PART 1 - GENERAL

1.1 OVERVIEW

A. This document provides planning, design and construction criteria for individual rooms and their suites used for the compounding, handling, storage, and delivery of non-hazardous and hazardous pharmaceuticals at The University of Texas MD Anderson Cancer Center (Owner). It is intended to create work environments that allow for the use of best practices by the Pharmacy team to ensure the safety of both the patient as well as the staff.

B. Refer to the “D” series Owner’s Design Guideline Elements for requirements relating to Mechanical, Plumbing, and Electrical work. Refer to Element D304104 for mechanical requirements specific to pharmaceutical air handling distribution.

C. The design of all spaces shall be in accordance with the following:

1. Design professionals shall provide a design walkthrough from these standards to the current standards at the time of the project, to allow the owner the choice of selection based on needs and authority having jurisdiction.
2. The United States Pharmacopeia Chapter <797>, Pharmaceutical Compounding-Sterile Preparations (CSP)
3. The United States Pharmacopeia Chapter <800>, Hazardous Drugs - Handling in Healthcare Settings.
4. The United States Pharmacopeia Chapter <795>, Pharmaceutical Compounding – Nonsterile Preparations
5. Texas State Board of Pharmacy (TSBP) Texas Administrative Code, Title 22, Part 15.
6. The Facility Guidelines Institute, Guidelines for Design and Construction of Healthcare Facilities (2018 Edition).
7. International Standards Organization, ISO Clean Room Standards.
8. FDA Code of Federal Regulations, Title 21, Part 211, Chapter 1, Subpart C, Sections 42, 44, 46, 48, and 52 (April 2017 Edition).

PART 2 - DESIGN CRITERIA

2.1 GENERAL

A. Prior to commencing programming or design, a consideration of services to be provided by the Pharmacy shall be conducted with pharmacy and clinical leadership. Pre-programming activities and/or a design charette shall determine the level and type of services to be provided by the new or renovated Pharmacy spaces.

B. The design of all pharmacy spaces shall allow for the safe efficient preparations/handling of all medications either sterile or non-sterile.

1. The Design professional shall ensure all areas with pressurization, Air change, temperature, and humidity requirements will be compliant 24/7 regardless of the operational hours of the facilities for all nonhazardous and hazardous areas.

2. Mechanical, Electrical and Plumbing systems should be designed with sufficient redundancy to prevent a single point of failure that would force a complete shutdown of a facility.

3. In general, a square or rectangular footprint, without any horizontal surfaces, is preferred for its relative design advantage in achieving uniformity of air flow in relation to the location of the PEC as well as to maintain a comfortable and easily cleanable working environment. This also will comply with the recommendations of the USP Guidelines of which states that “the design of Compounding rooms and Anterooms shall seek to eliminate all horizontal dust collecting surfaces. Where horizontal surfaces are necessary, include appropriate sloped coverage to prevent dust accumulation.” *See diagram 1.*

4. In general, the pharmacy shall be located in the building so as to prevent temperature and relative humidity variation outside of regulatory parameters. The desire is the design firm to understand variation or excursions outside regulatory mandates is not acceptable. This includes occupied and unoccupied operational conditions including but not limited to personnel and equipment heat loads.
    i. Sterile compounding suites shall not be on exterior walls and shall have wall enclosures complying with section 2 below.
    j. Spaces where drugs and other sensitive materials are stored shall not be on exterior walls or contain exterior windows and shall have wall enclosures complying with section 2 below.
    k. Pharmacy work areas can be on exterior windows but should have sufficient exterior wall designs or controls to prevent temperature swings.

C. For security, provide video/camera coverage at locations where pharmaceuticals are mixed, dispensed, stored, and distributed, and at locations approved by MDA Pharmacy Leadership, UTPD Refer to Owners Design Guideline Element D5038, CLN0539 Medication Security Policy, and Review the current the Med Diversion Committee requirements for additional information.
D. Access to the Pharmacy Suite, which includes the Compounding areas as well as all non-sterile work areas and support spaces shall be through secured doors with keyed entry and card access control hardware.
E. Signage shall be permanently posted and noticeably indicate at entry of any room where hazardous chemicals may be present such as at Compounding room(s) and their associated Anteroom(s), Storage, or Receiving (USP800).
F. General acoustical design for noise from building systems shall be a maximum of NC 40
G. Window openings shall have stainless steel frames in the rooms for vision between each other, and from the adjacent work/support spaces and shall prevent dust collection within the windowsill (USP 797).
    a. Drug storage shall not have windows.
    b. Design professional will review windows in non-drug storage areas and provide appropriate UV management for type of space and occupancy.
H. Space for waste materials (Soiled Utility) shall have dual sided access from inside as well as from outside the pharmacy. Refer to the Plumbing section for sink requirements. Refer to the Equipment section for equipment requirements.

2.2 ARCHITECTURAL REQUIREMENTS

A. ISO Classification and Function

1. Anteroom(s)
   i. The basic design for a compounding Anteroom shall be at a minimum an ISO class 8 when it only serves a Non-Hazardous Compounding Room (USP797) or an ISO class 7 when it serves a Hazardous Compounding Room (USP800).

2. Sterile Hazardous Buffer Room
   i. The basic design for a Hazardous Buffer Room shall consist of an ISO Class 5 Primary Engineering Control (PEC) located within an ISO class 7 Buffer room with a negative air flow (USP800).

