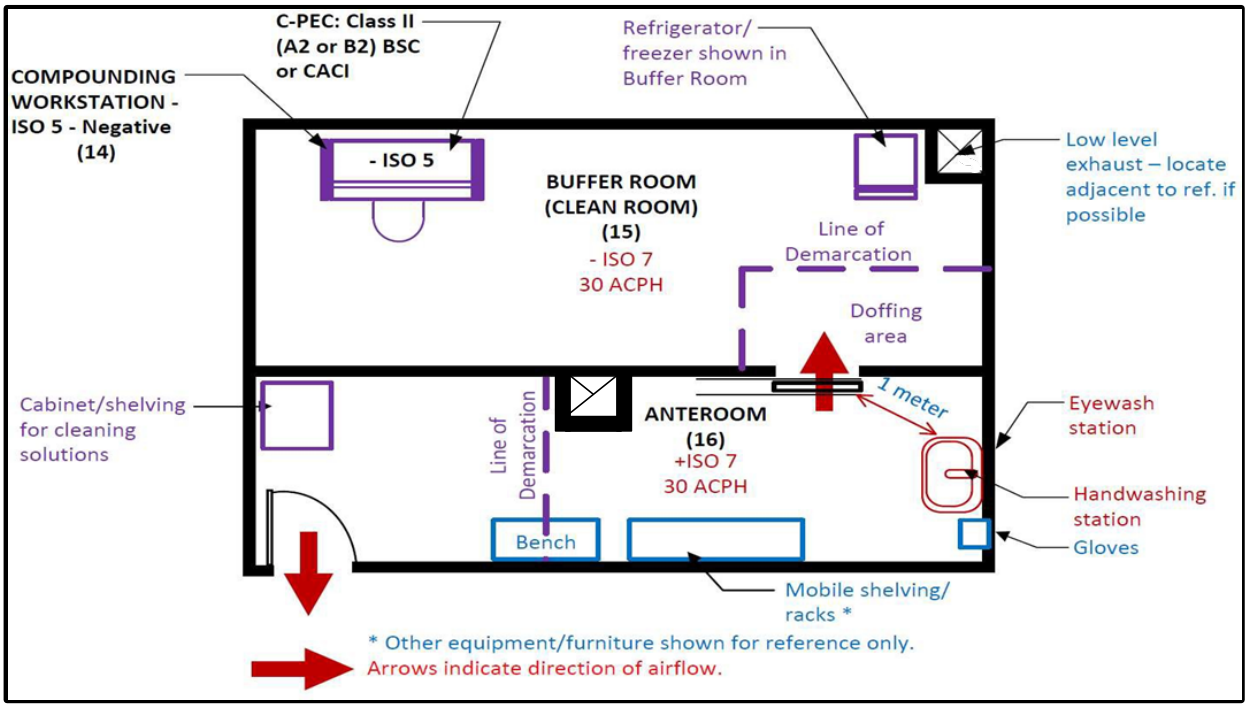
SPECIFIC ENVIRONMENT TYPE – SEGREGATED STERILE NON-HAZARDOUS (Limited to Beyond Use Date BUD < 12 hours)



* Other equipment/furniture shown for reference only.
Arrows indicate direction of airflow.

PROJECT SCOPING		
Compliance		
	Sheet/Detail	
		13. Compounding Workstation (PEC) (Refer to CBC 1224.19.3.2.4)
		a) Meets requirements of *Checklist* Item 5 above.
		b) ISO Class 5 - Positive Pressure through non-turbulent, laminar- flow, HEPA-filtered "first air." Coordinate with Pharmacist for specific type of PEC.
		(i) Laminar Airflow Workbench (LAFW)
		(ii) Compounding Aseptic Isolator (CAI)
		14. Segregated Sterile Compounding Area (SCA): (Refer to CBC 1224.19.3.2.4)
		a) Meets the general requirements of *Checklist* Item 8 .
		b) No ISO Class required - Unclassified.
		(i) Maintain airflows from clean to less clean areas. [CBC 1224.19.3.2.4.1, CMC 407.4.1]
		c) Line of Demarcation shall be established to define Segregated Compounding Area if this area is not separated by a wall with a door. Minimum clearance of 3.3ft (1 meter) between the PEC and the line of demarcation. [CBC 1224.19.3.2.4]
		d) See item 8g for eyewash requirements.
		e) All surfaces (e.g., walls, floors, counters, and equipment) in the SCA must be clean, uncluttered, and dedicated to compounding.
		f) Location shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation.
		g) Item 8f) handwashing fixture in or adjacent to the SCA minimum of 3.3 ft (1 meter) from PEC

