OSHPD

STERILE COMPOUNDING PHARMACIES

A2

FOR HOSPITAL FACILITIES

(OSHPD 1 Buildings)

Advisory Guide Series

December 2017

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INTRODUCTION

The California State Board of Pharmacy (BoP) has changed its regulations to ensure they reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565). The regulations also address the problem of ensuring that board regulations are aligned with compounding standards of United States Pharmacopeia (USP) <797> and USP <800>, which further ensures the safety of consumers receiving compounded drugs in California.

Specifically, the California State Board of Pharmacy has recently revised Title 16 California Code of Regulations (CCR), §1735 "Compounding in Licensed Pharmacies" & §1751 "Sterile Compounding," promulgated in July of 2016 and enforceable January 1, 2017. There is some alignment with USP <797> and <800>.

The US Pharmacopeia is currently in the process of revising Chapter <USP 797> "Pharmaceutical Compounding – Sterile Preparations" in its entirety, and has finalized the new Chapter <USP 800> "Hazardous Drugs – Handling in Healthcare Settings."

For further information on the California State Board of Pharmacy (BoP) regulations please refer to the Board of Pharmacy web page under the following address:

http://www.pharmacy.ca.gov/

Hospital facilities not currently meeting the subject regulations covered in these guidelines will require physical construction or alteration to a hospital building or its physical environment.

The BoP regulations became effective on January 1, 2017. Any compounding facilities not currently in compliance must submit a request for delay in compliance to the BoP if they have not already done so.

Suggested submittal items include:

- BoP Application
- Functional Program (see Checklist item 3)
- Validation of OSHPD Project Submittal (Preliminary or Final)

Please email all requests to: Compounding.Waivers@dca.ca.gov

The California Office of Statewide Planning and Development (OSHPD) has drafted this Advisory Guide in consultation with the California State Board of Pharmacy (BoP) and California Department of Public Health (CDPH).

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I. STERILE COMPOUNDING ENVIRONMENT TYPES

The diagrams and checklists in this *Advisory Guide* will present information for the two types of sterile compounding environments, each of which 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. Refer to "Hazardous" in the definitions, below, for application of this designation.

II. CODE REFERENCE INDEX

This *Advisory Guide* is the result of a joint effort between various regulatory authorities. Consequently, references from a number of code sources are included. The items/requirements on the following pages are categorized into groups as color-coded below:

RED –Code Sections designated in red are direct code requirements supported by Title 24, CCR, California Building Standards Code (CBSC) including the California Building Code (CBC), California Electrical Code (CEC), California Mechanical Code (CMC) and California Plumbing Code (CPC).

PURPLE – Code Sections designated in purple are indirect code requirements as standards referenced by the CBSC. These include requirements associated with Board of Pharmacy regulations Title 16 §1735 & §1751 and USP <797> & <800>. Although not direct requirements, they are referenced by the CBSC and will need to be in compliance with those regulations for licensure by the Board of Pharmacy and/or for CMS Sterile Compounding Pharmacies survey compliance.

BLUE – Items designated in blue are strongly recommended items and/or practical support of submitted project programmatic requirements.

BLACK – Black text is generally provided for reference and context.

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 California Administrative Code section 7-115.

III. DEFINITIONS

Ante-area: means 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. [1735.1(a)]

Beyond use date (BUD): means 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). [1735.1(b)]

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

Biological Safety Cabinet (BSC): means 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). [1735.1(c)]

> 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: means 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.

[1735.1(e)] 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 purposed of this guide. [USP <797>]

Compounding Aseptic Containment Isolator (CACI): means 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. [1735.1(f)]

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): means 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. [1735.1(g)]

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: means 20 degrees to 25 degrees C (68 degrees to 77 degrees F). [1735.1(j)]

Displacement airflow method: means 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. [1735.1(m)]

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

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

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

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

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. [1735.1(r)] 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 Air Flow 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 a unidirectional HEPA-fileted airflow. An LAFW shall not be used for the manipulation of hazardous drugs (HD's). [USP 797 & USP 800]

Parenteral: means 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. [1735.1(w)]

Personal protective equipment (PPE): means 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. [1735.1(x)]

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

Primary Engineering Control (PEC or C-PEC): means 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. [1735.1(ab)]

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: means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA. [1735.1(ad)]

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): means 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. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations. [1735.1(af)]

(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).

(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), the assigned BUD shall comply with section 1751.8(a-b) or (d).

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

IV. TITLE 16, DIVISION 17 CODE REFERENCES – SELECT EXCERPTS

ARTICLE 4.5

1735.6. COMPOUNDING FACILITES AND EQUIPMENT

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

ARTICLE 7. STERILE COMPOUNDING

1751. STERILE COMPOUNDING; COMPOUNDING AREA; SELF-ASSESSMENT

(a) Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.

(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:

(1) Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.

(2) Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within one meter of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

(4) There shall be a refrigerator and, where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

1751.4. FACILITY and EQUIPMENT STANDARDS for STERILE COMPOUNDING

(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, worktable surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, worktable surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic

containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

1751.5. STERILE COMPOUNDING ATTIRE

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) Personal protective equipment must be donned and removed in an ante-area or immediately outside the segregated compounding area. (Note: Per USP 800, for HD compounding, the outermost gown, glove and booties should be removed before exiting the Clean/Buffer Room and before entering the Ante Area/Room.)

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

(5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

V. TITLE 24, PARTS 2, 3, 4 and 5 CODE REFERENCES – SELECT EXCERPTS

PART 2: CALIFORNIA BUILDING CODE

1224.19 PHARMACEUTICAL SERVICE SPACE
…The pharmacy room or service space shall conform to the requirements of §1751, Article 7, Division 17, Title 16, California Code of Regulations as enforced by the California Board of Pharmacy.

1224.19.1.1 Handwashing fixture. *Handwashing fixture(s) shall be provided within each separate room where open medication is handled, or in an anteroom, or immediately outside the room where open medication is handled, still within the pharmaceutical service space.*

> ***Exception:*** *ISO Class 5 sterile preparation areas (e.g. chemotherapy and intravenous solutions) and their ISO Class 7 buffer area(s) shall not contain sources of water (sinks) or floor drains. However, the anteroom to the buffer area shall have a hand-washing fixture regardless of its intended ISO Classification (i.e. Class 7 or Class 8). Reference: U.S. Pharmacopeia (USP) 797 Pharmaceutical Compounding – Sterile Preparations.*

1224.19.1.2 Location. *Provide for immediate accessibility to staff toilet rooms and lockers (toilet room is not required in satellite pharmacy if other staff facilities are available nearby).*

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1250.1 Application. *This section applies to pharmacies listed in Section 1.4.1 regulated by the Department of Consumer Affairs.*

1250.2 Restrooms. *A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.*

1250.3 Sink. *All pharmacies shall be equipped with a sink within the pharmacy for pharmaceutical purposes. The sink shall be supplied with hot and cold running water.*

1250.4 Compounding area for parenteral solutions. *The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:*

1. *1. In accordance with Federal Standard 209 (b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100 HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.*

2. *Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.*

3. *The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions.*

4. *A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.*

5. *Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:*

   5.1 An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

   5.2 An ISO class 5 cleanroom.

   5.3 A barrier isolator that provides an ISO class 5 environment for compounding.

   Note: For additional pharmacy mechanical standard requirements, see Chapter 5, California Mechanical Code.

PART 3: CALIFORNIA ELECTRICAL CODE

517.33 Critical Branch.

(A) Task Illumination and Selected Receptacles. *The critical branch of the essential electrical system shall supply power for task illumination, fixed equipment, selected receptacles, and special power circuits serving the following areas and functions related to patient care:*

(3) Patient care areas - task illumination and selected receptacles in the following:

b. Medication preparation areas
c. Pharmacy dispensing areas

517.34 Equipment Branch Connection to Alternate Power Source. *The equipment branch shall be installed and connected to the alternate power source such that the equipment described in 517.34(A) is automatically restored to operation at appropriate time-lag intervals following the energizing of the essential electrical system. Its arrangement shall also provide for the subsequent connection of equipment described in 517.34(B). [99:6.4.2.2.5.2]*

(B) Equipment for Delayed Automatic or Manual Connection. *The following equipment shall be permitted to be arranged for either delayed automatic or manual connection to the alternate power source:*

(1.1) [OSHPD 1 & 4] Heating, ventilating and cooling equipment as required by the California Mechanical Code.

(7) Controls for equipment listed in 517.34.