3. Sterile Non-Hazardous Buffer Room
   i. The basic design for a Non-Hazardous Buffer Room shall consist of an ISO Class 5 Primary Engineering Control (PEC) located within an ISO class 7 Buffer room with a positive air flow (USP797)

4. Compounding Suite room environments not required to meet ISO Class 7 such as Storage and Receiving shall comply with the following minimum standards:

   i. The I.V. pump storage room (if provided) shall contain shelving for storage of miscellaneous items, as well as shelves for use in charging equipment. Provide a quantity of charging shelves and associated duplex electrical outlets based on equipment needs and requirements of the Facility Program, but not less than four (4) shelves, each with six (6) duplex outlets. It is preferred to have this room accessible from outside of the pharmacy and secured with access only by authorized staff from Clinical Engineering, Materials Management and Pharmacy.

   ii. Space for a large container for dirty personal protective equipment and external shipping containers (i.e., boxes) shall be provided in the receiving/break-down room or dirty-storage room, if provided. This space shall have dual access from both within the pharmacy suite and from a non-pharmacy corridor.

   iii. Provide handwashing sink, dual eyewash, PPE storage, and display of proper hazardous signage to rooms and/or locations (USP 800). See Attachment “A”

B. Access and Flow

1. At Exterior door to pharmacy provide a video phone for communications. Include remote door release. (Example: Air Phone)
2. Provide a dedicated adjacent restroom, possible to include with changing rooms.
3. Anteroom(s)
   i. Access to this room shall be restricted to authorized personnel only and shall be designed to provide direct access to Compounding Buffer Room(s) while preventing unrelated traffic through the space. All other exits from the Compounding suite shall be for emergency use only (USP 800)
   ii. Anteroom(s) shall be sized to accommodate the effective donning and doffing of PPE between the ‘dirty’ and ‘clean’ side of the line of demarcation while being out of the range of any door sensors. There shall be sufficient space for the receiving and handling of supplies that are to be moved and stored in the Buffer rooms.
   iii. Where space permits consider separating the “wet” portion of the ante room into a Pre-

Ante room where initial donning of PPE and handwashing will take place before moving into a “dry” Anteroom for final garbing and check before entering the compounding buffer rooms. ***See Diagram 2***

4. Sterile Hazardous Buffer Room
   i. Access to the Sterile Hazardous Buffer Room shall be through an ISO Class 7 Anteroom and restricted to authorized personnel only. Pharmacy design shall include an occupant circulation flow path that is unidirectional with one-way workflow with a single primary entrance and a distinct and separate primary exit. Pressurization separation and contamination control along with a PPE dothing area and gowning disposal is required at the exit however, a full anteroom is not required. Door interlocks shall be included, and door swings shall be from low pressure to high pressure.

   Design, occupancy, workflow, and circulation shall be laid out to have a single entrance through an anteroom and single separate exit with no other ingress or egress doors necessary for occupant safety. Layout shall account for and minimize distance for egress and paths of travel. Both the entrance and exit shall be into adjacent Pharmacy controlled space.
5. Sterile Non-Hazardous Buffer Room
   i. Access to the Sterile Non-Hazardous Buffer Room shall be through an ISO Class 8 (minimum) Anteroom and restricted to authorized personnel only. (USP800). Door swings shall be into anteroom.
6. Non compounding Work Areas
   i. Access to all other spaces within the pharmacy shall be through secured entry/exit doors from non-pharmacy space and restricted to authorized personnel only.
7. Segregated Compounding areas
   i. The segregated compounding area shall not contain unsealed windows or doors that connect to the outdoors or high traffic flow, or be located adjacent to construction sites, warehouses, or food preparation.
   ii. Provide 1 meter of dedicated space around the PEC within the segregated compounding area for sterile compounding.

C. Doors and Windows
   1. Compounding suite room environments required to meet ISO Class 7 such as Anteroom(s), Non-Hazardous and Hazardous Compounding Buffer room(s) shall comply with the following minimum standards:

      a. Openings shall be forty-two (42) inches wide minimum with a half clear glass vision panel and have stainless steel hardware. Aluminum sliding glass doors with seals/gaskets appropriate for maintaining air pressure differentials shall typically be accepted and preferred (USP 797).
      b. A clean room automatic door with impervious and hydrophobic finish and laminated monolithic clear glass coating shall be provided. Swing doors can be considered in lieu of sliding doors if it can be confirmed that the design (room shape, door separation, air device placement, etc.) will allow the room(s) to maintain proper air segregation/pressure differentials when doors are opened and closed (USP 797).
         1) Where swing doors are provided, doors at negative pressure Hazardous (Chemo or viral) rooms shall swing into the room, and doors at positive pressure Non-Hazardous Buffer rooms (IV positive pressure) and Anterooms shall swing outward from the space. (USP 797).

2) Seals and sweeps should not be installed at doors between the Buffer and Anteroom.

c. Access to Anteroom shall be capable of being secured with a deadbolt lock that disables the card reader function while still allowing free egress for life safety compliance. Basis of design, Assa Abloy 82300 Series Mortise lock with electromechanical function
d. Doors between compounding rooms shall be designed to interlock such that no two doors in any room can open at the same time to maintain pressure differential.

2. Non compounding suite environments shall comply with the following minimum standards:

i. Openings shall be forty-two (42) inches wide minimum with a narrow vision panel and have stainless steel hardware.
ii. Openings where bulk deliveries will be received shall be seventy-two (72) inches wide double doors.
iii. Door Frames shall be of painted steel with security hardware as prescribed by UTPD.
iv. Doors shall be wood cores with finishes approved by MD Anderson interiors team.
v. Doors shall have narrow vision lites.
vi. Refer to Section 2.4.B. for door security.

