Chapter 21.4 Mechanical Guidelines

Table of Contents

21.4.1 Introduction.

21.4.1.1 Purpose. The purpose of Chapter 21.4 to convey to Indian Health Service (IHS) staff, tribal staff, and Architect/Engineering designers, both general and specific guidelines regarding mechanical design features required for IHS health care facilities and quarters projects including tribal health care facilities when negotiated as part of a 638 agreement.

21.4.1.2 Applicability. The information found herein is applicable to all IHS new construction, major renovation, joint venture, small ambulatory, maintenance and improvement projects, and facility operations, unless otherwise noted.

21.4.1.3 Background. Reserved.

21.4.2 Definitions.

(1) **Installation Buildings.** All buildings associated with a health care program regardless of the function of the building, i.e., patient care, administration, boiler plant, personnel quarters.

(2) **Fully Sprinklered.** Fully sprinklered means that a building is completely protected by fire sprinklers in accordance with *National Fire Protection Association (NFPA) 13 - Standard for the Installation of Sprinkler Systems*, *13D - Standard for the Installation of Sprinkler Systems in One- and Two-Family Dwellings and Manufactured Homes*, or *13R - Standard for the Installation of Sprinkler Systems in Low-Rise Residential Occupancies*, based upon occupancy type.

(3) **Authority Having Jurisdiction.** Authority Having Jurisdiction (AHJ) is defined in Chapter 21.7 Codes and Standards.

21.4.3 Mechanical Guidelines (General). Reserved.

21.4.4 Ventilation (General). IHS Health Care Facilities shall be ventilated in accordance with the

most current edition of ASHRAE 170 – Ventilation of Health Care Facilities.

21.4.5 Ventilation – Dental.

21.4.5.1 Design Criteria. Design of dental facilities must comply with the requirements setforth in Table 1, "Ventilation Requirements for Areas in Dental Facilities. The ventilation rates in this table cover ventilation for comfort, as well as for asepsis and odor control in areas of dental facilities that directly affect patient care and are determined based on health care facilities being "No Smoking" facilities. Areas where specific ventilation rates are not given in the table shall be ventilated in accordance with American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) Standard 62.1, latest edition, "Ventilation for Acceptable Indoor Air Quality," and ASHRAE Handbook of HVAC Applications. OSHA standards and/or NIOSH criteria require special ventilation requirements for employee health and safety. Central systems shall be provided with MERV 13 filters. Refer to Table 1 footnotes for fuller explanation of specific requirements.

- ASHRAE Applications Handbook, 2003. Chapter 7, Health Care Facilities. American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Atlanta.

- Ninomura, P. and Byrns, G. ASHRAE Journal, Dental Ventilation, Theory and Applications. American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Atlanta, Feb 1998.

Table 1 Ventilation Requirements for Areas in Dental Facilities

Area Designation	Air movement relation-ship to adjacent area[1, 2]	Minimum air changes of outdoor air per hour[3]	Minimum total air changes per hour[4]	All air exhaust-ed directly to outdoors[5]	Relative humidity[6]	Design temperature[7] (degrees F/C)
Enclosed Dental Operatory (w/nitrous oxide) [8,9, 10, 11]	In	3	12	Yes	30-60%	75 (24)
Open Dental Operatory (w/nitrous oxide) [12]	---	---	---	---	---	---
Open Dental Operatory (w/o nitrous oxide)	---	2	6	---	30-60%	75 (24)
Decontamination / Sterilization[1,13]	In	2	10	Yes	---	75 (24)
Clean Workroom / Sterilization[13,14]	Out	2	64	---	Max 60%	75 (24)
Sterile Storage[14]	Out	2	64	---	Max 60%	78 (26)
Laboratory	In	2	6	Yes	---	75 (24)
Dark Room	In	2	10	Yes	---	75 (24)

Notes

[1] Design of the ventilation system shall provide air movement which is generally from clean to less clean areas except in the enclosed dental operatory where containment of nitrous oxide is desired. If any form of variable air volume or load shedding system is used for energy conservation, it must not compromise the corridor-to-room pressure balancing relationships or the minimum air changes required by the table.

[2] For areas with required "In" air movement relationships, the room exhaust will be at least 20% more than the supply. For areas with required "Out" air movement relationships, the room exhaust will be at least 20% less than the supply. Where physical separations are provided between rooms with required air relationships, the minimum required differential pressurization is 0.02 inch water column.