PART 4: CALIFORNIA MECHANICAL CODE

321.4 *All supply, return, and exhaust fans required to maintain the positive and negative air balances as required in Table 4-A.*

321.5 *All control components and control systems necessary for the normal operation of equipment required to have essential electrical power.*

407.4.1 *Design of the ventilation system shall provide air movement that is generally from clean to less clean areas.*

502.2.1 *Environmental Air Ducts. Environmental air duct exhaust shall terminate not less than 3 feet (914 mm) from a property line, 10 feet (3048 mm) from a forced air inlet, and 3 feet (914mm) from openings into the building. Environmental exhaust ducts shall not discharge onto a public walkway.*

502.2.2 *Product Conveying Ducts. Ducts conveying explosive or flammable vapors, fumes, or dusts shall terminate not less than 30 feet (9144 mm) from a property line, 10 feet (3048 mm) from openings into the building, 6 feet (1829 mm) from exterior walls or roofs, 30 feet (9144 mm) from combustible walls or openings into the building that are in the direction of the exhaust discharge, and 10 feet (3048 mm) above adjoining grade.*

Other product-conveying outlets shall terminate not less than 10 feet (3048 mm) from a property line, 3 feet (914mm) from exterior walls or roofs, 10 feet (3048 mm) from openings into the building, and 10 feet (3048 mm) above adjoining grade.

505.0 Product-Conveying Systems.

505.1 General. *A mechanical ventilation or exhaust system shall be installed to control, capture, and remove emissions generated from product use or handling where required in accordance with the building code or fire code and where such emissions result in a hazard to life or property. The design of the system shall be such that the emissions are confined to the area in which they are generated by air currents, hoods, or enclosures and shall be exhausted by a duct system to a safe location or treated by removing contaminants. Ducts conveying explosives or flammable vapors, fumes, or dusts shall extend directly to the exterior of the building without entering other spaces and shall not extend into or through ducts and plenums.*

Exception: Ducts conveying vapor or fumes having flammable constituents less than 25 percent of their Lower Flammability Limit (LFL) shall be permitted to pass through other spaces.

505.1.1 Incompatible Materials*. Incompatible materials shall not be conveyed in the same exhaust system. | [NFPA 91:4.1.2]*

505.1.2 Flammability Limit. *In systems conveying flammable vapors, gases, or mists, the concentration shall not exceed 25 percent of the lower flammability limit (LFL).*

Exception: Higher concentrations shall be permitted where the exhaust system is designed and protected in accordance with the Standard on Explosion Prevention Systems in Chapter 1 7, using one or more of the following techniques:

(1) Combustible concentration reduction
(2) Oxidant concentration reduction
(3) Deflagration suppression
(4) Deflagration pressure containment [NFPA 91:4.1.3, 4.1.3. 1]

Contaminated air shall not be recirculated to occupied areas unless contaminants have been removed. Air contaminated with explosive or flammable vapors, fumes, or dusts; flammable or toxic gases; or radioactive material shall not be recirculated.

***505.1.3 Mechanical Ventilation**. A mechanical ventilation system shall be interlocked to operate with the equipment used to produce vapors, fumes, or dusts that are flammable or hazardous.*

***505.2 Penetrations**. Fire dampers shall not be installed where the material being exhausted is toxic and where a risk evaluation indicates that the toxic hazard is more than the fire hazard. Exhaust ducts shall not pass through fire walls. [NFPA 91:4.1.10, 4.1.11]*

***505.3 Product-Conveying Ducts Classification.** Product-conveying ducts shall be classified according to their use, as follows:*

> *Class 1 - Ducts conveying nonabrasives, such as smoke, spray, mists, fogs, noncorrosive fumes and gases, light fine dusts, or powders.*
>
> *Class 2 - Ducts conveying moderately abrasive particulate in light concentrations, such as sawdust and grain dust, and buffing and polishing dust.*
>
> *Class 3 - Ducts conveying Class 2 materials in high concentrations and highly abrasive materials in low concentrations, such as manganese, steel chips, and coke.*
>
> *Class 4 - Ducts conveying highly abrasive material in high concentrations.*
>
> *Class 5 - Ducts conveying corrosives, such as acid vapors.*

***505. 7 Pharmacies** - CompoundingArea ofParenteral Solutions. [CA - Board ofPharmacy] The pharmacy shall have a designated area for the preparation ofsterile products for dispensing which shall he ventilated in a manner not interfering with laminar airflow.*

Note: For additional pharmacy building standard requirements, see Chapter 12, California Building Code.

> ***505. 7.1 Pharmacies** - Laminar Flow Biological Safety Cabinet. [CA - Board of Pharmacy] In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II TypeA or Class II TypeB vertical laminar airflow hood with bag in - bag out*

design. The pharmacy must ensure that contaminated air plenums that are underpositive air pressure are leak tight. Note: For additional pharmacy building standard requirements, see Chapter 12, California Building Code.

512.1 Dampers. *Dampers shall not be installed in exhaust ducts or exhaust duct systems. [NFPA 96:9.1.1]*

PART 5: CALIFORNIA PLUMBING CODE

416.0 Emergency Eyewash and Shower Equipment.

416.1 Application. *Emergency eyewash and shower equipment shall comply with ISEA Z358. 1.*

416.2 Water Supply. *Emergency eyewash and shower equipment shall not be limited in the water supply flow rates. Flow rate, discharge pattern, and temperature of flushing fluids shall be provided in accordance with ISEA Z358.1 based on the hazardous material.*

416.3 Installation. *Emergency eyewash and shower equipment shall be installed in accordance with the manufacturer's installation instructions.*

416.4 Location. *Emergency eyewash and shower equipment shall be located on the same level as the hazard and accessible for immediate use. The path of travel shall be free of obstructions and shall be clearly identified with signage.*

416.5 Drain. *A drain shall not be required for emergency eyewash or shower equipment. Where a drain is provided, the diseharge shall be in accordance with Section 811.0.*

VI. USP <797> – SELECT REQUIREMENTS for STERILE COMPOUNDING

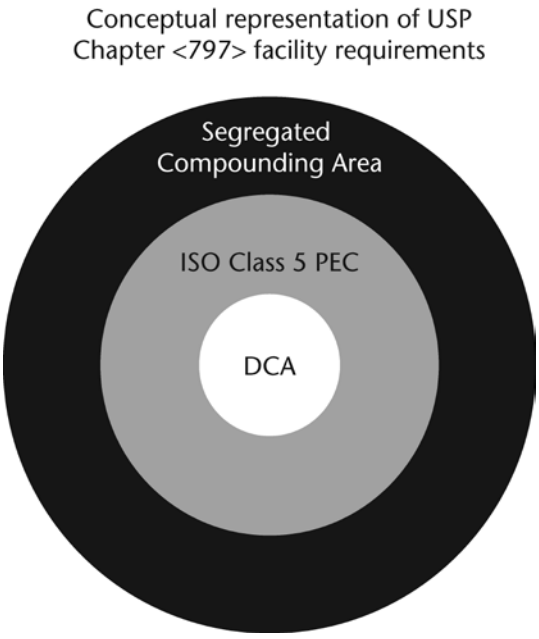


Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

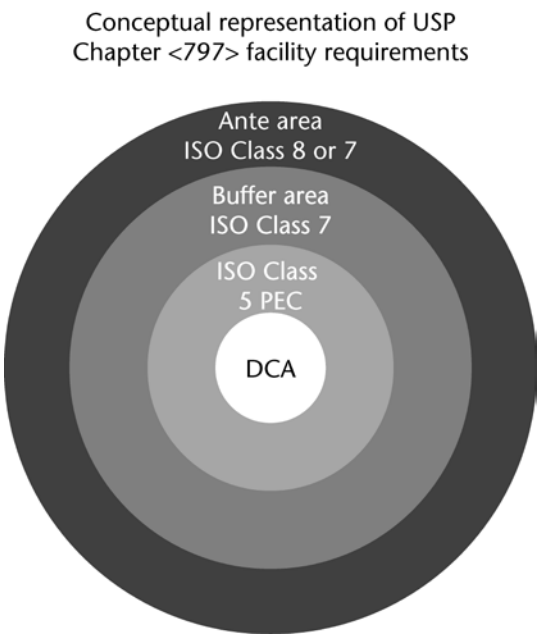


Figure 2. Conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level.

DCA = Direct Compounding Area

VII. USP <800> – SELECT REQUIREMENTS for HAZARDOUS DRUG STERILE COMPOUNDING

5.2 HD STORAGE

HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.

Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.

Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator should be considered.

5.3 COMPOUNDING

Sterile hazardous drugs (HD) must be compounded within a C-PEC located in a C-SEC. The C-SEC used for sterile compounding must:

- Be externally vented
- Be physically separated (i.e. a different room from other preparation areas)
- Have minimum air exchange rate of at least 30 ACPH / 12 ACPH for segregated environment
- Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas

The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC, or if it is used for sterile compounding. Refer to USP <800> regarding loss of power or shut-down.

A sink and eyewash must be readily available, however, restrictions regarding water sources and drains apply if placed within the C-SEC. Their placement must prohibit interference with required ISO classifications.

All water sources and drains must be located at least 1 meter away from the C-PEC.

(Refer to to USP <800> for further requirements regarding environments that compound both nonsterile and sterile HDs.)

5.3.2 STERILE COMPOUNDING

In addition to the requirements of USP <800>, sterile compounding must also meet the requirements of USP <797>.

All C-PECs used for sterile HDs must be externally vented and provide an ISO Class 5 or better air quality. Refer to USP <800> for specific types of allowable and prohibited C-PECs.