SPECIFIC ENVIRONMENT TYPE – STERILE HAZARDOUS

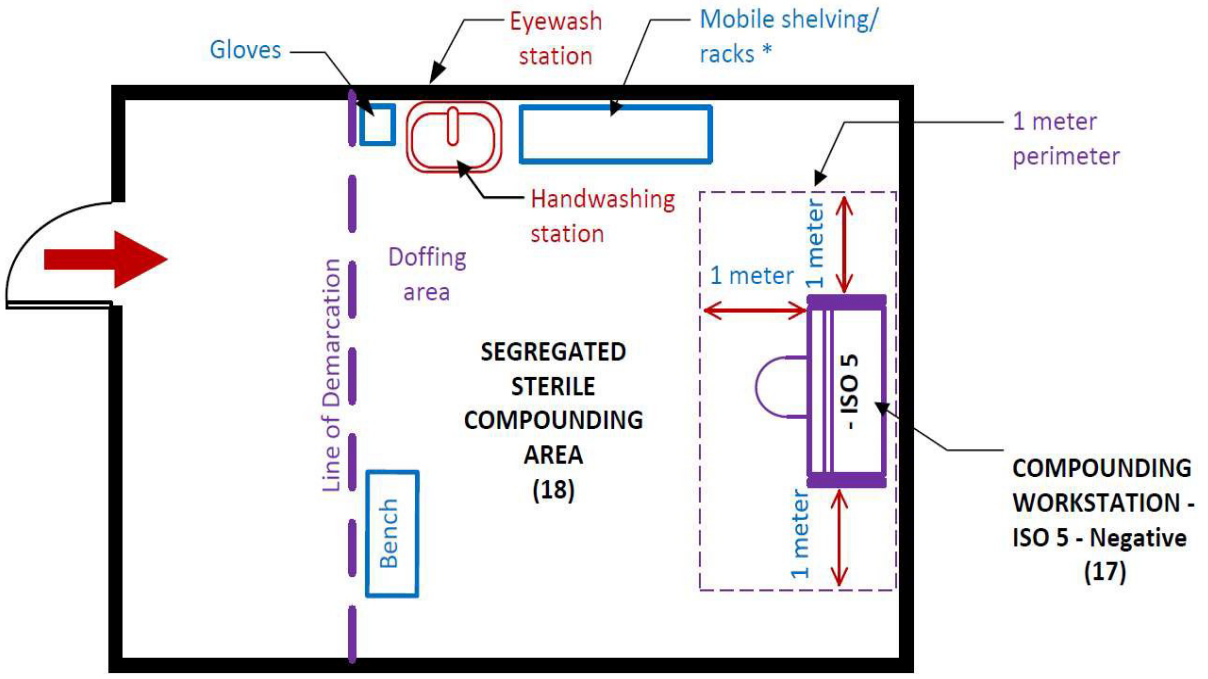


PROJECT SCOPING		
Compliance		
	Sheet/ Detail	
		15. Compounding Workstation (PEC): (Refer to CBC 1224.19.3.3.1)
		a) Meets the general requirements of *Checklist* Item 5, above.
		b) All compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar airflow hood with bag in – bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight. [Refer to CMC 505.12.1]
		c) ISO Class 5 - Negative Pressure through non-turbulent, laminar-flow, HEPA-filtered "first air." Must operate continuously. [CBC 1224.19.3.3.1]
		(i) Biological Safety Cabinet (BSC)
		(ii) Containment Aseptic Compounding Isolator (CACI)
		d) Exhaust – 100% dedicated direct exhaust to exterior. [CMC Table 4-A] Recommend N+1 exhaust fans per the SEC. Exhaust discharge from fans serving the compounding suite shall extend at least 7 feet above the roof and discharge vertically upward. Self-draining stacks or equivalent shall be used for rain protection. Rain caps which divert the exhaust toward the roof shall be prohibited. [CMC 507.7]
		(i) Termination of exhaust duct from hazardous drug PEC or hazardous drug buffer room shall be not less 10 feet from a property line, 3 feet from exterior walls or roofs, 25 feet from openings into the building, and 10 feet above adjoining grade. [Refer to CMC 502.2.2, 407.2.1, 407.2.2]
		(ii) Ducts conveying fumes shall extend directly to the exterior of the building without entering other spaces and shall not extend into or through ducts and plenums. [Refer to CMC 505.1]
		(iii) Air contaminated with fumes, toxic gases, or radioactive materials shall not be recirculated. [Refer to CMC 505.3.1]
		(iv) Exhaust fans shall be interlocked with PECs. [Refer to CMC 505.1.1]