3. Any area which provides a transaction window for interaction with the public shall meet the following requirements:
   i. The window and surrounding wall shall be hardened with protective materials sufficient to ensure the protection of staff. The degree of protection should respond to the security vulnerability assessment.
4. Doors for Narcotics or Controlled Substances areas shall meet the following requirements.
   i. Hardware shall have two-factor authentication.
   ii. Have sufficient hardening of the surrounding walls to prevent unauthorized entry.

D. Finishes
   1. Ceilings
      i. Ceilings within the Compounding suite
         1. shall be smooth and impervious suspended gypsum ceiling painted with a two-part epoxy coated paint (USP 797).
         2. Junctures of ceiling to walls shall be coved or caulked to avoid dirt accumulation (USP 797).
         3. Provide gasketed access doors (2’-0” x 4’-0” or larger) for all above-ceiling items requiring access.
         4. Where gypsum suspended ceiling is not possible, a smooth, durable, washable, suspended, gasketed ceiling tile system caulked to the grid structure with a non-off-gassing caulk is acceptable and shall be confirmed with Owner’s Project Manager (USP 797).
         5. Caulking shall be non-shrinking, non-shedding, and mold/mildew resistant.
         6. Design professional to minimize the required access hatch locations as much as possible.
      ii. Ceilings outside of the compounding suite
         1. Areas that are not required to be sterile can use a smooth, durable, washable, suspended ceiling tile system.

Walls

i. Partitions in Compounding Buffer Rooms shall be constructed of moisture, mold, and mildew resistant gypsum board with a minimum thickness of 5/8". The walls shall be covered with floor to ceiling vinyl wall covering or similar wall product that is sealed and seamless, material to be approved by MD Anderson interiors team. Provide integral cove trim (with approximately one-inch radius) at intersection with the ceiling and at inside corners of walls (USP 797).
ii. Partitions in Anterooms shall be constructed of gypsum board with a minimum thickness of 5/8". The walls shall be painted with a two-part epoxy paint finish and shall include forty-eight (48) inch high rigid sheet wall guard wainscot with integral corner guards where possible. Color of wall and corner guards to match the epoxy paint. Color and material to be approved by MD Anderson interiors team. Provide integral cove trim (with approximately one-inch radius) at intersection with the ceiling and at inside corners of walls (USP 797).
iii. Partitions outside of the Compounding Suites shall be constructed of gypsum board with latex paint finish and color to be approved by MD Anderson Facilities Interiors Team.
iv. Anteroom(s) shall include forty-eight (48) inch rigid sheet wall guard wainscot with integral corner guards where possible. Color of wall and corner guards to match epoxy paint above.
v. Walls in storage, receiving areas and Soiled Utility Rooms should include forty-eight (48) inch rigid sheet wall guard wainscot with integral corner guards where possible. Partitions that create protected or secured barriers (narcotics vaults, controlled public access) shall be sufficiently hardened to prevent unauthorize access.Consider locations for Floor to ceiling glass for visibility into rooms – less obstructedviews for oversight.

All walls shall be extended to the underside of the floor deck above for security.

2. Flooring
   i. Flooring in the Compounding Suite shall be a seamless homogeneous sheet vinyl with an integral coved base that is flush with the wall surface. Use of projecting trim at top of base is not acceptable (USP 797).
   ii. Flooring in the Anteroom shall be a seamless homogeneous sheet vinyl with an integral coved base that is flush with the wall surface. The flooring shall have two distinct colors and/or shade of the same color provided at the entrance to form a 'line of demarcation' between the 'dirty' area and the 'clean' area of the space (USP 797). Color to be approved by MD Anderson Facilities Interiors Team. This space shall be designed in such a way as to facilitate efficient donning and doffing of PPE garb while preventing the accidental opening of the door. This space shall be in close adjacency to the handwash sink.
   iii. Flooring outside of the Compounding Suite shall be a seamless homogeneous sheet vinyl. Use of a standard rubber base is acceptable.
   iv. Flooring in storage areas and Soiled Utility rooms shall be seamless homogeneous sheet vinyl. Use of a standard rubber base is acceptable.
   v. Flooring shall be turned up onto the wall when water sources are present.
   vi. Flooring at delivery areas shall be resistant to delivery equipment use/damage while meeting the need for integral cove bases when required by code. When no integral cove is required, sealed concrete can be considered.
3. Fixed Cabinetry
   i. There shall be no fixed cabinetry in Ante or Buffer rooms.
   ii. Any work surfaces in the Compounding Suite or any sterile area shallbe stainless steel work surfaces. Modular and mobile components are preferred when possible. (USP797)
   iii. Any fixed cabinetry in nonsterile storage areas where medications are handled should be stainless steel unless directed otherwise by the project team.

iv. Packaging or any areas where you are handling drugs – Stainless Steel cabinets.
v. Any fixed cabinetry in nonsterile work areas shall be plastic laminate with solid surface work tops.

E. Signage and Graphics – start here 9/15
1. Room signage shall follow MDA standards for display and numbering.
2. Specialty signage for hazardous locations shall comply with requirements outlined per Attachment "A."
3. Signage for equipment such as but not limited to items such as eyewashes, hoods, and other safety equipment shall be per MDA standards.