The C-PEC must be located in a C-SEC, which is to also be externally vented and may be either:

- An ISO Class 7 buffer room with an ISO Class 7 ante-room:
    - The buffer room must have fixed walls, HEPA-filtered supply air, and meet the C-SEC requirements in Table 3, below. It shall be negative pressure relative to the ante-room.
    - The ante-room must have fixed walls, HEPA-filtered supply air and maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas. It shall meet air quality of ISO Class 7 or better, with a minimum of 30 ACPH. A required sink capable of hand-washing up to the elbows must be placed a minimum of one meter away from the entrance to the HD buffer room.
- An unclassified containment segregated compounding area (C-SCA) with limitations on the BUDs per USP <797>:
    - Must have fixed walls, and meet the C-SCA requirements in Table 3, below.
    - A hand-washing sink capable of washing up to the elbows must be placed at least one meter from the C-PEC and may be either inside the C-SCA or directly outside the C-SCA.
    - Only applicable to low-risk and medium-risk HD CSPs, and must not exceed the BUDs described in USP <797> for CSPs prepared in a segregated compounding area.

Table 3. Engineering Controls for Sterile HD Compounding

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 buffer room with an ISO Class 7 ante-room	*Externally Vented * Examples: Class II BSC or CACI	*Externally vented * 30 ACPH * Negative pressure between 0.01 and 0.03 inches of water column relative adjacent areas	As described in USP <797>
Unclassified C-SCA	*Externally Vented * Examples: Class II BSC or CACI	*Externally vented * 12 ACPH * Negative pressure between 0.01 and 0.03 inches of water column relative adjacent areas	As described in USP <797> for CSPs prepared in a segregated compounding area

VIII. OSHPD SUBMITTAL INSTRUCTIONS

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.

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 *Checklist* portion of this guide in the following Appendix is provided to assist the design professional in responsible charge [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 to assist CDPH in their review of pharmacy projects. This checklist is required for all OSHPD submittals for sterile compounding projects.

5. OSHPD projects that were created with an open project number via the eServices Portal must have a functional program, as described in *Checklist* item 3, and either a preliminary or final submittal received by the Office within 10 days. Open OSHPD project numbers without an accompanying submittal within 10 days of the creation of that number will be cancelled. The Board of Pharmacy will be notified of project number cancellations.

6. Facilities intending to use **mobile units** as an interim solution to maintaining compounding operations during construction must submit:

    a. An application to the Board of Pharmacy with an accompanying functional program, in order 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. BoP requires a ramp or lift to the trailer to provide 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 clean room 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.

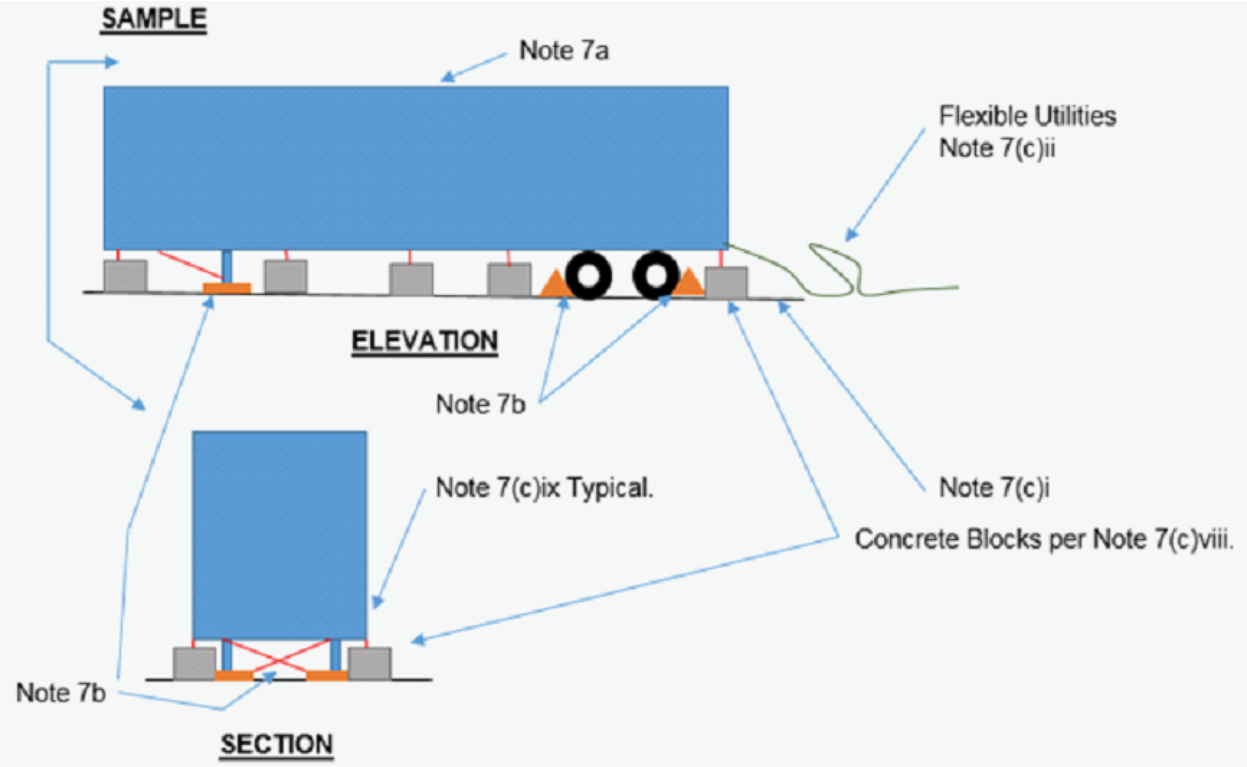
Please note that OSHPD approval is for construction identified in PIN 34. The Owner is to secure additional **separate** approvals as follows:

- 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 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 Permit – 180 day max*). *Extensions may be granted.
iv. 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.
v. 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.
vi. 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.
vii. Friction resisting force may be calculated by multiplying the static coefficient of friction by the operating weight of trailer plus the least weight of counter weights on one side of the trailer.
viii. Overturning may be resisted utilizing counter weights 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.

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 PROJECT #: _____ **DATE** _____

FACILITY NAME: _____ **FACILITY #** _____

[OSHPD-1]

STERILE COMPOUNDING PHARMACIES

CHECKLIST

CLEAR FORM

Compliance Guide for CBSC Requirements
Title 16 §1735 & §1751, and UPS <797> & <800>
ARCHITECTURAL, MECHANICAL & ELECTRICAL COMMENTS

PROJECT SCOPING			
		Compliance	
			Sheet/Det
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. Sterile compounding must be located within a compliant licensed hospital building. This means, such service(s) shall be located 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. Refer to 1751(B) and/or 1735.1(af) for restrictions regarding placement. Remote placement will be subject to BoP and CDPH approval.	☐	
3.	**Functional Program:** 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 also include:

a) Overall floorplan identifying all department boundaries and the location of the project on the floor.

b) Enlarged floorplan of the compounding spaces/areas and HD 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.

GENERAL REQUIREMENTS – ALL ENVIRONMENT TYPES

	Compliance	
		Sheet/Det
5. Compounding Work Station *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 [1751.4(d) & (e)]	☐	
(i) If not built against the wall, all sides of the work station 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.	☐	
c) Accessibility – Employee Work Station [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. [1751.4(f)] ☐

f) All PEC stands/bases are required to be anchored and braced per ASCE 7-10, Sections 13.3, 13.4 and CBC Part 2, Section 1616A. Such anchorage and bracing shall be substantiated by engineering calculations and shall be submitted with the design/construction documents. ☐

Alternatively, OSHPD OPM(s) for the PEC Stand/bases may be referenced on the design documents in order to satisfy this requirement.

g) 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. ☐

6. Buffer Room / Cleanroom (SEC) *and* Buffer Area / Clean Area (SCA):

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 Air Flow - Designated area for the preparation of sterile products shall be ventilated in a manner not interfering with laminar airflow. [CMC 505.7 & 1751(b)] ☐

a. Air Supply - Air must be introduced through ceiling HEPA units. [USP <797> *Facility Design and Environmental Controls*] ☐

b. Low Return/Exhaust – Return and exhaust grilles should be low on the wall, creating a top-down dilution of area air with HEPA-filtered make-up air. Ceiling mounted returns are not recommended. [USP <797> *Facility Design and Environmental Controls*] ☐

i. One return/exhaust should be placed near the refrigerator's compressor. ☐

(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 4A for IV Prep, Pharmacy/Medicine)] ☐

b. Controls [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 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to be maintained for personnel. [1751.4(k)] ☐

c) Sealed-tight room with automatic/self-closing doors, similar to an Airborne infection isolation room [*1224.4.4.1.3*], except for Segregated Buffer Areas. ☐

(i) Controlled door operators shall be readily openable in the egress direction without the use of a key or special knowledge or effort. [1010.1.9] ☐