		(v) Fire dampers shall not be installed where the material being exhausted is toxic. [Refer to CMC 505.6.1] Exhaust ducts shall not pass through fire walls. [Refer to CMC 505.6.3]
		(vi) Class 5 ductwork required if corrosive vapors are being exhausted. [Refer to CMC 505.8]
		16. Buffer Room/Cleanroom (SEC): (Refer to CBC 1224.19.3.3.2)
		a) Hazardous drug compounding shall be completed in an externally vented, physically separate room with fixed walls. [CBC 1224.19.3.3, CMC Table 4-A]
		b) Meets the general requirements of *Checklist* Item 6, above.
		c) Hazardous environment doffing when exiting the Buffer Room. Demark doffing area with hamper, inside buffer/cleanroom at the door to the anteroom. [CBC 1224.19.3.3.2.6]
		d) ISO 7 – Negative HEPA-filtered.
		(i) 30 ACPH minimum. [CMC Table 4-A]
		(ii) Negative 0.01 to 0.03 inches water column (w.c.) relative to the anteroom. [CBC 1224.19.3.3.2.2, CMC Table 4-A]
		(iii) Continuous monitoring. Pressure differential, temperature, humidity.
		e) Exhaust – 100% exhaust to exterior. [CMC Table 4-A]
		(i) Termination of exhaust duct from hazardous drug PEC or hazardous drug buffer room shall be not less than 3 10 feet from a property line, 3 feet from exterior walls or roofs, 10 feet from openings into the building, and 10 feet above adjoining grade and 7 feet above the roof of the building. [refer to CMC 502.2.2, 507.7]
		(ii) Ducts conveying fumes shall extend directly to the exterior of the building without entering other spaces and shall not extend into or through ducts and plenums. [refer to CMC 505.1]
		(iii) Air contaminated with fumes, toxic gases, or radioactive materials shall not be recirculated. [refer to CMC 505.3.1]
		(iv) Exhaust fans shall be interlocked with PECs. [refer to CMC 505.1.1]