2.3. MECHANICAL, ELECTRICAL, & PLUMBING SYSTEMS

A. Engineering Controls and Air Distribution Requirements
1. Refer to Owner's Design Guideline Element D304104 for additional information and requirements.
2. Texas Pharmacy Board requirements include a 1 CFU fungal spore limit for failures, in which designs should work to maintain environments to stay compliant with this requirement.
3. Areas for clean or dirty storage, receiving/breakdown-rooms or receiving vestibules (depending on the size of the pharmacy) for drugs shall be or negative pressure relative to the surrounding areas. The space shall be designed with normal/neutral or negative air pressure with respect to adjacent spaces, and with twelve (12) air changes/hour. The storage/breakdown area must be externally vented and have means to contain spills and provide PPE to staff (USP 800).
4. Areas that are not a part of the Compounding Suite and are not otherwise designated as requiring positive or negative pressure (pump rooms, housekeeping, non-sterile work areas, etc.) shall be neutral or negative pressure relative to the surrounding areas. The space shall be designed with normal/neutral or negative air pressure with respect to adjacent spaces, and with twelve (12) air changes/hour. The storage/breakdown area must be externally vented and have means to contain spills and provide PPE to staff (USP 800).
5. Designed Environmental Air conditions for the Cleanroom Suite shall be designed such that, when fully operational and occupied, can always achieve a temperature at or below sixty-four (64) degrees Fahrenheit and coincidental humidity at or below fifty-five (55) percent relative humidity (USP 797). Environmental conditions must also be maintained during unoccupied and maintenance periods.
6. Separately differentiate Hazardous storage (ASHRAE 170) from Hazardous Drug Storage (USP800), if these activities occur in the same space, design, label, and provide graphics per the most stringent requirements.
7. The room shall have BAS alarm monitoring. In addition to monitoring a dashboard created using Clockworks © shall be delivered for each Pharmacy.
8. Design professionals shall consider the owner may deploy wireless sensors throughout the spaces for redundancy and will not design materials or configurations that impede the use of these devices.
9. Monitoring and alarming for critical spaces, equipment, and storage will include a secondary certified system redundant to the BAS.
10. Non-Hazardous and Hazardous Buffer rooms and Anterooms shall be designed for a minimum of thirty (30) air changes/hour (ACPH). If recirculating BSC(s) are used (only with non-Hazard room), they may provide up to fifteen (15) of the total air changes/hour required in a room.
11. Hazardous Compounding Buffer Rooms shall contain BSC(s) that are hard ducted and externally exhausted. The BSC(s) shall not provide the sole means of exhaust in a space (USP 800) and the ACH needs to be calculated based on the amount of supply air provided.

12. Pressure gauges with environmental monitors shall be provided to continuously monitor the ACPH, temperature, humidity and the differential air pressure between the Compounding room(s), Anteroom(s), and general pharmacy environment, through tie-in to the BAS. A visual status displays shall be located outside each room in a location that will not be affected by travel and cross-drafts (USP 797).
    i. The Room Pressure Monitor located outside the Anteroom(s) shall be programed to display room pressures and temperatures of all compounding rooms and anterooms. This programing functionality does not remove the requirements to have RPMs outside of each compounding room.
    ii. The following pressure relationships shall be maintained.
        1. Non-Hazardous Compounding Buffer Rooms shall maintain a minimum of 0.020-inch w.c. positive air pressure with respect to their anterooms (USP 797).
        2. Hazardous Compounding Buffer Rooms shall maintain a 0.01-inch w.c. to 0.03-inch w.c. negative air pressure with respect to adjacent areas, (USP 800). The Buffer Room shall have an operational design objective of 0.02-inch w.c. negative air pressure.
        3. Anterooms shall maintain at least a 0.02-inch w.c. positive air pressure with respect to adjoining circulation/workroom spaces (USP 800).

    HEPA supply filters shall be located at ceiling level (USP 797 revision). Provide gasketed ceiling access doors as needed to facilitate testing and recertification from inside the room. Design Team should consider the use of Fan Filter Units (FFU) with HEPA Filters for ACPH augmentation as well as utilizing HEPA units that allow for a testing port to avoid removing the grills.
13. Standalone ¾" or larger Aerosol ports should be located to support dynamic testing protocols at the appropriate locations.
14. HVAC sterilizing technology shall be considered, and recommendations be provided to the owner for possible inclusion into pharmacy projects.
15. Air distribution grilles at Non-Hazardous and Hazardous Compounding Buffer Rooms and Anterooms:
    i. Locate HEPA-filtered supply air grilles and return/exhaust grilles to avoid the formation of areas of relatively low, or no air movement within the room, and to create a general top-down dilution of the area air. Typically, locating supply air at the ceiling and return/exhaust air at walls twelve (12) inches from the floor, with adequate dispersion of the various types of devices around the room, is required to achieve this goal. Ceiling- mounted return/exhaust air devices shall not be used (USP 797).
        1. Downward, unidirectional air flow for supply air is preferred, provided an overall laminar flow design, without turbulence, can be achieved across all rooms within the Cleanroom Suite (USP 797).
        2. Supply air grilles shall not be located directly over, or at the front of BSCs (USP 797).
        3. Low-mounted exhaust and return air grilles shall be installed in rooms with BSCs to allow for functionality in the event a BSCs becomes inoperable. Ceiling mounted returns are not acceptable (USP 797).
    ii. In suite air pattern analysis via visual smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow from the ceiling to the returns verifying there are no stagnant areas in the room, in addition conduct a visual smoke study of any pass-thrus to verify no air is flowing into negative pressure space, prior to substantial completion during construction (USP 797).
16. Provide an exhaust adjacent to the compressor for each refrigerator and/or freezer located in a negative pressure Compounding Buffer Room.

17. Provide for an air curtain, high velocity air, from above to below near entrance to anteroom/PPE garbing areas to wash particles and bio matter from people and materials. This should keep particulate from infiltrating into the anteroom.
18. Air flow and room/area based continuous particle count monitoring at or near the return grill shall be conducted through tie-in with the BAS and local indication/monitoring at compounding and ante rooms.
19. When the project allows, install sample testing ports in rooms where the monitoring electronics are located remotely.
20. Provide stainless steel ductwork for areas and equipment exposed to corrosive chemicals. EH&S can identify locations for this requirement.
21. Refer to current Pharmacy sampling plan for any additional requirements.