[3] To satisfy exhaust needs, replacement air from the outside is necessary. The Table does not attempt to describe specific amounts of outside air to be supplied to individual spaces except for those listed. Distribution of the outside air, added to the system to balance required exhaust, shall be as required by good engineering practice. Minimum outside air quantities shall remain constant while the system is in operation.

[4] Number of air changes may be reduced when the room is unoccupied if provisions are made to ensure that the number of air changes indicated is reestablished any time the space is being utilized. Adjustments shall include provisions so that the direction of air movement shall remain the same when the number of air changes is reduced. Areas not indicated as having continuous directional control may have ventilation systems shut down when space is unoccupied and ventilation is not otherwise needed, if adjacent pressure balancing relationships are not compromised.

[5] Air from areas with contamination (i.e. bioaerosals, respirable particulates, nitrous oxide, and/or odor problems) shall be exhausted to the outside and not recirculated to other areas.

[6] The ranges listed are the minimum and maximum limits where control is specifically needed.

[7] A single figure indicates a heating or cooling capacity of at least the indicated temperature. Nothing in these guidelines shall be construed as precluding the use of temperatures lower than those noted when the patients' comfort and medical conditions make lower temperatures desirable.

[8] National Institute for Occupational Safety and Health (NIOSH)"Technical Report: Control of Nitrous Oxide in Dental Operatories" indicates a need for both local exhaust (scavenging) systems and general ventilation of the areas in which the respective gases are utilized.

[9] Air flow patterns shall be controlled to reduce nitrous oxide exposure to the staff. Supply registers shall be located in the ceiling. Supply registers shall be selected to provide airflow that provides air mixing.

[10] Exhaust grilles shall be located in the wall, at a height between 6to 12-inches above the floor (bottom of grille) sized to remove a minimum of 20 percent of the total room exhaust volume.

[11] For facility operations, or maintenance and improvement projects: Where minimum air changes are achieved, but are insufficient to control nitrous oxide below the IHS adopted exposure limit (e.g. due to Inadequate air mixing as a result of HVAC/room layout), provisions for sweep fans may be provided. If sweep fans are to be provided, fans should be selected to provide a velocity of approximately 50 to 75 fpm in the vicinity of the breathing zone of the dental staff. The fan should be located so the air is blown past the dentist toward the patient. The effectiveness of the sweep fan can be maximized by locating the exhaust grille in the wall opposite from the location of the sweep fan. Use, selection, and placement of sweep fans should be determined through the collaboration of the dental supervisor, facility manager, safety officer, infection Preventionist, and Area institutional environmental health officer.

[12] Nitrous oxide administration in an open dental operatory is not allowed. Nitrous oxide exposure to staff cannot be effectively controlled in this setting.

[13] The instrument processing area should be divided into sections for 1) receiving, cleaning, and decontamination; 2) preparation and packaging; 3) sterilization; and 4) storage. Ideally, walls or partitions should separate the sections to control traffic flow and contain contaminants generated during processing. When physical separation of these sections cannot be achieved, adequate spatial separation might be satisfactory if work practices are implemented to prevent contamination of clean areas. Space should be adequate for the volume of work anticipated and the items to be stored.

[14] Installation of monitoring equipment for temperature, relative humidity, and pressure relationship(s) should be considered to facilitate routine monitoring by dental department to meet accreditation standards.

21.4.6 Nitrous Oxide Guidelines

21.4.6.1 Background.

The Indian Health Service uses nitrous oxide in three areas; (1) dental operatories for analgesia/sedation, (2) surgeries for anesthesia, and (3) treatment rooms for cryosurgery. In the first and second cases, nitrous oxide is used at low pressure under 260 kPa (40 psi). In the third

case, to operate the cryosurgical units, nitrous oxide must be delivered at 5200 kPa (750 psi). At the present time, the third case poses the greatest health risk because in some facilities the units are not being vented to the outside.

21.4.6.2 Discussion. Currently, nitrous oxide is made available at locations requiring low pressure delivery in one of two ways:

(1) by individual portable gas bottles or cylinders that are delivered to and used at the location, or
(2) through a central system consisting of a manifold of gas cylinders and a piped distribution system.

The advantages and disadvantages of each system are as follows:

(1) Portable Cylinder System

The advantages include the following:

- lower initial cost,
- limited volumes which reduce chance of extensive exposure due to leaks, and
- flexibility.