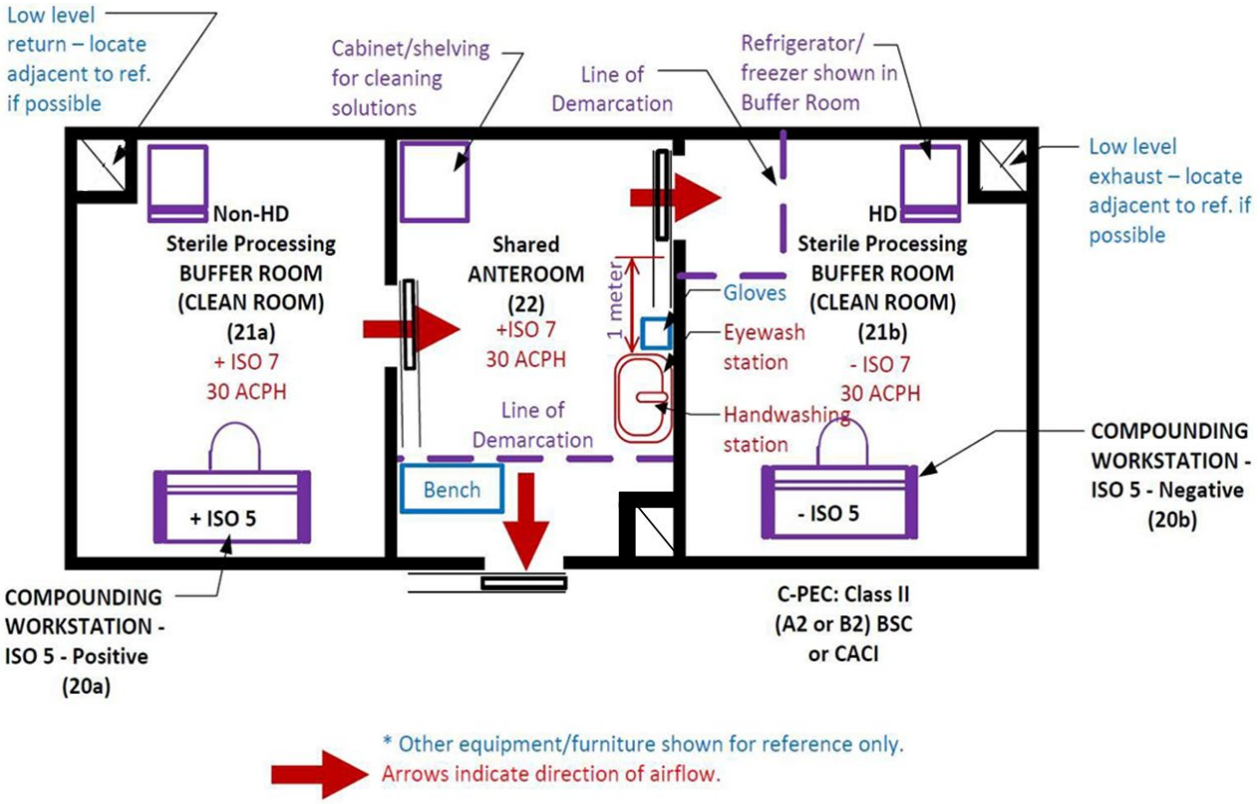
		(v) Fire dampers shall not be installed where the material being exhausted is toxic. [Refer to CMC 505.6.1] Exhaust ducts shall not pass through fire walls. [refer to CMC 505.6.3]
		(vi) Class 5 ductwork required if corrosive vapors or being exhausted. [refer to CMC 505.8]
		17. Anteroom: (Refer to CBC 1224.19.3.3.3)
		a) Must have fixed walls.
		b) Meets the requirements of *Checklist* Item7 above.
		c) Sized to accommodate a demarked area for donning and doffing, and anticipated staging of carts and supplies. [CBC 1224.19.3.3.3.1]
		d) ISO Class 7 - Positive Pressure HEPA-filtered.
		(i) 30 ACPH minimum. [CMC Table 4-A]
		(ii) Positive at least 0.02 inches water column (w.c.) relative to all adjacent unclassified areas. [CBC 1224.19.3.3.3.2, CMC Table 4-A]
		(iii) Continuous monitoring. Pressure differential, temperature, humidity.
		e) Handwash sink capable of washing up to elbows shall be at least one meter away from the door to the Buffer Room. Refer to CBC 1224.19.3.3.3.3.