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 1010.1.4.2 and 11B-404.3. ☐

(iii) Special purpose horizontal sliding, accordion or folding doors shall comply with the requirements of CBC 1010.1.4.3 and 11B-404.2.9. ☐

d) Finishes – Non-porous and cleanable surfaces, ceilings, walls, and floors, subject to wet cleaning [1751.4(d)] – The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and non-shedding. The surfaces shall be resistant to damage by disinfectant agents. [USP <797>] Organic material or plastic laminate over organic core not acceptable on counters, casework, doors, etc. ☐

(i) 1250.4(2), 1735.6(e)(4), 1751.4(d) – Smooth, seamless, impervious, and non-shedding ☐

(ii) *1224.4.11.1.3 [Floor finishes] Wet Cleaning – not affected by cleaning solutions*. ☐

(iii) *1224.4.11.2.2 [Floors and Wall Bases] Wet Cleaning – coved. monolithic without joints (similar to Operating Room).* ☐

(iv) *1224.4.11.3 Wall finishes (similar to Sterile Supply) – washable, smooth, and able to withstand cleaning with chemicals.* ☐

(v) *1224.4.11.4.1 Ceiling finishes (restricted area) – monolithic, scrubbable, and able to withstand cleaning and/or disinfecting chemicals.* [USP <797>] Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. ☐

(vi) [USP <797>] Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. ☐

(vii) [USP <797>] Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility. ☐

(viii) [USP <797>] 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. ☐

(ix) [USP <797>] The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. ☐

e) Sources of water (sinks) or floor drains are not permitted in the Buffer Room/Area. [1224.19.1.1, 1250.4, 1751(b)(3), USP <797>] ☐

f) Eyewash station - Required wherever there is compounding and mixing. May either be placed in Buffer Room or Ante-area. When placed in the Buffer Room, it should be located just inside the door and at least one meter from the rim of the sink to the (PEC). No drains are permitted within the Buffer Room/Area, thus the eyewash must be "dry", unless in use. (PEC). [CPC 416.0, 1735, 1751(b)(3), USP <800>, & OSHA 1910.151(c)] ☐

(i) When considering placement of eyewash within the Buffer Room, consideration should be given to weekly testing requirements. ☐

(ii) Water temperature to be tepid. ☐

(iii) Eyewash location to be in an accessible location that requires no more than 10 seconds to reach – refer to ISEA Z358.1.

g) Refrigerator on Essential Power required within the Buffer Room or Ante-area [1751(b)(4)]. ☐

(i) Provide critical branch power source. [517(A)(9)] ☐
(ii) If used for HD storage, refrigerator must be in negative pressure room [USP 800, 5.2]. ☐
(iii) Pass-through refrigerators are not permitted between a HD Buffer Room and any adjacent space. ☐

h) Dedicated environmental services (cleaning materials & supplies for Buffer Room & Anteroom) [1751.4(d)(4)] 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. [USP <797>] ☐

i) Accessibility – Employee Work Station [11B-203.9] – Provide common use circulation, turning area & door clearance. ☐

j) 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] ☐

7. 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) 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 4A for IV Prep, Pharmacy/Medicine)] ☐

b. Controls [CEC 517.34(B)(7), CMC 321.5] ☐

(ii) 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 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to be maintained for personnel. [1751.4(k)] ☐

c) Donning and Doffing Area

(iii) Refer to processes in 1751.5 *Sterile Compounding Attire*, and USP <797> *Garb and Glove Requirements* for non-Hazardous environment donning and doffing. ☐

(iv) Refer to processes in 1751.5 *Sterile Compounding Attire*, USP <797>, and USP <800>, *Section 6 Personal Protective Equipment* for Hazardous environment donning and doffing. ☐

- Seating and/or other provisions for gowning at Demarcation Line to restricted area ☐
- Storage for sterile gowns, gloves & booties ☐
- Storage for contaminated gown, gloves & booties ☐

d) Finishes – Non-porous 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.

(i) 1250.4(2), 1735.6(e)(4), 1751.4(d) – Smooth, seamless, impervious, and non-shedding ☐

(ii) *1224.4.11.1.3 [Floor finishes] Wet Cleaning – not affected by cleaning solutions* ☐

(iii) *1224.4.11.2.2 [Floors and Wall Bases] Wet Cleaning – coved. monolithic without joints (similar to Operating Room).* ☐

(iv) *1224.4.11.3 Wall finishes (similar to Sterile Supply) – washable, smooth, and able to withstand cleaning with chemical* ☐

(v) *1224.4.11.4.1 Ceiling finishes (restricted area) – monolithic, scrubbable, and able to withstand cleaning and/or disinfecting chemicals.* ☐

e) Scrub Sink (or handwashing fixture capable for scrubbing to elbows) [1224.19.1.1, 1751.(b)(3), & 797-3.2] ☐

f) Eyewash Station – Required wherever there is compounding and mixing. May either be placed in Buffer Room with restrictions as noted above, or Ante-area. [1751(b)(3), 797-5.3, CPC 416.0, OSHA 1910.151(c)] ☐

(i) Water temperature to be tepid. ☐

(ii) Eyewash location to be in an accessible location that requires no more than 10 seconds to reach – refer to ISEA Z358.1. ☐

g) Refrigerator on Essential Power required within the Buffer Room or Ante Room [1751(b)(4)]. Refrigerator to be in Ante area for Segregated environment. ☐

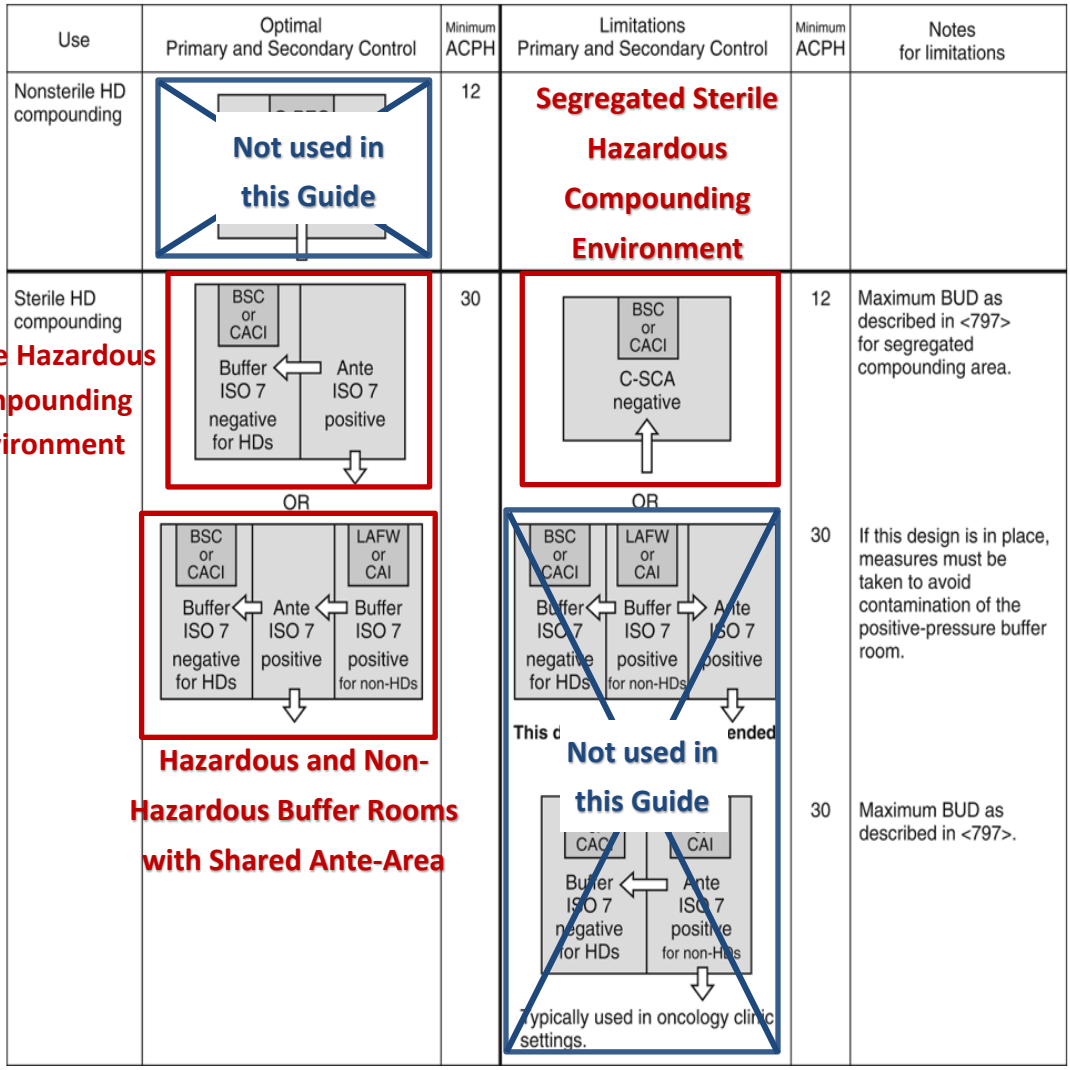
(i) Provide critical branch power source. [CEC 517(A)(9)] ☐
(ii) If used for HD storage, refrigerator must be in negative pressure room [USP 800, 5.2]. ☐
(iii) Pass-through refrigerators are not permitted between a HD Buffer Room and any adjacent space. ☐

h) 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. [1751.4(d)(4)] Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. [USP <797>]		
i)	Accessibility – Employee Work Station [CBC 11B-203.9] – Common use circulation, turning area & door clearance.	☐	
j)	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]	☐	
	(v) Controlled door operators, if provided, shall be readily openable in the egress direction without the use of a key or special knowledge or effort. [CBC 1010.1.9]	☐	
	(vi) Exit travel distance limitations shall apply. Travel distance shall be in compliance with CBC Section 1017.	☐	
k)	Automatic/self-closing doors, if provided, shall meet the requirements listed in *Checklist* item 6c.	☐	