The disadvantages include the following:

- extra security required to prevent pilferage,
- proper storage required,
- increased clutter in clinical space,
- higher cost of small quantity purchases,
- portability promotes use in improperly ventilated areas,
- limited volumes may run out during medical and/or dental procedures, and
- frequent handling of cylinders increases risk of accident.

(2) Central Supply, Piped Gas System

The advantages include the following:

- convenient access in specific areas,
- inexpensive product,
- product security increased,
- auto-switching manifolds provide uninterrupted supply, and
- simplified supply procedures by single point.

The disadvantages include the following:

- alarm systems do not detect slow leaks in check valves
- which may result in extensive occupational exposure,
- low pressure piped gas systems will not operate cryosurgical units,
- higher initial installation costs, and
- regular surveillance required to detect leakage at outlets.

Note: In either case, facilities that use cryosurgical procedures must have cylinders available because these units operate at 5200 kPa (750 psi).

21.4.6.3 Guidelines.

21.4.6.3.1 Low Pressure Nitrous Oxide. At health care facilities where **low pressure** nitrous oxide is in **three or more** locations, nitrous oxide should be supplied in a piped medical gas system with a multiple cylinder, auto- switching manifold and appropriate alarm systems.

All nitrous oxide anesthetizing locations shall have Waste Anesthetic Gas Discharge (WAGD) systems designed in accordance with NFPA 99. Use of medical vacuum is not recommended for evacuation. Dental surgical vacuum may be used for anesthesia scavenging in enclosed dental operatories where a central system is installed.

21.4.6.3.2 Dental Design Considerations. Before design that includes installation or modification of nitrous oxide, the designer should review the current Indian Health Service Oral Health Program Guide, Chapter 6, Section D: Nitrous Oxide Safety, pages 3 through 12. Also, refer to Table 1 – Ventilation Requirements for Areas in Dental Facilities above.

21.4.6.3.3 Cryosurgical Units.

21.4.6.3.3.1 General. Beyond engineering controls, cryosurgical units require administrative controls and exposure monitoring. Refer to Publication No. 99-105 (1999) Control of Nitrous Oxide During Cryosurgery.

21.4.6.3.3.2 Planning and Design Considerations

(1) In existing facilities, where no medical vacuum is available, the facility should consider substitution of carbon dioxide, which can also be used as a cryogenic gas on many of the cryosurgical units. However, since it does not cool as low as nitrous oxide, medical providers should be consulted concerning the implications of changing to carbon dioxide as the freeze agent as this may not be a medically viable option in all cases. If substitution is not an option, consult with the manufacturer to determine which exhaust methods they recommend for their equipment.

(2) In major renovations or new construction, rooms used for cryosurgery should contain a medical vacuum outlet equipped with a regulator to allow the mechanical venting of the unit.

21.4.7 Color Code, Signage, and Identification of Building Utility Piping Systems.

21.4.7.1 Purpose. This section provides guidelines on color code, signage, and identification of building utility piping systems and physical hazards in Indian Health Service health care facilities and quarters, and/or tribal health care facilities.

21.4.7.2 Reference Standards. The following standards are to be applied during planning, design, and construction, including renovation, improvement, and/or expansion, of all IHS health care facilities and tribal health care facilities when negotiated as part of a 638 agreement:

(1) Piping - American National Standards Institute latest edition, A13.1, Scheme for Identification of Piping Systems;
(2) Medical Gases Signage - National Fire Protection Association 99 latest edition, Standard for Health Care Facilities, Gas Systems Information and Warning Signs;
(3) Gas Cylinder - Compressed Gas Association Pamphlet latest edition, C-9, Standard Color-Marking of Compressed Gas Cylinder Intended for Medical Use; and
(4) Physical Hazards - Occupational Safety and Health Act, 29 CFR 1910.144, Safety Color Code for Marking Physical Hazards.

21.4.8 Fire Sprinkler Protection.

21.4.8.1 General. Criteria for determining the need for and methods of design and installation of automatic fire protection sprinkler systems shall be based upon the most current edition of the NFPA 101 Life Safety Code and other NFPA standards referenced therein.