B. Electrical, IT and Security Systems
    1. Lighting
        i. All areas of a pharmacy shall provide a comfortable and well lighted working environment. (USP 797).
        ii. Compounding areas shall have light fixtures that are designed for clean room applications, flush with the surface of the ceiling, and have smooth sealed lenses. Fixture perimeter and any openings shall be sealed to ceiling (USP 797).
        iii. UV light cleaning systems shall be considered in design of critical spaces. UV could be included at air handling units and/or in room locations.
    2. Electrical
        i. Within the hospital environment, emergency power shall be provided to, work areas, storage, lighting, AHUs, PECs, FFUs, Exhaust fans, controls, and equipment as required to maintain proper temperature, cleanliness,security, and humidity of critical pharmaceuticals. Confirm requirements with the Facility Program.
        ii. Distribution of Emergency power shall be reviewed by the Facilities Program Manager and be provided at any equipment critical to pharmacy operations.
            1. Critical equipment includes but is not limited to the following items: hoods, alarms, door access, Pyxis, cameras/security, refrigerators/freezers, incubators for storage, BAS components that serve the pharmacy areas, and the project team will verify other items during design reviews.
        iii. In Compounding suite wire mold is not permitted due to the presence of horizontal surfaces that can accumulate dust and particulate.
        iv. In a non-hospital environment emergency power shall be provided, where available, to, work areas, storage, lighting, and equipment as required to maintain proper temperature, cleanliness, and humidity of critical pharmaceuticals as well as for basic life safety. Confirm requirements with the Facility Program.
        v. Pyxis units should be reviewed to provide appropriate UPS or power configuration in order to have continuous operation with no disruptions to preserve electronic components.

C. Plumbing Systems
    1. In general, any plumbing systems should be designed to avoid being above the cleanroom suite and drug storage spaces. Where this is not possible due to existing conditions utilize a containment system such as double wall piping, drip pans with moisture alarms to alert Engineering of any leaks.
    2. Compounding Buffer room(s) shall not contain any source of moisture including sinks and floor drains.
    3. The Anteroom(s) shall contain a handwashing sink in a location that is inside of the line of demarcation and is a minimum of 1 meter from the entrance of a Compounding Buffer room

(USP 797, 800) or Dry Anteroom. Arrangement of the sink in relationship to the 'line of demarcation' is critical to the process of donning of PPE and hand hygiene and should minimize the number of steps taken by staff and offer a unidirectional flow of the space. Sinks shall be located so as not to cause a splash, overspray, or aerosol hazard for purposes of infection control. (Splash guards, shields that do not interfere with eye wash) see other ODGs for recommendations.

i. Fixture size should be 24" width Stainless scrub type sink for ISO 7 cleanroom with a minimum distance of (10) inches from the faucet discharge to drain and shall be of adequate dimensions to allow for washing up to the elbows.
ii. Fixture controls should be hands-free and operated with separate hot and cold mixer so that temperature can be adjusted by hospital post-installation. Hot water shall be provided at a consistent one hundred (105) degrees Fahrenheit minimum. Recommend knee operated scrub sink (USP797)
iii. A dual eyewash shall be located at the handwashing sink with the ability to be used in the sink or detached for emergency shower use. The eyewash shall comply with the requirements outlined in ODG D201001.
iv. If the eyewash and sink are in the same unit, they shall include separate mixing valves for different temperature configurations.

4. The Anteroom(s) shall not contain a floor drain.

2.4 EQUIPMENT & FURNISHINGS:

A. Equipment

1. PEC

The PEC function in the Buffer Rooms shall be satisfied with six (6) foot, minimum, ClassII-B2 Biological Safety Cabinet (BSC) with sufficient clearance. The type of BSC specifiedshall satisfy the nature of work being performed in the space. Four (4) foot hoods are not acceptable by MD Anderson except in cases where space limitations do not allow for theeffective design with a six (6) foot hood.

i. BSCs used for hazardous drug preparation must be externally vented and should be HEPA filtered exhaust for environmental protection. Use of another type of PEC in Hazardous or Non-Hazardous Compounding rooms, such as a laminar airflow workstation, must be approved by pharmacy leadership for specific use cases, otherwise is not acceptable.
ii. Where a BSC is exhausted to the exterior, the fan shall be: dedicated to the unit, and provided with emergency power.
iii. Where possible provide a closure panel between the top of the BSC and the ceiling and in accordance with the manufacturer recommendations and requirements.
iv. The BSC shall be located out of traffic patterns and away from circulating air currents (USP 797).
v. Provide a minimum of two (2) BSCs in each compounding room. Overall design shall enable one or more BSCs to remain in use should the other(s) become inoperable.
vi. The following minimum clearances shall be provided around the individual BSC: ***See Diagram 3***
    a. Forty (40) inches by the full length of BSC, as workspace, in front.
    b. Twelve (12) inches to nearest side wall or column.
    c. Forty (40) inches additional walking space beyond the workspace for a total of eighty (80) inches clear from face of the BSC.

d. Forty (40) inches to stationary items at perpendicular walls.

e. Sufficient space around fixed equipment to clean and maintain behind equipment.

vii. Where rooms contain multiple BSCs, a staggered design arrangement is preferred. If offsetting of BSCs cannot be accomplished, the following minimum clearances should be provided at the BSCs:

a. Ten (10) feet, when two BSCs are facing each other.

b. Twenty-four (24) inches, when located next to each other along the same wall.

c. Four (4) feet, when located along perpendicular walls.

d. The design professional shall validate the design layout and BSC quantities meet the manufacturer recommendations, total system performance, and the indoor air quality, for the space they are occupying.