SPECIFIC ENVIRONEMNT TYPE – SEGREGATED STERILE HAZARDOUS (Limited Beyond Use Date BUD < 12 hours)



PROJECT SCOPING		
Compliance		
	Sheet/Detail	
		18. Compounding Workstation (PEC):
		a) Meets the requirements of *Checklist* item 14, above, except as noted herein.
		b) ISO Class 5 - Negative Pressure through non-turbulent, laminar-flow, HEPA-filtered "first air." Must operate continuously.
		(i) Biological Safety Cabinet
		(ii) Containment Aseptic Compounding Isolator
		19. Segregated Sterile Compounding Area (SCA): (Refer to CBC 1224.19.3.3.4)
		a) Meets the requirements of *Checklist* item 8, above, except as noted herein.
		(i) Hazardous drug compounding shall be completed in an externally vented, physically separate, dedicated room with fixed walls. [CBC 1224.19.3.3.4, CMC Table 4-A].
		b) Unclassified – Negative pressure. [CBC 1224.19.3.3.4.1, CMC Table 4-A]
		(i) 12 ACPH minimum. [CMC Table 4-A]
		(ii) Negative 0.01 to 0.03 inches water column (w.c.) relative to all adjacent spaces.
		(iii) Continuous monitoring. Pressure differential, temperature, humidity.
		(iv) Maintain airflows from clean to less clean areas. [CBC 1224.19.3.3.4.1, CMC 407.4.1]
		c) Line of Demarcation shall be established to define Segregated Compounding Area if this area is not separated by a wall with a door.
		d) The 1-meter perimeter around PEC shall not contain the sink. [CBC 1224.19.3.3.4.2] See item 6f) for eyewash requirements.
		e) Item 8f) handwashing fixture in or adjacent to the SCA minimum of 3.3 ft (1 meter) from PEC

SPECIFIC ENVIRONMENT TYPE – HAZARDOUS AND NON-HAZARDOUS BUFFER ROOMS WITH SHARED ANTEROOM



PROJECT SCOPING		
Compliance		
	Sheet/ Detail	
		20. Compounding Workstation (PEC):
		a) For non-hazardous compounding refer to *Checklist* item 9, above.
		b) For hazardous compounding refer to *Checklist* item 14, above.
		21. Buffer Room/Cleanroom (SEC):
		a) For non-hazardous compounding refer to *Checklist* item 10, above.
		b) For hazardous compounding refer to *Checklist* item 15, above.
		22. Ante-area:
		a) Meets the requirements of *Checklist* Item 16 above.
		b) Consideration should be given to separate dedicated Ante- areas for hazardous drug and non-hazardous drug Buffer Rooms, so that contamination affecting one Ante-area allows the other to remain in use.
		c) Sized to accommodate a demarked area for donning and doffing, and anticipated staging of carts and supplies. [CBC 1224.19.3.2.3.1 and 1224.19.3.3.3.1]
		d) Provide a minimum of 5 feet between the buffer room doors and provide automatic door controls sequencing such that only one of the buffer room doors may be open at one time. Egress provisions shall not be impeded. [CBC 1224.19.3.2.3.1]