21.4.8.2 Methodology.

21.4.8.2.1 Existing Buildings. All existing IHS facilities that are not currently provided with automatic fire protection sprinkler systems shall be retrofitted to be fully sprinklered with such systems during major renovations or when life safety evaluations identify an immediate need and prioritized as follows:

1) Buildings required to be sprinklered by the relevant Existing Occupancy chapter of the most current edition of NFPA 101.
2) Sites not protected by a full time fire department
3) Inpatient sites (hospital and residential board and care, including Youth Regional Treatment Centers)
4) Health Center
5) Staff Quarters
6) Modular Dental Unit
7) Health Station
8) Alcohol and Substance Abuse Center
9) Buildings housing essential utilities (e.g., boiler plants)
10) Buildings housing other health care support functions

11) Administrative Building
12) Warehouse

21.4.8.2.2 New Buildings. All new construction shall be protected by automatic sprinkler systems as required by the NFPA 101 Life Safety Code. In addition, the following requirements apply:

1) New construction of facilities that provide health care services shall be protected by automatic sprinkler systems even when not required to do so by NFPA 101.
2) New construction of facilities that provide administration space shall be protected by automatic sprinkler systems even when not required to do so by NFPA 101.
3) All new staff quarters units shall be provided with hard wired smoke detectors even when not required to do so by NFPA 101.

21.4.9 Design Requirements for Compounded Sterile and Hazardous Drug Preparation Areas.

21.4.9.1 General. This section 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).

21.4.9.2 Applicability. This Section applies to all new construction and renovation for IHS health care facilities. This Section 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. This document should be used in conjunction and/or consultation with the IHS Pharmacist, the Area Institutional Environmental Health officer, and the Director of Facilities Management.

For facilities constructed prior to the adoption date of this section and not otherwise scheduled for renovation, the multi-disciplinary team listed above should evaluate facility compounding needs, practices, equipment, and environment to determine appropriate actions to address United States Pharmacopeia (USP) 797-2008 and USP 800-2016.

21.4.9.3 Background. In 2002, the Centers 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.

This update reflects incorporation of updated requirements from the publication of USP 797 (2008) and the initial issuance of USP 800 (2016).

21.4.9.4 Definitions.

(1) **Ante Area/Room.** An International Standards Organization (ISO) Class 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 (USP-797-2008).

(2) **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).

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

(4) **Compounding Aseptic Containment Isolator (CACI).** A 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 volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation. (USP-797-2008)

(5) **Compounding Aseptic Isolator (CAI).** A form of isolator specifically designed for compounding sterile, non-hazardous pharmaceutical ingredients or preparations. 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 microbially retentive filter (HEPA minimum). (USP-797-2008)

(6) **Compounded Sterile Preparation (CSP).** For the purposes of this chapter, CSPs include any of the following:

- Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.
- Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling. (USP-797-2008)

(7) **Containment Ventilated Enclosure (CVE).** A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment

(8) **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” is published by the National Institute for Occupational Safety and Health (NIOSH) and titled “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare

Settings, 2016". 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."

(9) **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).

(10) **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).

21.4.9.5 Guidelines.

21.4.9.5.1 General Design Criteria for Facilities

(1) Elements Common to Sterile and Hazardous Drug Compounding

a) 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.

b) PECs should operate continuously to maintain the required pressure differentials and ISO Class environments. These systems should be considered for inclusion on emergency power supply.

c) In locations with a physical barrier and a doorway or other penetration is present between locations (buffer room, ante room, hazardous drug prep room and/or adjacent hallways), a permanently installed pressure gauge must be used to constantly monitor the relative pressure status. This gauge must include an audible alarm to alert staff when improper relative pressure occurs.

d) 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.

(2) Elements specific to Sterile Drug Compounding

a) 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.

b) 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.

c) In sterile drug compounding areas, supply air diffusers should be located in or near the ceiling, while air returns should be located low on the wall.

(3) Elements specific to Hazardous Drug Compounding

a) LAFW and CAI shall not be used for hazardous drug preparation or compounding. Class I BSCs may only be used for non-sterile hazardous drug procedures. Only

Class II or III BSCs, or CACIs shall be used for hazardous drug procedures. Refer to the Tables below for environmental requirements related to selection of the PEC.

- For occasional nonsterile HD compounding, a Class II BSC or CACI used for sterile compounding may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that containment PEC.

b) All BSCs and CACIs used for hazardous drugs must have the exhaust HEPA filtered and be vented to the exterior, or have redundant HEPA filters before recirculation for non-sterile preparations.

c) Hazardous drug compounding areas must be separated from other preparation areas and must maintain between 0.01 and 0.03 inches of water column negative pressure differential.

d) Antineoplastic HDs must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their shipping containers in sterile compounding areas or in positive pressure areas.

e) Hazardous drug non-sterile compounding areas require 12 Air Changes per Hour (ACH). Hazardous drug sterile compounding areas require either 12 ACHs or 30 ACHs, depending upon Beyond Use Dates (BUDs) for segregated compounding areas.

f) Hazardous drug storage areas should have at least 12 ACHs and be externally vented.