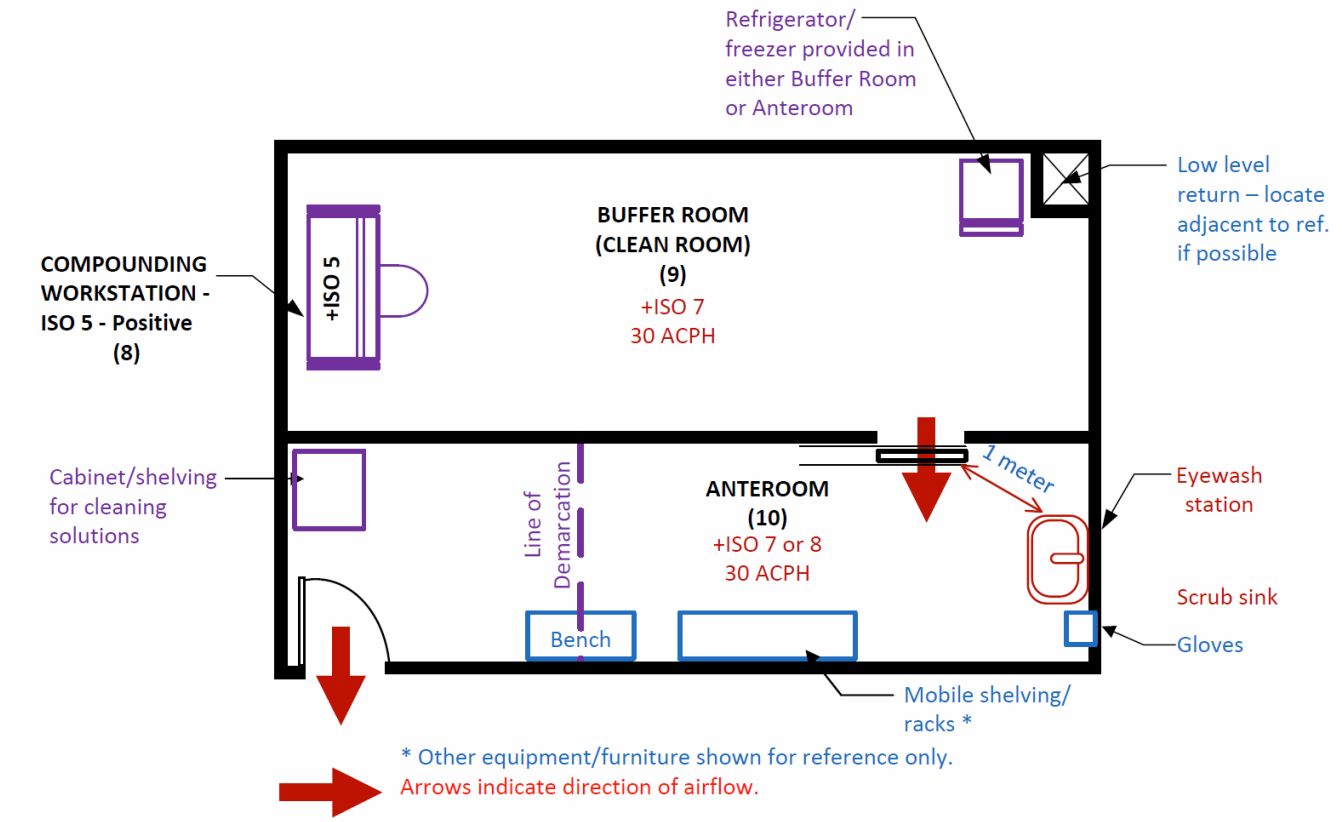
GENERAL ROOM RELATIONSHIPS – VARIOUS ENVIRONMENT TYPES

The following chart, referenced from <USP 800> regulations, provides a high-level overview of the required relationships between the various environments, and their associated allowable Beyond Use Dates (BUDs).



The illustrations on the following pages represent specific environment types to highlight unique requirements pertinent to the 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.

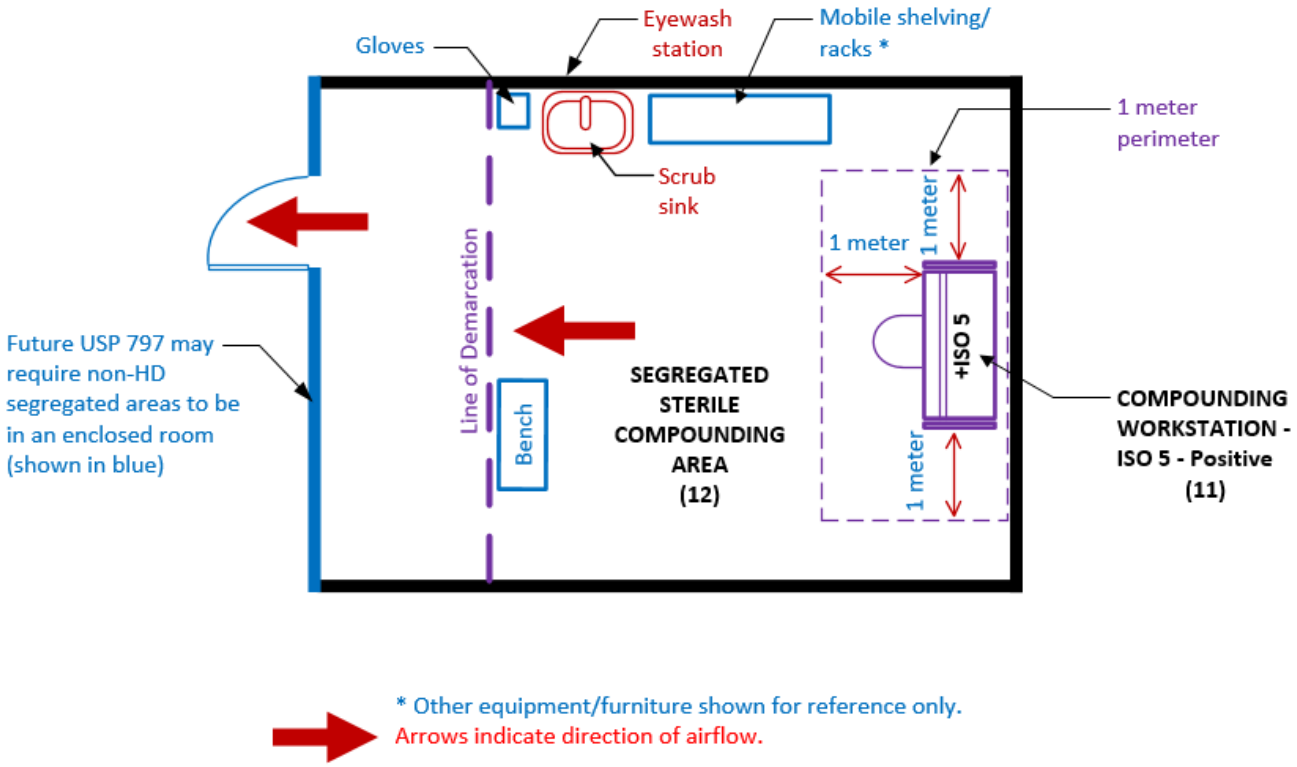
SPECIFIC ENVIRONMENT TYPE – STERILE NON-HAZARDOUS



	Compliance	
		Sheet/Det
8. Compounding Work Station (PEC):		
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." [USP 797-4.1]. Coordinate with Pharmacist for specific type of PEC.	☐	
(i) LAFW [USP <797>]	☐	
(ii) CAI [1735.1(g)]	☐	
9. Buffer Room / Cleanroom (SEC):		
a) Meets the general requirements of *Checklist* Item 6, above.	☐	
b) ISO 7 - Positive Pressure HEPA-filtered [USP <797>4.1].	☐	
(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 ACHP). [USP <797> Facility Design and Environmental Controls]	☐	