2. BSCs shall not be located near entry doors due to cross traffic (USP 797). If locating BSCs a substantial distance from in-use doors is not possible, a minimum distance of forty (40) inches at the side and five (5) feet at the front of the BSC to the nearest door jamb shall be provided.

2. Pass Thru Cabinets

i. Pass-through(s) shall be provided (in addition to an Anteroom) to minimize the need for movement between general pharmacy work areas and Compounding rooms (USP 797 pg. 12).
   a. Chambers shall be a minimum of eighteen (18) inches and maximum thirty-six (36) inches, length by width by height in size and have double interlocking doors to maintain air pressure differentials.
   b. Pass-throughs shall be sealed and gasketed to meet USP guidelines. Pass-through refrigerators shall not be used. Other methods of containment (such as sealed containers) may be used if needed.
   c. All pass-through cabinets shall be subject to and pass a visible smoke test to ensure the pass-through cabinets seals fully prior to acceptance.

3. Anteroom Equipment

i. All equipment and furnishings stationed in the Anteroom shall be limited to functions related to donning and doffing of PPE and hand hygiene. And shall be easily wipeable.

4. Other Equipment

i. Provide standard refrigerators, ultra-low refrigerators, rolling shelving units, and movable workstations as required by the Facility Program.
   1. All refrigerators and freezers shall be provided with emergency power and be monitored through the BAS.
   2. Compounding equipment, such as BSCs shall be provided with emergency power.
   3. Additional sensitive equipment may be provided with emergency power depending on Facility Program requirements.
   4. The Program shall include for Hazardous and Non-Hazardous Drug Storage rooms to provide an extra fridge and freezer for redundancy/downtime.

ii. A stainless-steel garbing storage unit that is cleanable and impermeable, shall be provided in Anteroom.

iii. A stainless-steel bench that allows for access to both sides of the line of demarcation for sitting/garbing, shall be provided in Anteroom.
iv. All EVS/Housekeeping carts, shelving, mobile workstations, and similar items within Non-Hazardous and Hazardous Compounding Buffer Rooms and Anterooms shall be cleanable and wipeable and shall be provided with cleanable casters to promote mobility. Any metal mesh shelving shall be composed of stainless steel (USP 797). This shall be separate units from garbing units.
v. Automated systems to be used in the pharmacies need to be considered during the design process and coordinated with the Engineering systems. These include but are not limited to automated dispensing units (ADU), barcode scanning for inventory receipt, and automatic dosing systems.
    1. Provide data connections and electrical power to equipment as required by the Facility Program.
    2. Automated dispensing units shall be provided with emergency power.
vi. The status board requirements are to be satisfied through use of large-format monitors mounted to the walls.
vii. Trash bins, when provided, should have lids.
viii. Spill kits containing all the materials needed to clean hazardous drug spills shall be readily available in all areas where hazardous drugs are routinely handled (USP 800).
ix. All surfaces of fixtures, shelving, and cabinets/workstations, etc. shall be smooth, non-reactive, impervious, and without cracks, crevices or other designs which would make cleaning and infection control difficult. Plastic laminate (PLAM) is not an acceptable solution. 316 Grade Stainless steel counters, shelves, and carts are preferred.
x. All equipment except BSCs exhausted thru fixed building systems, shall be equipped with cleanroom compatible castors.
xi. Non-hazardous and Hazardous storage rooms shall have similar cleanable surfaces to compounding areas for cleanliness and infection control.
    1. All layouts and designs within the pharmacy shall be reviewed by the EHSSEM team for ease of access, cleaning, and maintenance.

B. Furniture
    1. Chairs shall be provided per MD Anderson standards.
        i. Chairs need to meet cleaning and particle testing requirements for ISO class 7 spaces or better.
        ii. Chairs/stools need to be impermeable material for the sterile and non-sterile compounding, also cleanable and wipeable with chemicals/cleaners used in the pharmacy.

PART 3 - SPECIAL CONTRACT DOCUMENT REQUIREMENTS

3.1 GENERAL

A. Obtain approval from Owner's Project Manager/Planner Designer for all finish schedules prior to issuance of Construction Documents.

B. All finishes should reflect the standard finish application for the specific building in which the pharmaceutical compounding rooms and support spaces are located.

C. Include general notes which require testing of components and systems for proper functioning at the earliest opportunity during construction, and prior to any testing required to attain

Substantial Completion. Smoke visualization testing shall be conducted at intervals, when practical, and shall be observed by Owner, at its option.