APPENDIX B
PHARMACY SUMMARY CHECKLIST

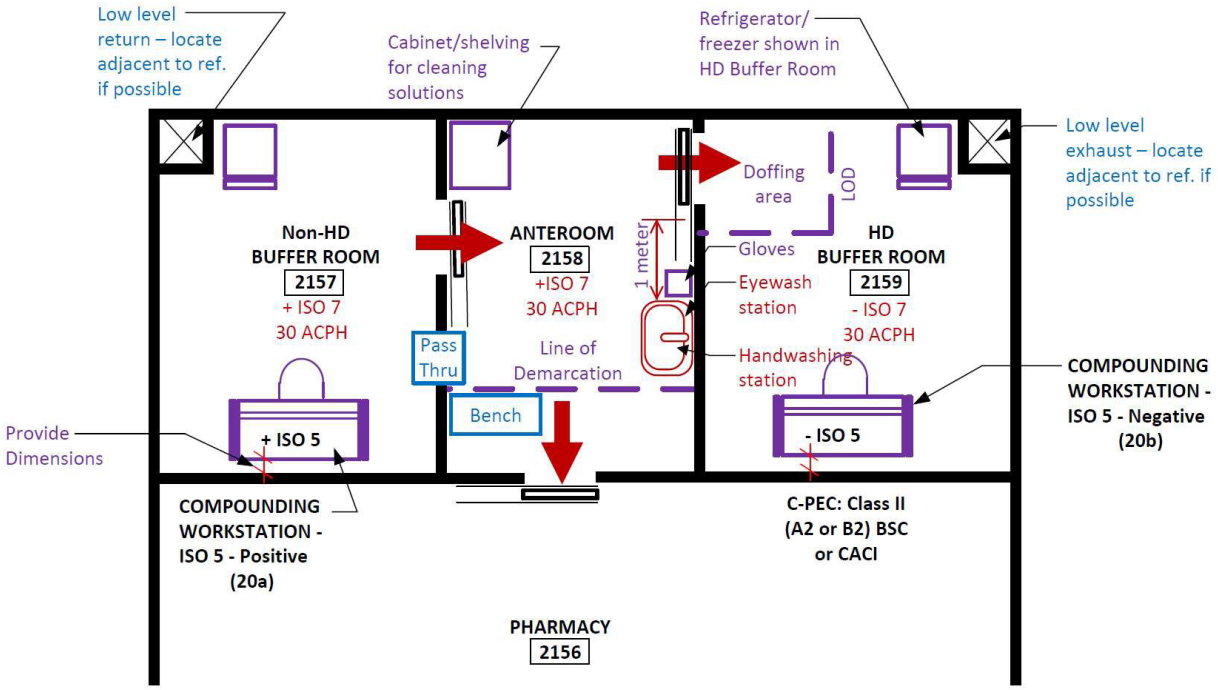
Facility Name:	Click or tap here to enter text.		
OSHPD Project Number:	Click or tap here to enter text.		
Facility Number:	Click or tap here to enter text.	Date:	Click or tap here to enter text.

	1. Provide simplified overall plan identifying all department boundaries and location of project on the floor.
	2. Provide diagram (see sample attached) identifying all compounding components below, equipment and clearance dimensions.
	3. Submit Appendix B as separate file.
A) General	
Intended Compounded Sterile Products (CSP's) - check all that apply:	
	Non-Hazardous CSP's
	1. Low risk CSP's
	2. Medium risk CSP's
	3. High risk CSP's
	Hazardous CSP's
	1. Low risk CSP's
	2. Medium risk CSP's
	3. High risk CSP's
	4. Radiopharmaceutical CSP's
	Beyond-Use Dates (BUDs)
	1. Equal to or less than 12 hours at controlled room temperature
	2. Greater than 12 hours at controlled room temperature

N/A = not applicable No = does not meet standard Yes = meets standard NR = insufficient information to review	N/A	No	Yes	NR
1. Design supports the BUDs to be assigned?				
2. Room names identified?				
3. Pressure arrows (negative/positive).				
B) Ante-area				
1. Positive pressure to general environment (+0.02 min)?				
2. ISO 8 unless connected to HD buffer, then ISO 7.				
3. ISO 7 then 30 ACPH.				
4. Sink type and location (greater than 1 meter from entrance to HD buffer area).				
5. Line of Demarcation.				
6. Refrigerator(s).				
7. Pass through's (if applicable).				
8. Relative humidity of 20°C (68°F) or below				
C) Buffer Area				
1. ISO 7 or better.				
2. Positive pressure to ante-area (+0.02 min). (+0.02 to +0.05 if physically separated between buffer and ante)				
3. 30 ACPH minimum (no more than half from hoods).				
4. Type(s) of Primary Engineering Control (PEC) Workstations (include cut sheets)?				