(ii)	30 ACPH minimum [USP <797> Facility Design and Environmental Controls]	☐	
(iii)	Positive 0.02 to 0.05 in water column (w.c.) vs. all adjacent areas/spaces. [1735.1(e)(1), USP <797> Pressure Differential Monitoring]	☐	
(iv)	Continuous monitoring. [USP <797> Pressure Differential Monitoring]	☐	
10.	**Ante-area:**		
a)	Meets the requirements of *Checklist* Items 6a and 7, above.	☐	
b)	ISO Class 8 or better - <u>Positive Pressure</u> HEPA-filtered [1735.1(a) & USP <797> Facility Design and Environmental Controls]	☐	
(i)	30 ACPH minimum [USP <797> Facility Design and Environmental Controls]	☐	
(ii)	Continuous monitoring [USP <797> Pressure Differential Monitoring]	☐	

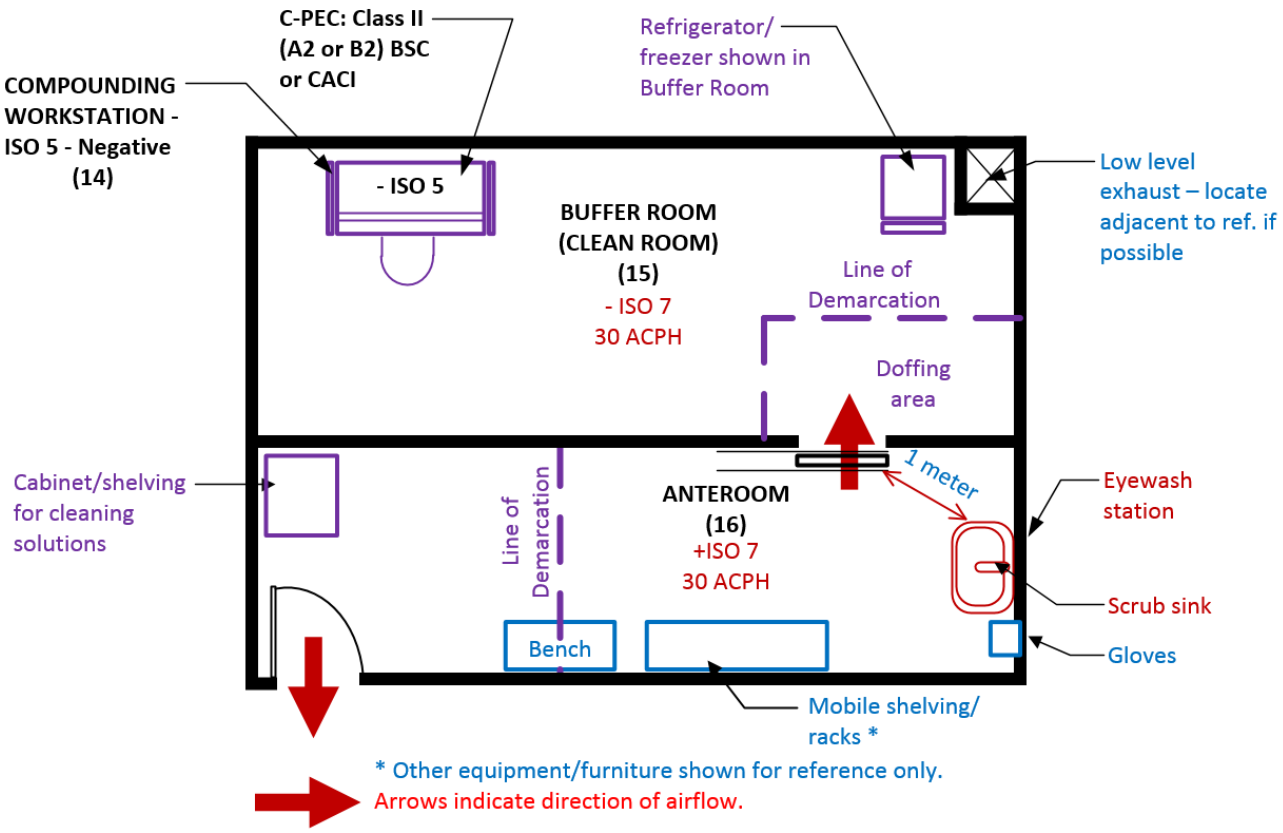
SPECIFIC ENVIRONMENT TYPE - SEGREGATED STERILE NON-HAZARDOUS (Limited to Beyond Use Date BUD < 12 hours)



	Compliance	
		Sheet/Det
11. Compounding Work Station (PEC):		
a) Meets requirements of *Checklist* Item 8, above.	☐	
(iii) LAFW [USP <797>]	☐	
(iv) CAI [1735.1(g)]	☐	
12. Segregated Sterile Compounding Area (SCA):		
a) Meets the general requirements of *Checklist* Item 6 & 7, above, except as noted herein.	☐	
b) No ISO Class required - Unclassified.		
(i) Maintain airflows from clean to less clean areas. [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. [1735.1(af), USP<797>]	☐	

d) The 1 meter perimeter around PEC shall not contain the sink. [1735.1(af), USP<797>] See item 6f for eyewash requirements.	☐	
e) 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.	☐	
f) Item 6a)(i)a not required.	☐	
g) Item 6c not required.	☐	
h) Item 6d applicable within designated Segregated Compounding Area only.	☐	

SPECIFIC ENVIRONMENT TYPE – STERILE HAZARDOUS



	Compliance	
		Sheet/Det
14. Compounding Work Station (PEC):		
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. [CMC 505.7.1]	☐	
c) ISO Class 5 - Negative Pressure through non-turbulent, laminar-flow, HEPA-filtered "first air." [1735.6(e), 1751.4(g), USP <800> Appendix "A"] Must operate continuously. [USP <800>5.3]	☐	
(i) Biological Safety Cabinet (BSC) [1735.1(c)]	☐	
(ii) Containment Aseptic Compounding Isolator (CACI) [1735.1(f)]	☐	
d) Exhaust – 100% dedicated direct exhaust to exterior. Recommended one dedicated exhaust per each PEC. [1735.1(c), 1735.1(f) & 1735.6(e)(3), 1751.4(g) & USP 800-5.3].	☐	

(i) Termination of exhaust duct from HD PEC or HD buffer room shall be not less than 3 feet from a property line, 10 feet from a forced air inlet, and 3 feet from openings into the building. They shall not discharge onto a public walkway. [CMC 502.2.1] If the duct is conveying explosive or flammable vapors, fumes, or dusts it shall terminate not less than 30 feet from a property line, 10 feet from openings into the building, 6 feet from exterior walls or roofs, 30 feet from combustible walls or openings into the building that are in the direction of the exhaust discharge, and 10 feet above adjoining grade. Other product-conveying outlets shall terminate not less than 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. [CMC 502.2.2] ☐

(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. [CMC 505.1] ☐

(iii) Air contaminated with fumes, toxic gasses, or radioactive materials shall not be recirculated. [CMC 505.1.2] ☐

(iv) Exhaust fans shall be interlocked with PECs. [CMC 505.1.3] ☐

(v) Fire dampers shall not be installed where the material being exhausted is toxic. Exhaust ducts shall not pass through fire walls. [CMC 505.2] ☐

(vi) Class 5 ductwork required if corrosive vapors are being exhausted. [CMC 505.3] ☐

(vii) Dampers shall not be installed in exhaust ducts or exhaust duct systems. [CMC 512.1] ☐

15. Buffer Room / Cleanroom (SEC):

a) Hazardous drug compounding shall be completed in an externally vented physically separate room with fixed walls. [1735.6(e), USP <800>5.3, USP <800>5.3.2 for ISO Class 7 buffer room with ISO Class 7 ante-room] ☐

b) Meets the general requirements of *Checklist* Item 6, above. ☐

c) ISO 7 – <u>Negative</u> HEPA-filtered [USP 800-5.3.2]. ☐

(i) 30 ACPH minimum [1735.6(e)(1), USP <797>, USP <800>] ☐

(ii) <u>Negative</u> 0.01 to 0.03 in water column (w.c.) relative to the ante-room. [1735.6(e)(2), USP<797>, USP<800>5.3.2] ☐

(iii) Continuous monitoring. [USP <797> Pressure Differential Monitoring] ☐

d) Exhaust – 100% exhaust to exterior. [USP <800>, 1735.6(e)] ☐

(i) Termination of exhaust duct from HD PEC or HD buffer room shall be not less than 3 feet from a property line, 10 feet from a forced air inlet, and 3 feet from openings into the building. They shall not discharge onto a public walkway. [CMC 502.2.1] If the duct is conveying explosive or flammable vapors, fumes, or dusts it shall terminate not less than 30 feet from a property line, 10 feet from openings into the building, 6 feet from exterior walls or roofs, 30 feet from combustible walls or openings into the building that are in the direction of the exhaust discharge, and 10 feet above adjoining grade. Other product-conveying outlets shall terminate not less than 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. [CMC 502.2.2] ☐

(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. [CMC 505.1] ☐

(iii) Air contaminated with fumes, toxic gasses, or radioactive materials shall not be recirculated. [CMC 505.1.2] ☐

