
OFFICE OF ENVIRONMENTAL HEALTH AND ENGINEERING TECHNICAL HANDBOOK
INDIAN HEALTH SERVICE
VOLUME III - HEALTH CARE FACILITIES DESIGN AND CONSTRUCTION
PART 21 - DESIGN CRITERIA AND STANDARDS

**CHAPTER 21-4.10 - DESIGN REQUIREMENTS FOR COMPOUNDED STERILE AND
HAZARDOUS DRUG PREPARATION AREAS**

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21-4.10.1 INTRODUCTION

A. Purpose

This chapter provides guidance on minimum requirements for the designing of IHS pharmacies to ensure safe and contamination free storage and processing of compounded sterile preparations (CSP) and hazardous drugs (HD).

B. Scope

This Section 10 of Chapter 21-4 applies to all new construction and renovation for IHS and Tribal health care facilities. This guidance addresses aspects of the built environment, e.g., architectural, mechanical, and electrical, etc., as these relate to the environmental conditions for compounding sterile preparations and storage and processing of hazardous drugs.

C. Background

In 2002, the Center's for Disease Control and Prevention (CDC) published a Morbidity and Mortality Weekly Report, which advised that "clinicians should consider the possibility of improperly compounded medications as a source of infection in patients." This recommendation from the CDC was the beginning of an increased focus to provide controlled environments and practices when compounding sterile preparations.

D. Definitions

Ante Area/Room - An International Standards Organization (ISO) 8 or better area/room where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating procedures are performed (United States Pharmacopeia (USP)-797-2008).

Biological Safety Cabinet (BSC) - A ventilated cabinet for protection of Compounded Sterile Preparations, personnel, product and/or the environment, which has an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection (USP-797-2008).

Buffer Area/Zone - An ISO 7 or better area/zone where the primary engineering control (PEC) is physically located (USP-797-2008).

Compounding aseptic containment isolator (CACI) - An environmental isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes (USP-797-2008).

Compounded Sterile Preparations (CSP)- A biologic, diagnostic, drug, nutrient, or pharmaceutical which is prepared according to the manufacturer's labeled instructions, contains non-sterile ingredients or uses non-sterile components/devices that need to be sterilized before use (www.pharmacyisolators.com).

Hazardous Drugs (HD)- A group of drugs that are associated with or suspected of causing adverse health effects. A current list of drugs commonly classified as "hazardous drugs" may be found at www.cdc.gov/niosh. Additional "hazardous drug" information and IHS requirements may be found at The Indian Health Manual (IHM) Part 3 - Professional Services, Chapter 27, "Controlling Occupational Exposure to Hazardous Drugs."

Laminar Air Flow Workbench (LAFW) - A controlled environment created by a high efficiency particulate air (HEPA) filter to retain airborne particles and microorganisms (Compounding Sterile Preparations, 2nd ed., Buchanan, Schneider).

Primary Engineering Control (PEC) - A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Examples include BSCs, CACIs and LAFWs (USP-797-2008).

21-4.10.2 GUIDELINES

A. General Design Criteria

- (1) When practical, locate air handling unit outside of pharmacy area to avoid dust/debris generation within pharmacy area during maintenance activities, e.g., filter replacement, etc.
- (2) For facilities that perform "Low" and/or "Medium" risk procedures, as defined in the USP 797-2008, an ante area or ante room shall be provided adjacent to the buffer room. Please see "Diagram 1 - Clean Room: Low & Medium Risk CSP's"
- (3) For facilities that perform "High" risk procedures, as defined in USP 797-2008, the buffer room shall be physically separated and adjacent to the ante room.
- (4) For CSP and hazardous drug buffer rooms/areas, the square footage should be as small as functionally necessary, to limit the storage of unnecessary materials. For facilities that anticipate compounding small volumes of hazardous drugs, these facilities should store their hazardous drugs, outside of their cardboard containers, in the buffer zone, which would be under negative pressure.
- (5) For facilities that perform hazardous drug procedures, as defined in USP 797-2008, the hazardous drug prep room should be located immediately adjacent to the CSP buffer zone or area. See Diagram 2, "CSP and Hazardous Drug Prep Rooms," on page 12.
- (6) For guidance in determining the design, equipment, and construction needs that most appropriately meet the requirements for preparing, and handling CSPs and Hazardous Drugs, please refer to Table 3, "CSP/HD Questionnaire," on page 4 and Table 4 "CSP/HD Decision Matrix - Flow Sheet," on page 9.