5. Pressure monitoring devices noted.				
6. Relative humidity of 60% or below and temperature 20°C (68°F) or below				
D) Hazardous buffer area (C-SEC)				
1. Externally vented, room and C-PEC.				
2. ISO 7 or better.				
3. Negative pressure to ante-area (-0.01 to -0.03).				
4. 30 ACPH minimum.				
5. Type(s) of Primary Engineering Control (PEC) Workstations (include cut sheets)?				
6. Does not include a pass-through refrigerator (not allowed).				
7. Chemo PPE don/doff area inside the room, next to the entrance.				
8. Refrigerator(s).				
9. Pressure monitoring devices noted.				
10. Relative humidity of 60% or below and temperature 20°C (68°F) or below				
E) Segregated compounding area (non-hazardous)				
1. Placed in an appropriate area of the hospital.				
2. Area is defined.				
3. Sink (greater than 1 meter away from hood).				
F) Segregated compounding area (C-SCA) (hazardous)				
1. Enclosed by walls and a door.				
2. Externally vented room and hood.				
3. 12 ACPH minimum.				

4. Negative pressure to general area (-0.01 to -0.03).				
5. Chemo PPE don/doff area inside the room, next to the entrance.				
6. Sink (greater than 1 meter away from hood).				
G) One room with ante and buffer area, no dividing wall and door				
1. Line of demarcation.				
2. Airflow 40 ft/min or more from the buffer area to the ante-area, wall-to-wall and ceiling-to-floor, across the line of demarcation.				
H) CAI located in worse than ISO 7				
1. Does the hood meet the bullet points for location outside an ISO 7 buffer?				
I) Hazardous drug storage area				
1. Externally vented room.				
2. Negative pressure.				
3. 12 ACPH.				



Provide schematic diagram showing all rooms and components identified in Appendix B
Arrows indicate direction of airflow.

SAMPLE ONLY

APPENDIX C
PHARMACY SERVICE SPACE DRUG ROOM

Less than 100-bed Pharmacy Permit Exception. Hospitals under a Hospital Pharmacy Permit Exception shall provide all basic pharmaceutical services and shall be licensed by the Board of Pharmacy. Exempt hospitals shall have less than 100 licensed beds, and may not have a full-time pharmacist, nor be eligible for a sterile compounding license. Exempt hospitals may purchase drugs at wholesale for administration and shall provide the following pharmacy service space in accordance with CBC 1224.19.1.2:

- Drug Room: Licensed pharmaceutical space with drug distribution under the supervision of a physician and be monitored by a pharmacist consultant. The drug room shall include the following:
  - A room or area for receiving, breakout, and inventory control of drugs used in the hospital.
  - Cleanable work counters and space for automated and/or manual dispensing activities.
  - An area for reviewing and recording.
  - An area for storage, exchange, and restocking of carts.
  - Security provisions for drugs and personnel in the dispensing counter area.
- A hand-washing station shall be provided in the area where medication(s) are handled or be immediately accessible, without going through a door unless the door is equipped with hands-free operation.
- Cabinets, shelves, and/or separate rooms or closets shall be provided for the following:
  - Bulk storage.
  - Active storage.
  - Refrigerated storage.
  - Storage for volatile fluids and alcohol in accordance with applicable fire safety codes for the substances involved.
  - Secured lockable storage for controlled drugs.
  - Equipment and supply storage for general supplies and equipment not in use.

REVISION HISTORY

Version 4.0	September 2025	Provided a new Section 8 specifically for SCA requirements. Added mechanical requirements to Section 7. Added website locations where Title 24 codes referenced in the Guide may be found. Revised code excerpts to be from Title 24 only. Updated to reflect the changes in the 2022 and 2025 edition of Title 24. Eliminated references to CBC 1250. Provided clarification regarding which requirements are enforced by OSHPD, and which are for reference only.
Version 3.0	May 2020	Second Revision
Version 2.0	November 2019	First Revision
Version 1.0	April 2017	First Issued