(iv) Exhaust fans shall be interlocked with PECs. [CMC 505.1.3] ☐

(v) Fire dampers shall not be installed where the material being exhausted is toxic. Exhaust ducts shall not pass through fire walls. [CMC 505.2] ☐

(vi) Class 5 ductwork required if corrosive vapors or being exhausted. [CMC 505.3] ☐

(vii) Dampers shall not be installed in exhaust ducts or exhaust duct systems. [CMC 512.1] ☐

16. Ante-area:

a) Must have fixed walls. [USP <800>5.3.2] ☐

b) Meets the requirements of *Checklist* Items 6a and 7, above. ☐

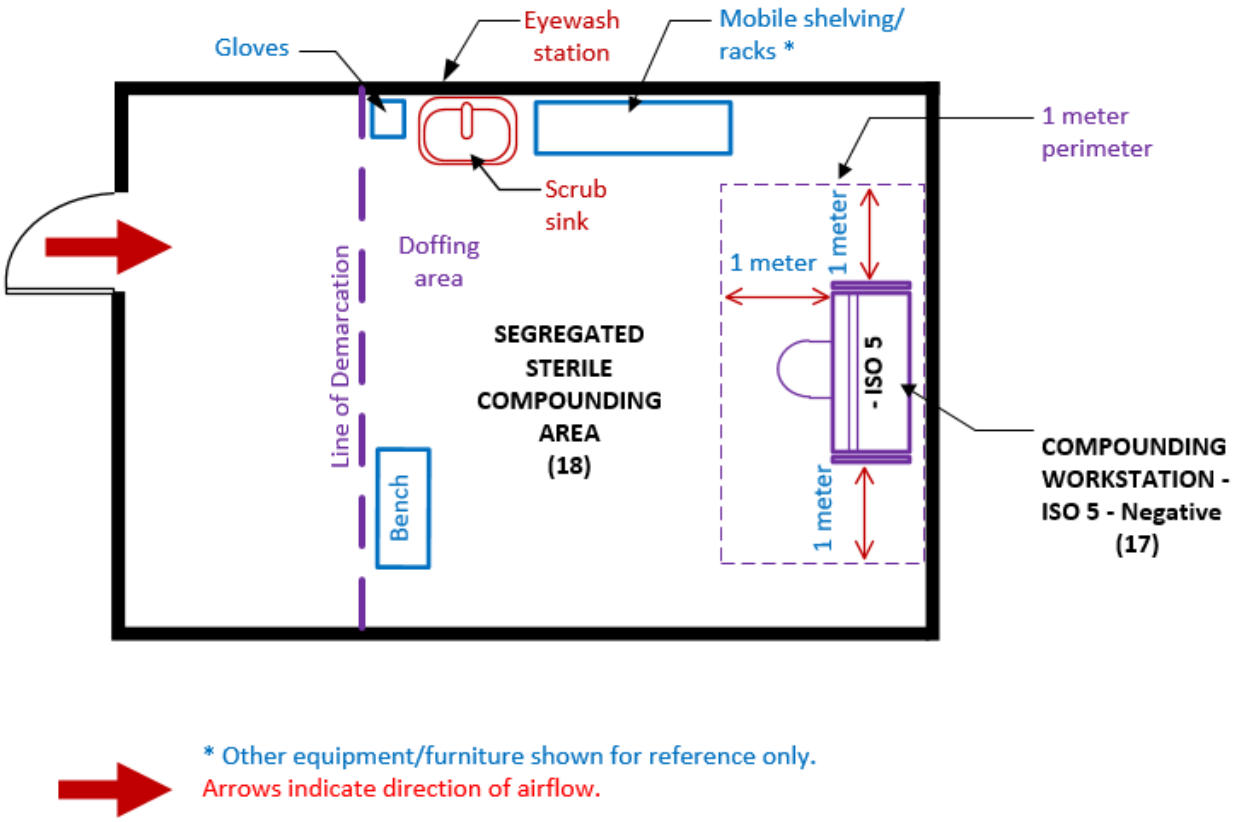
c) ISO Class 7 - <u>Positive Pressure</u> HEPA-filtered [1735.1(a), USP <800>5.3.2] ☐

(i) 30 ACPH minimum [USP <800>5.3.2] ☐

(ii) <u>Positive</u> at least 0.02 in water column (w.c.) relative to all adjacent unclassified areas. [USP<800>5.3.2] ☐

(iii) Continuous monitoring. [USP <797> Pressure Differential Monitoring] d) Handwash sink capable of washing up to elbows shall be at least one meter away from the door to the Buffer Room. [USP <800>5.3.2]	☐ ☐	

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



	Compliance	
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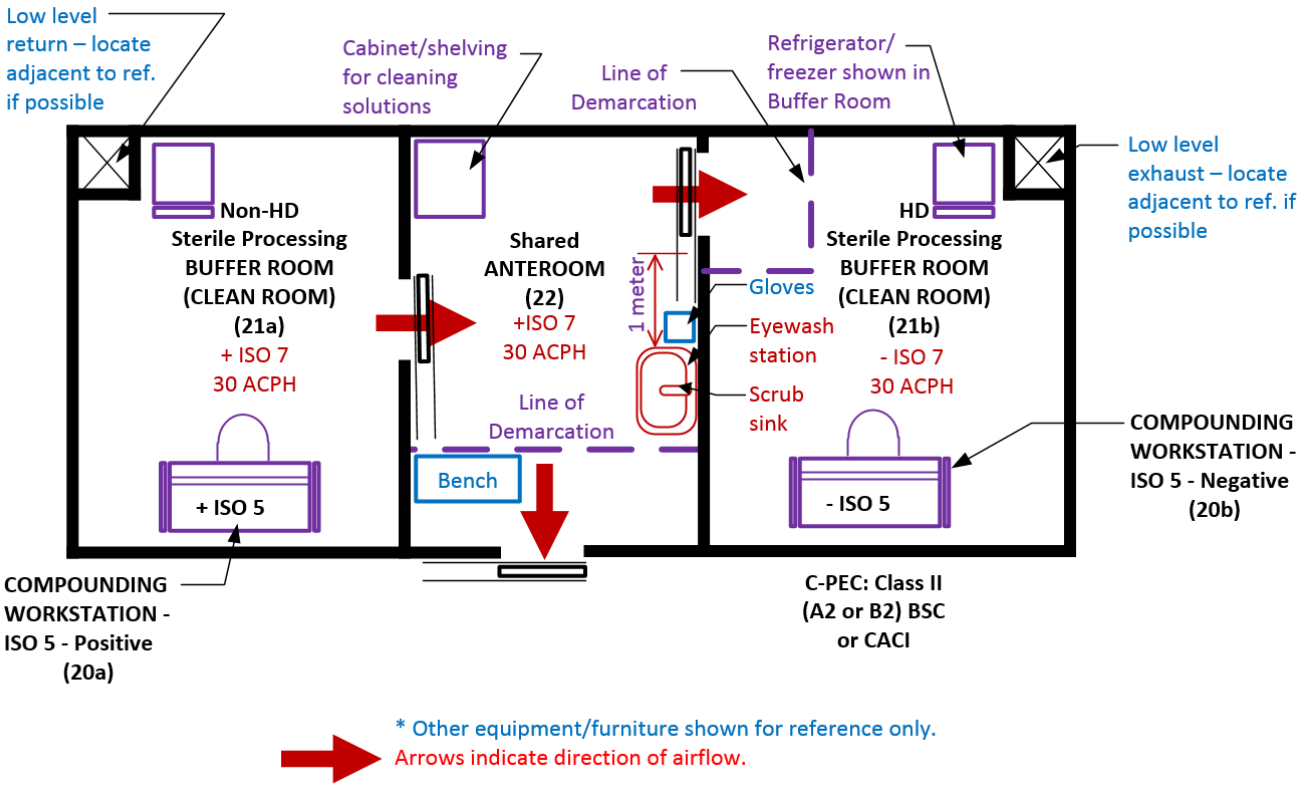
17. Compounding Work Station (PEC):		
a) Meets the requirements of *Checklist* item 14, above, except as noted herin.	☐	
b) ISO Class 5 - Negative Pressure through non-turbulent, laminar-flow, HEPA-filtered "first air." [USP 797-4.1]. Must operate continuously. [USP <800>5.3]	☐	
(i) Biological Safety Cabinet (BSC) [1735.1(c)]	☐	
(ii) Containment Aseptic Compounding Isolator (CACI) [1735.1(f)]	☐	
18. Segregated Sterile Compounding Area (SCA):		
a) Hazardous drug compounding shall be completed in an externally vented physically separate room with fixed walls. [1735.6(e), USP <800>5.3, USP <800>5.3.2 for C-SCA]	☐	

b) Meets the requirements of *Checklist* item 15, above, except as noted herein.	☐	
(i) Item 15 c) not required.	☐	
(ii) Item 6 a)(i)a not required.	☐	
(iii) Item 6 c) not required.	☐	
c) Unclassified – Negative pressure. [USP <800>5.3.2]	☐	
(i) 12 ACPH minimum [1735.6(e)(1), USP <797>, USP <800>]	☐	
(ii) Negative 0.01 to 0.03 in water column (w.c.) relative to all adjacent spaces. [1735.6(e)(2), USP<797>, USP<800>5.3]	☐	
(iii) Continuous monitoring. [USP <797> Pressure Differential Monitoring]	☐	
(iv) Maintain airflows from clean to less clean areas. [CMC 407.4.1]	☐	
d) Line of Demarcation shall be established to define Segregated Compounding Area if this area is not separated by a wall with a door. [1735.1(af), USP<797>]	☐	
e) The 1 meter perimeter around PEC shall not contain the sink. [1735.1(af), USP<797>] See item 6f for eyewash requirements.	☐	