- Items such as refrigerated anti-neoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with 12 ACH. 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.

g) An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. However, care must be taken to locate them in areas where their presence will not interfere with required ISO classifications.

h) Exhaust from hazardous drug compounding area should be clearly marked as to the hazard where the exhaust leaves the building.

21.4.9.5.2 Design Criteria for facilities using BSCs and LAFWs. The rooms used for compounding sterile and hazardous drug preparations shall comply with the design recommendations listed below in the Tables.

21.4.9.5.3 Design Criteria for facilities using CAIs and CACIs. If a facility uses a CAI or CACI that meet USP 797-2008 requirements as listed below in Subsection (1), the environmental requirements as listed in Subsection (2) are not as strict as for facilities using a BSC or a LAFW.

(1) CAI/CACI requirements for reduced environmental requirements

(Copied from USP 797-2008, "Placement of Primary Engineering Controls" Section):

- *The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.*
- *Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.*
- *Not more than 3520 particles (0.5 µm and larger) per m3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.*

It is incumbent on the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-µm and larger particles. When isolators are used for sterile compounding, the 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.

(2) Potentially applicable reduced environmental requirements

a) **Sterile Drug Compounding**
- CAI's may be placed outside a Class 7 buffer area if they meet the above requirements. The unclassified area must maintain at least 0.02 to 0.05 inch water column positive pressure and 12 air changes per hour.
- If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

b) **Hazardous Drug Compounding**
- Low- and medium risk hazardous drug CSPs may be prepared in a Class II BSC or CACI placed outside an ISO Class 7 buffer area, if the compounding area maintains a minimum negative pressure of 0.01 in water column, is vented to the exterior, and has a minimum of 12 ACHs.
- Facilities should consider placing the CACI in a negative pressure room with the stored hazardous drugs.

21.4.9.5.4 Typical Room Layouts. Refer to USP-800 (Feb 2016), appendix 2, for illustrative examples of typical room layouts. You may contact the IHS Pharmacist or the Area Institutional Environmental Health Officer to request a copy.

21.4.9.6 Tables: Construction Guidelines for Pharmacy Compounding Rooms. Tables 1, 2A, 2B, 3, 4, and 5 are provided on the following pages.

Table 1: Requirements Common to All Locations and Compounded Pharmaceuticals (Note 1)

Requirement Category	Requirement
Buffer Area Minimum Outdoor ACH (Note 2)	2 ACH
Buffer Area Humidity (Note 3)	d60% RH
Buffer Area Temperature °C / °F	d20° C (d68° F) Note 4.
Ante Room Pressure Differential to Adjacent Areas	Positive to all other adjacent areas (out): At least 0.01" H_2O for ISO Class 8 or unclassified areas and at least 0.02" H_2O for ISO Class 7 areas.
Provisions for hand-washing.	Faucets should be designed to be hands-free, such as motion sensitive or foot controlled.
Ceilings *(Note 5)*	Smooth, impervious, free from cracks and crevices, non shedding and resistant to sanitizing agents. For example: • 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.
Floor *(Note 5)*	Smooth, impervious, free from cracks and crevices, non shedding and resistant to sanitizing agents. Typically: • 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 5)*	Smooth, impervious, free from cracks and crevices, non shedding and resistant to sanitizing agents. For example: • Smooth finish drywall with epoxy-painted finish or FRP sheets (FRP=Fiber Reinforced Plastic)
Shelving & Fixtures	Smooth, impervious, free from cracks and crevices, non shedding and resistant to sanitizing agents.
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.

Note 1: References USP 797, 2008 revision and USP-800, 2016 revision, except as otherwise noted.

Note 2: Source: ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities. Extrapolated value for Outside Air. See tables 2 – 5 for minimum total ACH.

Note 3: Humidity range recommendation based on central supply clean workroom guidelines in Table 7.1 from ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities. Table 7.1 has no humidity requirement for pharmacies. USP 797 states that bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers.