B. Specific Design Criteria

The rooms used for compounding sterile preparations shall comply with the design recommendations listed below in Table 1, "Construction Guidelines for Pharmacy Compounding Sterile Preparation Rooms," on page 4, and Table 2, "Guidelines for Pharmacy Compounding Sterile Preparation Critical Work Environments - New Construction and Major Renovations," on page 6. For additional information, please refer to Diagram 1, "Clean Room Low and Medium Risk CSPs," on page 11 and Diagram 2, "CSP and Hazardous Drug Prep Rooms," on page 12.

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Table 1 Construction Guidelines for Pharmacy Compounding Sterile Preparation Rooms - New Construction and Major Renovation

	Compound Sterile Preparation	Hazardous Drug Preparation	Ante Area/Room
Air Quality (Note 1)	ISO Class 7 in buffer area/zone.	ISO Class 7 in buffer area/zone	ISO Class 8
Air filtration	Air supply shall be filtered with filters rated as 90% efficient filter (MERV 14)		
Minimum total Air Changes per Hour (ACH) (Notes 2 & 3)	15 ACH	15 ACH For hazardous drug storage areas, 12 ACH	15 ACH
Minimum outdoor Air Changes per Hour (ACH) (Note 4)	2 ACH	2 ACH	2 ACH
Air Movement relationship to adjacent areas For additional information, please refer to Diagrams 1 & 2	Out	In (from Compound Sterile Preparation area)	In (from Compound Sterile Preparation area) Out (to all other adjacent areas).
Pressure Differential Monitoring (Note 5)	In locations with a physical barrier and a doorway or other penetration is present between locations (buffer <u>room</u> , ante <u>room</u> , hazardous drug prep <u>room</u> and/or adjacent hallways) a permanently installed visual mechanism to constantly monitor the relative pressure status shall be installed. In these locations with physical barriers, a relative pressure differential shall be 0.01" water gauge (2.5 Pa)		
	Locations with a line of demarcation, (buffer <u>area</u> and ante <u>area</u>) shall be designed such that air will move/flow from "clean" to "less clean" areas, as displayed in Diagrams 1 and 2.		
Humidity (Note 4)	30 – 60% RH	30 – 60% RH	30 – 60% RH
Temperature °C / °F (note 6)	20-23°C (68-73°F)	20-23°C (68-73°F)	20-23°C (68-73°F)
Floor drains and sinks	No floor drains or sinks in buffer area/zone	No floor drains or sinks in buffer area/zone	Provisions for hand-washing in ante area/room. Faucets should be designed to be hands-free, such as motion sensitive or foot controlled.

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Table 1 Construction Guidelines for Pharmacy Compounding Sterile Preparation Rooms - New Construction and Major Renovation

Ceilings (Note 7)	Smooth, impervious, free from cracks and crevices, non shedding and resistant to sanitizing agents. For example: <ul style="list-style-type: none"> • Smooth finish drywall with epoxy-painted finish • Vinyl coated ceiling tiles in anodized aluminum T-bar grid (lock down clips required). Ceiling tiles should be sealed to the grid and perimeter of grid should be caulked. • USG Interior Acoustical Tile Panel Model 3270-15096, 5/8 inch thick; rated “G”. (Note 8)
Floor (Note 7)	Smooth, impervious, free from cracks and crevices, non shedding and resistant to sanitizing agents. Typically: <ul style="list-style-type: none"> • Seamless sheet vinyl with joint sealing technique of grooved, melted, welded, vinyl for an impervious waterproof seal. Provide seamless sheet vinyl base integral with the flooring, using the same joint sealing technique.
Wall finish (Note 7)	Smooth, impervious, free from cracks and crevices, non shedding and resistant to sanitizing agents. For example: <ul style="list-style-type: none"> • Smooth finish drywall with epoxy-painted finish or FRP sheets
Doors	Epoxy-painted door/frame with no ledges (flush with walls).
Windows	Anodized aluminum frames with no ledges with tempered safety glass.
Light fixtures	Recessed “clean room” fixture sealed to grid or fixture frame. Acrylic lens with baked enamel finish.
Shelving & Fixtures	Stainless Steel Wire racks/shelving, washable counters, and minimal horizontal surfaces.