SPECIFIC ENVIRONMENT TYPE - HAZARDOUS & NON-HAZARDOUS BUFFER ROOMS WITH SHARED ANTEROOM



	Compliance	
		Sheet/Det
20. Compounding Work Station (PEC):		
a) For non-hazardous compounding refer to *Checklist* item 8, 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 9, above.	☐	
b) For hazardous compounding refer to *Checklist* item 15, above.	☐	
22. Ante-area:		
a) Consideration should be given to separate dedicated Ante-areas for HD and Non-HD Buffer Rooms, so that contamination affecting one Ante-area allows the other to remain in use.	☐	

Pharmacy Summary Checklist

Appendix B

Facility:
OSHPD Number:
Date:

Provide simplified overall plan identifying all department boundaries and location of project on the floor ❑
Provide diagram (see sample attached) identifying all compounding components below ❑

General

Intended Compounded Sterile Products (CSP's) - check all that apply:

Non-Hazardous CSP's
❑ Low risk CSP's
❑ Medium risk CSP's
❑ High risk CSP's

Hazardous CSP's
❑ Low risk CSP's
❑ Medium risk CSP's
❑ High risk CSP's

❑ Radiopharmaceutical CPS's

Beyond Use Date (BUDs)

❑ Equal to or less than 12 hours
❑ Greater than 12 hours

Design supports the BUDs to be assigned? No Yes NR
Room names identified? No Yes NR
Pressure arrows (negative/positive). NA No Yes NR

Ante-area NA
Positive pressure to general environment (0.02 min)? NA No Yes NR
ISO 8 unless connected to HD buffer, then ISO 7. NA No Yes NR
ISO 7 then 30 ACPH. NA No Yes NR
Sink type and location (greater than 1 meter from entrance to HD buffer area). NA No Yes NR
Line of Demarcation. NA No Yes NR
Refrigerator(s). NA No Yes NR
Pass through's (if applicable). NA No Yes NR

Pharmacy Summary Checklist

Appendix B

Facility:
OSHPD Number:
Date:

Buffer Area NA
ISO 7 or better. NA No Yes NR
Positive pressure to ante-area (0.02 min). NA No Yes NR
30 ACPH minimum (no more than half from hoods). NA No Yes NR
Type(s) of Primary Engineering Control (PEC) Workstations (include cut sheets)? NA No Yes NR
Pressure monitoring devices noted. NA No Yes NR

Hazardous buffer area (C-SEC) NA
Externally vented, room and C-PEC. NA No Yes NR
ISO 7 or better. NA No Yes NR
Negative pressure to ante-area (-0.01 to -0.03). NA No Yes NR
30 ACPH minimum. NA No Yes NR
Type(s) of Primary Engineering Control (PEC) Workstations (include cut sheets)? NA No Yes NR
Does not include a pass-through refrigerator (not allowed). NA No Yes NR
Chemo PPE don/doff area inside the room, next to the entrance. NA No Yes NR
Refrigerator(s). NA No Yes NR
Pressure monitoring devices noted. NA No Yes NR

Segregated compounding area (non-hazardous) NA
Placed in an appropriate area of the hospital. NA No Yes NR
Area is defined. NA No Yes NR
Sink (greater than 1 meter from hood). NA No Yes NR

Segregated compounding area (C-SCA) (hazardous) NA
Enclosed by walls and a door. NA No Yes NR
Externally vented room and hood. NA No Yes NR
12 ACPH minimum. NA No Yes NR
Negative pressure to general area (-0.01 to -0.03). NA No Yes NR
Chemo PPE don/doff area inside the room, next to the entrance. NA No Yes NR
Sink (greater than 1 meter from hood). NA No Yes NR

One room with ante and buffer area, no dividing wall and door NA
Line of demarcation. NA No Yes NR
AF 40 ft/min, wall to wall and ceiling to floor, across the line. NA No Yes NR

CAI located in worse than ISO 7 NA
Does the hood meet the bullet points for location outside an ISO 7 buffer? NA No Yes NR

Pharmacy Summary Checklist

Appendix B

Facility:
OSHPD Number:
Date:

Hazardous drug storage area NA
Externally vented room. NA No Yes NR
Negative pressure. NA No Yes NR
12 ACPH. NA No Yes NR

NA=not applicable, No=does not meet standard, Yes=meets standard, NR=insufficient information to review

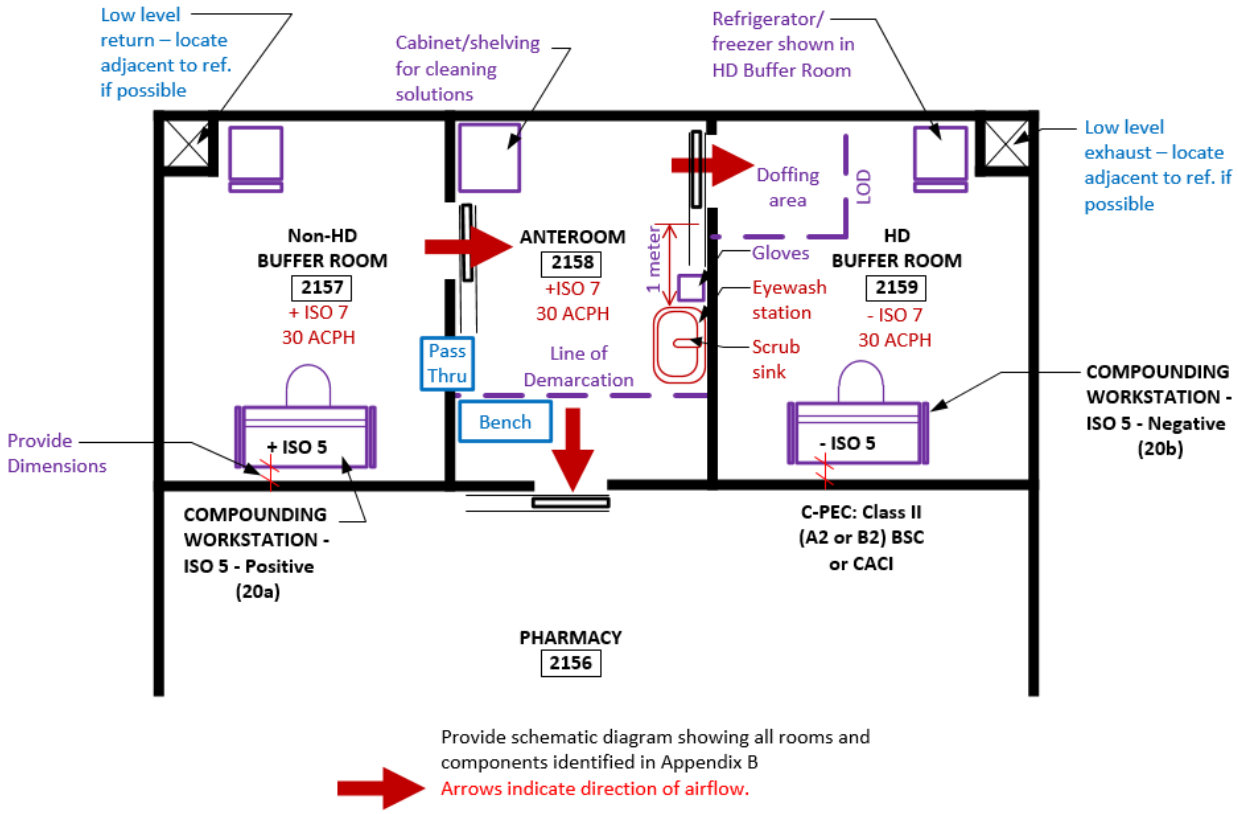
Pharmacy Summary Checklist

Appendix B

Facility:

OSHPD Number:

Date:



Provide schematic diagram showing all rooms and components identified in Appendix B

Arrows indicate direction of airflow.

SAMPLE ONLY

Appendix C

- ***Less than 100-bed Pharmacy Permit Exemption.*** *Hospitals 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. Exempt hospitals may purchase drugs at wholesale for administration and shall provide the following pharmacy service space:*
    - *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.*
        - *Reserved*
        - *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 immediately accessible to the area where medication(s) are handled.*
    - *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*