Note 4: Temperature range of <68F is designed for staff comfort while in PPE. Where buffer area is also used for storage, USP 797 recommends 68-77F

Note 5: Avoid condensation /trapping warm moist air on cold, impervious surfaces resulting in moisture accumulating on gypsum wall board

Table 2A: Standard Requirements for Low and Medium Risk CSPs (Note 1)

Requirement Category	Standard Sterile CSP Requirement	Standard Sterile Haz. Drug Requirement
Types of PECs	LAFW, BSC	Class II BSC (A2, B1 and B2), Class III BSC, or CACI
Air Quality within PEC	ISO Class 5	ISO Class 5
PEC Exhaust (Note 2)	Not Specified	To Exterior
Air Quality in buffer area	ISO Class 7	ISO Class 7
Buffer Area Minimum total ACH (Note 3)	15 ACH (Note 4)	30 ACH **supply** air
Buffer and Ante-area Air filtration	HEPA (Note 5)	HEPA (Note 5)
Physical separation between Buffer, Ante-Areas, or other Compounding Areas	Required	Required
Buffer Area Air Movement and Pressure Differential (Note 6)	Positive (Out) 0.02 to 0.05" H_2O	Negative (In) 0.01 to 0.03" H_2O
Exhaust for buffer area	Not Specified	To Exterior (Note 4)
Ante Room Air Quality	ISO Class 8	ISO Class 7
Ante Room Minimum ACH	20 ACH Note 7	30 ACH HEPA filtered **supply** air
Storage area Air Movement	Not specified	Negative (In)
Storage Areas Minimum ACH	Not specified	12 ACH for antineoplastic requiring manipulation or any active pharmaceutical ingredient
Floor drains and sinks	No sinks or floor drains in ISO 7 buffer area	Sink is at least 1 meter from the PEC • A sink and eyewash station must be available for emergency access to water for removal of hazardous substances from skin and eyes.

Note 1: References USP 797, 2008 revision and USP-800, 2016 revision, except as otherwise noted.

Note 2: Outdoor air intakes and exhaust discharges shall meet the requirements of ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, Section 6.3 to ensure adequate separation

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: This minimum of 15 ACH are to be provided exclusively by the room, with up to an additional 15 ACH to be provided by the PEC. A total of 30 ACH must be maintained.

Note 5: As an alternative to HEPA filters, MERV-14 rated filters may be used as the secondary filter bank at that Air Handling Unit if tertiary HEPA filters are installed within the portion of the HVAC system serving these spaces. (Based on principle from ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, Table 6.4, Footnote C related to protective environment rooms)

Note 6: Rapid movements can create unacceptable turbulence in a critical area. Such movements disrupt the unidirectional airflow, presenting a challenge beyond intended cleanroom design and control parameters. The principle of slow, careful movement should be followed throughout the cleanroom.

Note 7: Source: FDA Aseptic Processing Guide recommends a minimum of 20 ACPH to maintain ISO 8.

Table 2B: Reduced Requirements for Low and Medium Risk CSPs in Compliant Isolators (Notes 1 and 2)

Requirement Category	Sterile CSP Reduced Requirement Allowances	Sterile Haz. Drug Reduced Requirement Allowances
Types of PECs	Compliant CAI or CACI (Note 2)	Compliant CACI (Note 2)
Air Quality within PEC	ISO Class 5	ISO Class 5
PEC Exhaust (Note 3)	Not Specified	To Exterior
Air Quality in buffer area	Unclassified	Unclassified
Buffer Area Minimum total ACH (Note 4)	12 ACH	12 ACH **supply** air
Buffer and Ante-area Air filtration (Note 5)	filters rated as 90% efficient filter (MERV 14)	filters rated as 90% efficient filter (MERV 14)
Physical separation between Buffer, Ante-Areas, or other Compounding Areas	Not required	Required
Buffer Area Air Movement and Pressure Differential (Note 6)	Positive (Out) 0.02 to 0.05" H_2O (Note 7)	Negative (In) 0.01 to 0.03" H_2O
Exhaust for buffer area	Not Specified	To Exterior (Note 3)
Ante Room Air Quality	Unclassified	Unclassified
Ante Room Minimum ACH	10	10
Storage area Air Movement	Not specified	Negative (In)
Storage Areas Minimum ACH	Not specified	12 ACH for antineoplastic requiring manipulation or any active pharmaceutical ingredient
Floor drains and sinks	Sink is at least 1 meter from the CAI/CACI	Sink is at least 1 meter from the PEC • A sink and eyewash station must be available for emergency access to water for removal of hazardous substances from skin and eyes.