PART 4 - PRODUCTS

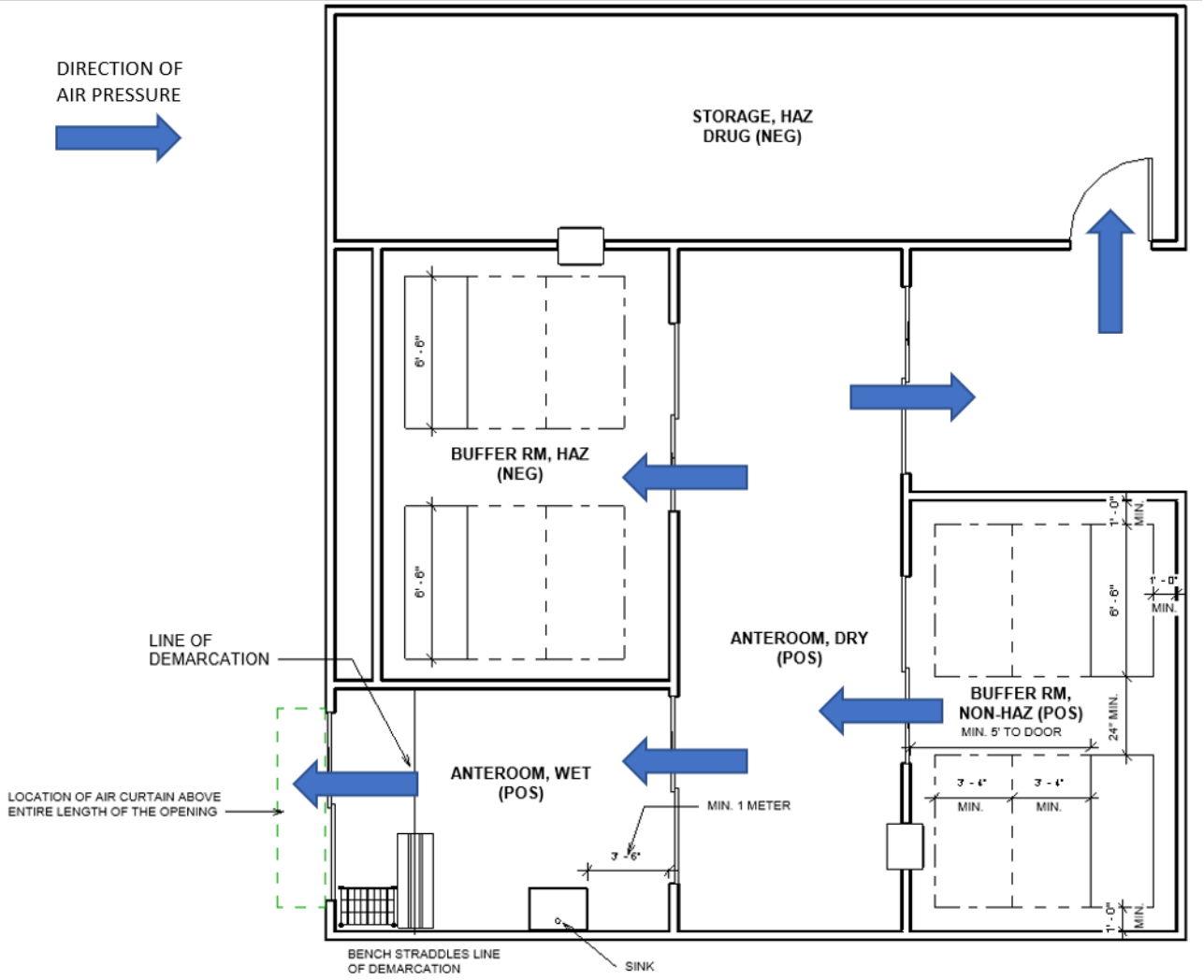
4.1 GENERAL

A. For all projects (renovation and new), refer to Owner's Interior Finishes Standards. These are available on the Owner's Design Guidelines website: http://www2.mdanderson.org/depts/cpm/standards/interiors.html

B. For renovation projects, refer to Owner's Master Construction Specifications. These are available on the Owner's Design Guidelines website: http://www2.mdanderson.org/depts/cpm/standards/specs.html

PART 5 – DIAGRAMS & ATTACHMENT

Diagram 14


DIRECTION OF AIR PRESSURE
STORAGE, HAZ DRUG (NEG)
BUFFER RM, HAZ (NEG)
6' - 6"
6' - 6"
LINE OF DEMARCATION
ANTEROOM, DRY (POS)
BUFFER RM, NON-HAZ (POS)
MIN. 5' TO DOOR
ANTEROOM, WET (POS)
LOCATION OF AIR CURTAIN ABOVE ENTIRE LENGTH OF THE OPENING
MIN. 1 METER
3' - 6"
1' - 0" MIN.
1' - 0" MIN.
6' - 6"
24" MIN.
3' - 6" MIN.
3' - 6" MIN.
BENCH STRADDLES LINE OF DEMARCATION
SINK