Note 1: Reference USP 797, 2008 revision.

Note 2: These 15 ACH are to be provided exclusively by the room, with an additional 15 ACH to be provided by the PEC.

Note 3: In order to maintain the specified relative pressure relationships, the PEC’s rate of exhausted air must be considered. More than 15 ACH (Supply) may be required to overcome the PEC’s exhaust rate.

Note 4: Humidity range from AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities (2006)

Note 5: AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities (2006) Table 2.1-2 Foot Notes 2 and 11.

Note 6: AIA Guidelines for Design and Construction of Hospitals and Health Care Facilities (2006) Table 2.1-2. 20-23°C (68-73°F) is the design temperature for rooms where additional protective clothing and Personal Protective Equipment are also worn to reduce contamination and ultimately microbial growth and infection.

Note 7: Avoid condensation /trapping warm moist air on cold, impervious surfaces resulting in moisture accumulating on gypsum wall board.

Note 8: (Source: Specifications for Health Center at Annette Island, AK)

Table 2 Guidelines for Pharmacy Compounding Sterile Preparation Critical Work Environments - New Construction and Major Renovations

(see Note 9)

	COMPOUND STERILE PREPARATION	HAZARDOUS DRUG PREPARATION
Critical work environment	LAFW (See Note 10)	Biological Safety Cabinet; Class II Type B1, Class II Type B2, or Class III. LAFW's are not to be used for hazardous drug preparations. Compounding Aseptic Containment Isolators should not be used (Note 10)
Air Quality	ISO Class 5	ISO Class 5

Note 9: The "critical work environment" is the site where drugs are exposed to air in the physical environment and where active manipulation occurs. For CSPs, this will be the workbench of the LAFW or inside the BSC. For hazardous drugs, this will be the inside of the BSC.

Note 10: At the time of this issuance, CACI's are not currently recommended, except for unique applications. There is a general consensus that instead of using CACI's, it is more practical and efficient to use either: 1) LAFWs for compounding sterile preparations (CSP's) or 2) BSCs for CSP's and/or hazardous drugs.

Table 3 CSP/HD Questionnaire

The following questionnaire should be used with the “CSP/HD Decision Matrix - Flow Sheet” in Table 4 on page 9 to assist in determining the appropriate equipment and/or construction, if any, required to ensure safe handling of Compounded Sterile Preparations (CSP)/Hazardous Drug (HD) services in compliance with United States Pharmacopeia (USP) guidelines. The process of determining the equipment and construction needs for a pharmacy should involve pharmacy and possibly facilities staff depending on the matrix factors that are involved.

1. Clinical Need for HD's (# of HD's Prepared/month)

a. Current Need (1-5 year)		b. Projected Need (5-10 year)	
None		None	
Low	< 5/mth	Low	< 5/mth
Medium	5-20/mth	Medium	5-20/mth
High	> 20/mth	High	> 20/mth

2. Clinical Need for CSP's (# CSP's Prepared/month)

a. Current Need (1-5 year)		b. Projected Need (5-10 year)	
None		None	
Low	< 5/mth	Low	< 5/mth
Medium	5-20/mth	Medium	5-20/mth
High	> 20/mth	High	> 20/mth

3. Availability of HD Services

Are HD services reasonably available from other sources (IHS or Contract)?

Shipping, travel, transportation, timely, reliability, cost, etc.

a. HD Services available (1-5 year)		b. HD Future availability (5-10 year)	
Yes		Yes	
No		No	

4. Availability of CSP Services

Are CSP services reasonably available from other sources (IHS or Contract)?