Note 1: References USP 797, 2008 revision and USP-800, 2016 revision, except as otherwise noted.

Note 2: Compliant or Non-compliant with requirements in USP 797, 2008, as excerpted in Section 21-4.10.2.C in this document.

Note 3: Outdoor air intakes and exhaust discharges shall meet the requirements of ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, Section 6.3 to ensure adequate separation.

Note 4: 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 5: Source: ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities. Extrapolated value for filtration

Note 6: Rapid movements can create unacceptable turbulence in a critical area. Such movements disrupt the unidirectional airflow, presenting a challenge beyond intended cleanroom design and control parameters. The principle of slow, careful movement should be followed throughout the cleanroom.

Note 7: Locations with a line of demarcation, (buffer area and ante area) shall be designed such that air will move/flow from "clean" to "less clean" areas)

Table 3: Requirements for Low Risk CSPs w/ BUD <12 hours (Note 1)

Requirement Category	Sterile CSP Requirement	Sterile Haz. Drug Requirement
Types of PECs	LAFW, BSC, Noncompliant CAI or CACI (Note 2)	Class II BSC (A2, B1 and B2), Class III BSC, or CACI
Air Quality within PEC	ISO Class 5	ISO Class 5
PEC Exhaust (Note 3)	Not Specified	To Exterior
Air Quality in buffer area	Unclassified	Unclassified
Buffer Area Minimum total ACH (Note 4)	15 ACH (Note 5)	12 ACH HEPA filtered **supply** air
Buffer and Ante-area Air filtration (Note 6)	filters rated as 90% efficient filter (MERV 14)	filters rated as 90% efficient filter (MERV 14)
Physical separation between Buffer, Ante-Areas, or other Compounding Areas	Not required	Required
Buffer Area Air Movement and Pressure Differential (Note 7)	Positive (Out) 0.02 to 0.05" H_2O (Note 8)	Negative (In) 0.01 to 0.03" H_2O (Note 8)
Exhaust for buffer area	Not Specified	To Exterior (Note 3)
Ante Room Air Quality	Unclassified	Unclassified
Ante Room Minimum ACH	10	10
Storage area Air Movement	Not specified	Negative (In)
Storage Areas Minimum ACH	Not specified	12 ACH for antineoplastic requiring manipulation or any active pharmaceutical ingredient
Floor drains and sinks	Sink is at least 1 meter from the PEC	Sink is at least 1 meter from the PEC • A sink and eyewash station must be available for emergency access to water for removal of hazardous substances from skin and eyes.

Note 1: References USP 797, 2008 revision and USP-800, 2016 revision, except as otherwise noted.

Note 2: Compliant or Non-compliant with requirements in USP 797, 2008, Section: Placement of Primary Engineering Controls, Paragraph 2, Bullets 1 - 3 regarding maintaining ISO Class 5 conditions during dynamic operating conditions.

Note 3: Outdoor air intakes and exhaust discharges shall meet the requirements of ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, Section 6.3 to ensure adequate separation.

Note 4: 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 5: This minimum of 15 ACH are to be provided exclusively by the room, with up to an additional 15 ACH to be provided by the PEC. A total of 30 ACH must be maintained.

Note 6: Source: ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities. Extrapolated value for filtration

Note 7: Rapid movements can create unacceptable turbulence in a critical area. Such movements disrupt the unidirectional airflow, presenting a challenge beyond intended cleanroom design and control parameters. The principle of slow, careful movement should be followed throughout the cleanroom.

Note 8: Locations with a line of demarcation, (buffer area and ante area) shall be designed such that air will move/flow from "clean" to "less clean" areas).

Table 4: Requirements for High Risk CSPs (Note 1)