Shipping, travel, transportation, timely, reliability, cost, etc.

a. CSP Services available (1-5 year)		b. CSP Future availability (5-10 year)	
Yes		Yes	
No		No	

5. Availability of Pharmacy staff to prepare CSP's/HD's In-house

(Includes permanent, temporary, and/or contract staff/service)

Are Pharmacy staff available to prepare CSP's/HD's In-house?

a. CSP staff available (1-5 year)		b. CSP future staff available (5-10 year)	
Yes		Yes	
No		No	

6. Technical Expertise – Clinical Staff (Nursing, Physicians, etc.)

(Includes permanent, temporary, and/or contract staff/service)

Are Staff available to prescribe, administer, and manage HD's/CSP's?

a. Current staffing (1-5 years)		b. Future staffing (5-10 year)	
Yes		Yes	
No		No	

Table 3 CSP/HD Questionnaire

7. Technical Expertise – Support Programs (Maintenance, Biomed, Certifiers, etc.)

(Includes permanent, temporary, and/or contract staff/service)

Are staff available to operate/maintain rooms (Heating, Ventilation, and Air Conditioning (HVAC), High Efficiency Particulate Air (HEPA) filters, etc.) and equipment: LAFW, BSC, and/or Compounding Aseptic Containment Isolator (CAICACI).

- | | |
|--|---|
| <p>a. Current staffing (1-5 years)</p> <p style="padding-left: 20px;">Yes</p> <p style="padding-left: 20px;">No</p> | <p>b. Future staffing (5-10 year)</p> <p style="padding-left: 20px;">Yes</p> <p style="padding-left: 20px;">No</p> |
|--|---|

Estimated Capital and Operational Costs for Planning Purposes

8. 2007 Room/Equipment Operational Costs (PMs, Certification, Testing/Sampling)

Room PM costs (HEPA filters, belts, etc.)	\$ 300.00/Year
(Particle & Biological sampling)	\$ 200.00/Year
LAFW PM costs (Filters, Testing/etc.)	\$ 200.00/Year
(6 month certification x 2/year)	\$ 400.00/Year
BSC PM (Filters, Testing/etc.)	\$ 200.00/Year
(6 month certification x 2/year)	\$ 400.00/Year
CAICACI PM costs (Filters, Testing/Certifications)	\$ 200.00/Year
(6 month certification x 2/year)	\$ 400.00/Year

9. 2007 Capital Costs (Room, HVAC, & Equipment)

CSP room with HD room (300 square feet)	\$ 60,000.00
LAFW with installation & initial certification	\$ 4,800.00
BSC with installation & initial certification	\$ 7,500.00
CAICACI & initial certification	\$ 17,000.00

Note 1: USP-797 allows a BSC to be placed into the CSP room/area if less than 5 HD preparations/week. This would reduce the capital costs of construction, increase the administrative procedures (staff protection), and would reduce maintenance PM costs.

Note 2: All cost estimates are in 2007 dollars.

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Table 4 CSP/HD Decision Matrix - Flow Sheet	
Questions 1 & 2 address the “clinical need” for HD’s and/or CSP’s.	
FACTOR	DECISION
If the answer to 1a & 1b are “none”	No HD room/equipment is needed.
If the answer to 2a & 2b are “none”	No CSP room/equipment is needed.
If the answer to 1a & 1b are “low” and The answer to 3a & 3b are “yes”	No HD room/equipment is needed if HD services are provided by sources outside of the facility.
If the answer to 2a & 2b are “low” and The answer to 4a & 4b are “yes”	No CSP room/equipment is needed.
All other answer combinations for 1a, 1b, 2a, & 2b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	
Questions 3 & 4 address the availability of HD and/or CSP services through other facilities (IHS, private/contract). This information should be used in a cost/benefit analysis (contract vs. build).	
Question 5 addresses availability of Pharmacy staff to prepare HD’s and/or CSP’s.	
FACTOR	DECISION
If the answer to 5a & 5b are “no”	No HD/CSP room(s) should be built.
All other answer combinations for 5a & 5b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	
Question 6 addresses availability of clinical staff (nursing, physicians, etc.).	
FACTOR	DECISION
If the answer to 6a & 6b are “no”	No HD/CSP room(s) should be built.
All other answer combinations for 6a & 6b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	

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Table 4 CSP/HD Decision Matrix - Flow Sheet	
Question 7 addresses availability of support staff (maintenance, biomedical, & certifiers).	
FACTOR	DECISION
If the answer to 7a & 7b are “no”	No HD/CSP room(s) should be built.
All other answer combinations for 7a & 7b will need to be thoroughly evaluated using the information from the remainder of the questionnaire prior to deciding to build or not build a HD/CSP room(s).	
The paragraph entitled <i>Estimated Capital and Operational Costs for Planning Purposes</i> that follows Question 7 provides operational and construction costs associated with the physical room(s) and hoods only. This data does not address “Pharmacy-related” operational costs (supplies, drugs, staff time, biological monitoring, etc.). The numbers in Questions 8 and 9 should be used in a cost/benefit analysis (contract vs. build). A cost multiplier should be used for remote locations to account for shipping, labor, etc. associated with remote locations.	

Diagram 1 Clean Room Low and Medium Risk CSPs

Diagram 1 – Clean Room: Low & Medium Risk CSP's

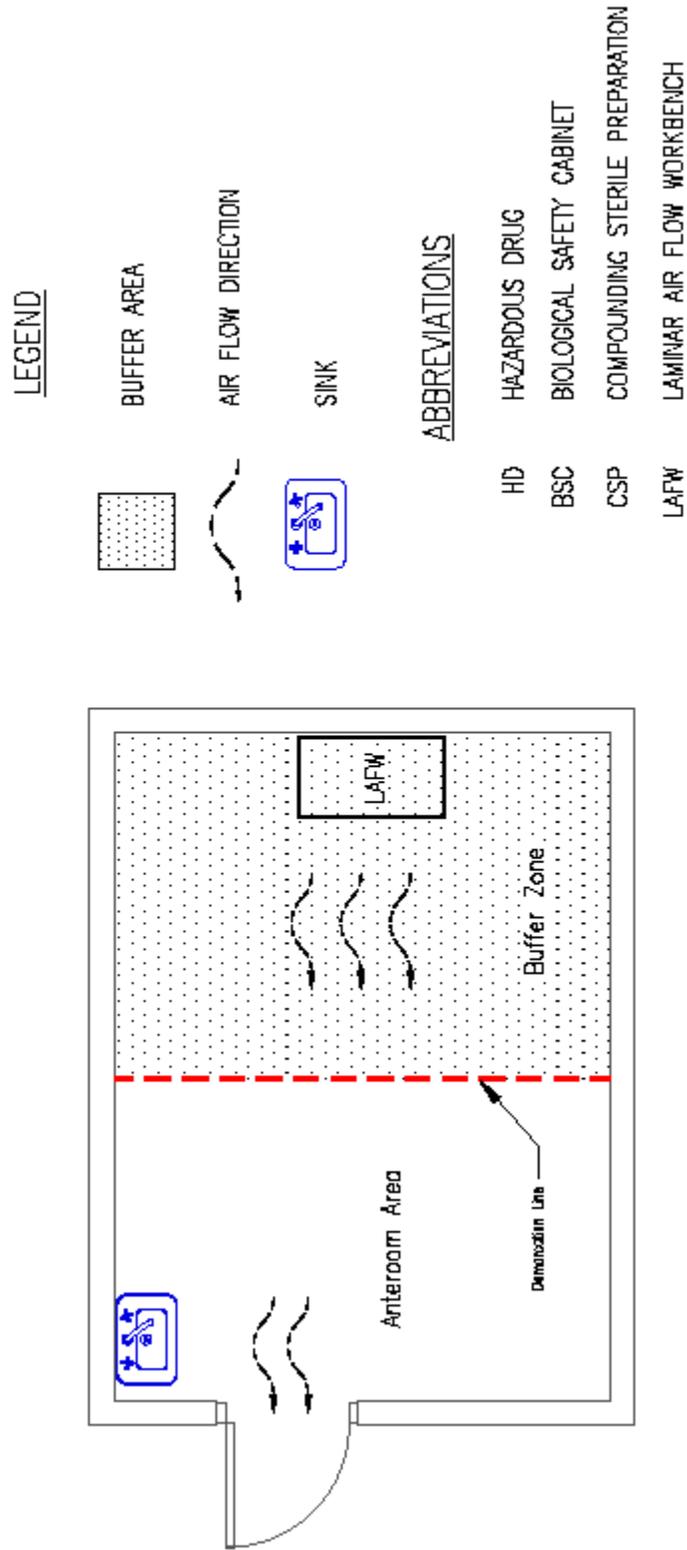


Diagram 2 CSP and Hazardous Drug Prep Rooms

Diagram 2 – CSP & Hazardous Drug Prep Rooms