Requirement Category	Sterile CSP Requirement	Sterile Haz. Drug Requirement
Types of PECs	LAFW, BSC, CAI, CACI	Class II BSC (A2, B1 and B2), Class III BSC, or CACI
Air Quality within PEC	ISO Class 5	ISO Class 5
PEC Exhaust	Not Specified	To Exterior (Note 2)
Air Quality in buffer area	ISO Class 7	ISO Class 7
Buffer Area Minimum total ACH (Note 3)	15 ACH (Note 4)	30 ACH **supply** air
Buffer and Ante-area Air filtration	HEPA (Note 5)	HEPA (Note 5)
Physical separation between Buffer, Ante-Areas, or other Compounding Areas	Required	Required
Buffer Area Air Movement and Pressure Differential (Note 6)	Positive (Out) 0.02 to 0.05" H_2O	Negative (In) 0.01 to 0.03" H_2O
Exhaust for buffer area	Not Specified	To Exterior (Note 2)
Ante Room Air Quality	ISO Class 8	ISO Class 7
Ante Room Minimum ACH	20 ACH (Note 7)	30 ACH HEPA filtered **supply** air
Storage area Air Movement	Not specified	Negative (In)
Storage Areas Minimum ACH	Not specified	12 ACH for antineoplastics requiring manipulation or any active pharmaceutical ingredient
Floor drains and sinks	No floor drains or sinks in ISO Class 7 buffer area/zone	• No floor drains or sinks in buffer area/zone, and at least 1 meter from entrance to buffer room • A sink and eyewash station must be available for emergency access to water for removal of hazardous substances from skin and eyes.

Note 1: References USP 797, 2008 revision and USP-800, 2016 revision, except as otherwise noted.

Note 2: Outdoor air intakes and exhaust discharges must meet the requirements of ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, Section 6.3 to ensure adequate separation.

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: This minimum of 15 ACH are to be provided exclusively by the room, with up to an additional 15 ACH to be provided by the PEC. A total of 30 ACH must be maintained.

Note 5: As an alternative to HEPA filters, MERV-14 rated filters may be used as the secondary filter bank at that Air Handling Unit, if tertiary HEPA filters are installed within the portion of the HVAC system serving these spaces. (Based on principle from ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, Table 6.4, Footnote C related to protective environment rooms)

Note 6: Rapid movements can create unacceptable turbulence in a critical area. Such movements disrupt the unidirectional airflow, presenting a challenge beyond intended cleanroom design and control parameters. The principle of slow, careful movement should be followed throughout the cleanroom.

Note 7: Source: FDA Aseptic Processing Guide recommends a minimum of 20 ACPH to maintain ISO 8.

Table 5: Requirements for Non-sterile Hazardous Drug Manipulations (Notes 1, 2, and 3)

Requirement Category	Non-Sterile Hazardous Drug Requirement
Types of PECs	BSC Class I or II, CVE or CACI
Air Quality within PEC	Unclassified
PEC Exhaust (Note 4)	To Exterior or redundant HEPA filters in series
Air Quality in buffer area	Unclassified
Buffer Area Minimum total ACH	12 ACH
Buffer and Ante-area Air filtration (Note 5)	filters rated as 90% efficient filter (MERV 14)
Physical separation between Buffer, Ante-Areas, or other Compounding Areas	Required
Buffer Area Air Movement and Pressure Differential (Note 6)	Negative (In) 0.01 to 0.03" H_2O
Exhaust for buffer area	To Exterior (Note 4)
Ante Room Air Quality	Unclassified
Ante Room Minimum ACH	10
Ante Room Pressure Differential to Unclassified Areas	Not Specified
Storage area Air Movement	Negative (In)
Storage Areas Minimum ACH	12 ACH for antineoplastic requiring manipulation or any active pharmaceutical ingredient
Floor drains and sinks	Sink is at least 1 meter from the PEC • A sink and eyewash station must be available for emergency access to water for removal of hazardous substances from skin and eyes.

Note 1: References USP 797, 2008 revision and USP-800, 2016 revision, except as otherwise noted.
Note 2: A PEC is not required if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses.
Note 3: For occasional non-sterile HD compounding, a PEC used for sterile HD compounding (e.g., Class II BSC or CACI) may be used, but must be decontaminated, cleaned, and disinfected before resuming sterile HD compounding
Note 4: Outdoor air intakes and exhaust discharges shall meet the requirements of ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities, Section 6.3 to ensure adequate separation.
Note 5: Source: ANSI/ASHRAE/ASHE Standard 170-2013: Ventilation of Health Care Facilities. Extrapolated value for filtration
Note 6: Rapid movements can create unacceptable turbulence in a critical area. Such movements disrupt the unidirectional airflow, presenting a challenge beyond intended cleanroom design and control parameters. The principle of slow, careful movement should be followed throughout the cleanroom.

End of Chapter 21.4 Mechanical Guidelines

Contributing Authors 2019 Revision:

Paul Ninomura, PE (DES)
CDR Charles Woodlee (EHS)
Brian Hroch (Albuquerque Area)
David Cramer (Phoenix Area)
K Cook (ANTHC)
M Box (ANTHC)