Z4075 Pharmaceutical Compounding Rooms

Diagram 2

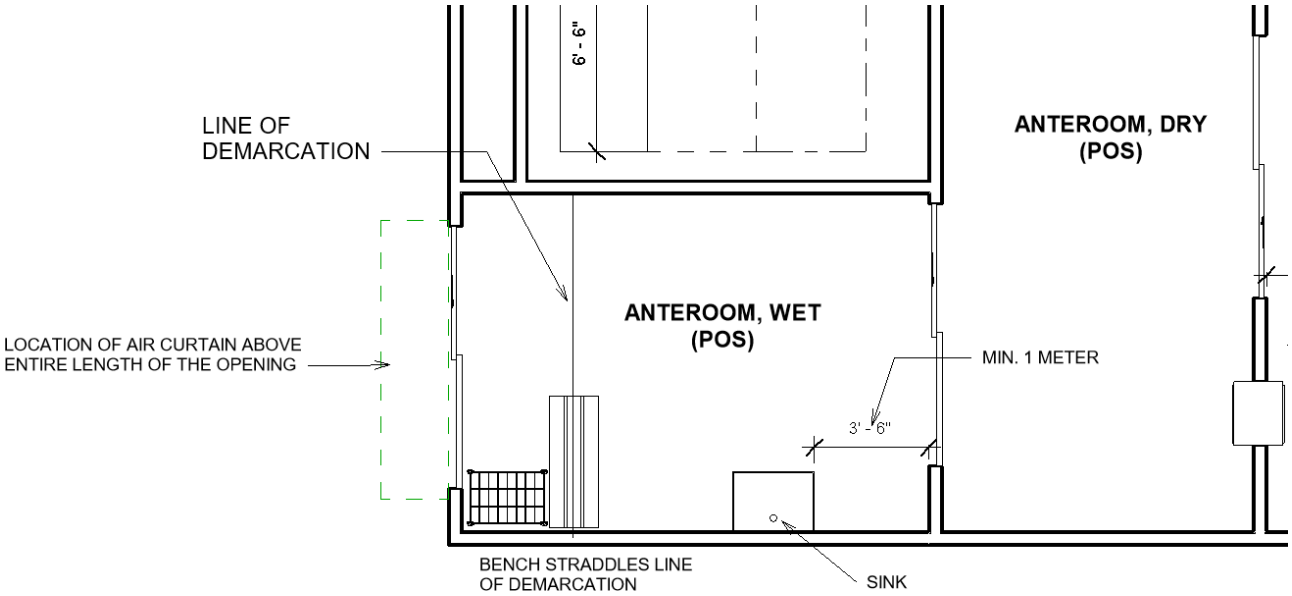
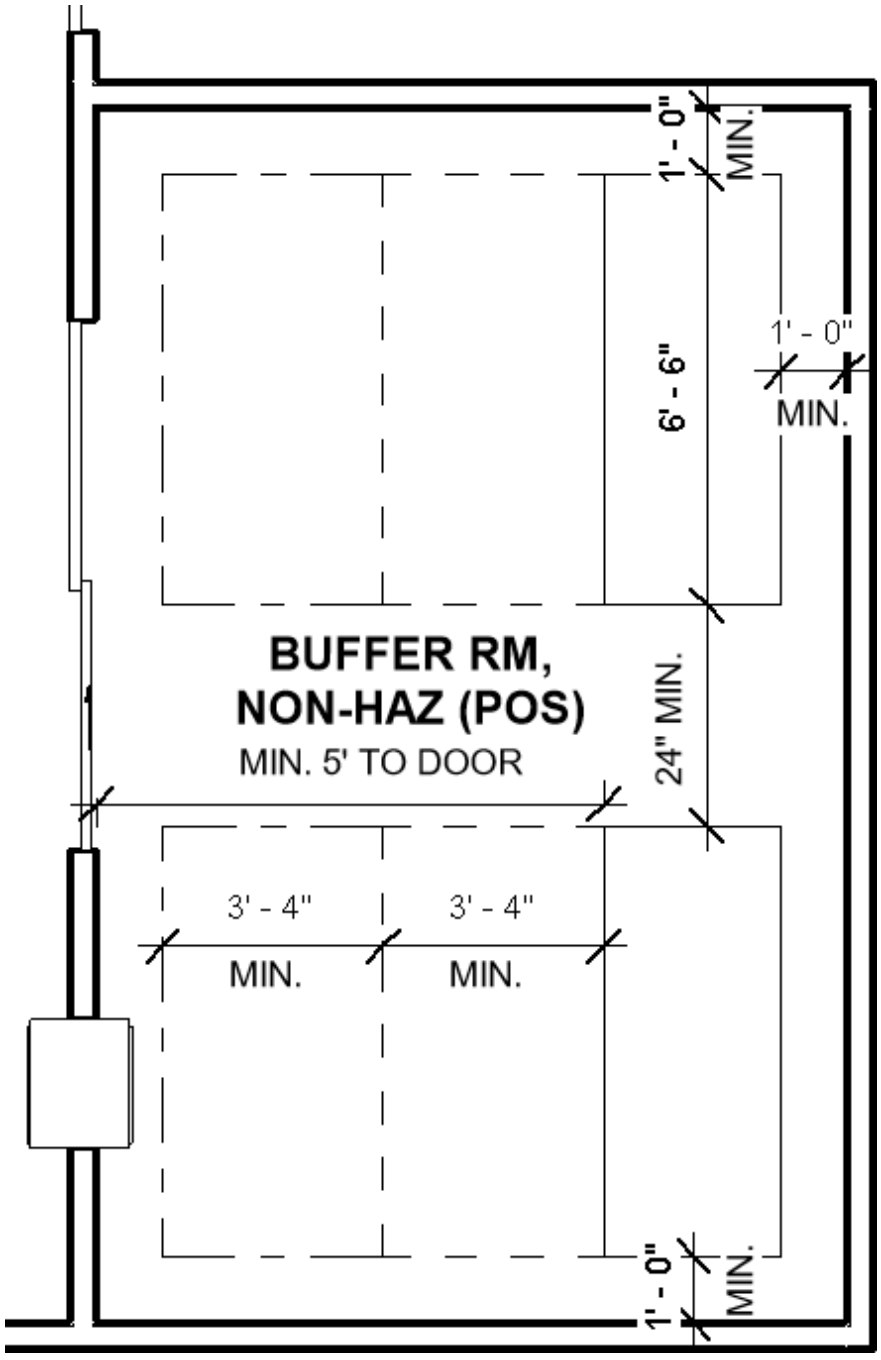


Diagram 3


1' - 0"
MIN.
6' - 6"
1' - 0"
MIN.
BUFFER RM,
NON-HAZ (POS)
MIN. 5' TO DOOR
24" MIN.
3' - 4"
MIN.
3' - 4"
MIN.
1' - 0"
MIN.

ATTACHMENT “A”

Signage to be 7” x 10”

PART 6 - DOCUMENT REVISION HISTORY

Issue	Date	Revision Description	Reviser
	20151021	Initial Adoption of Element	FPDC
Rev. 1	20180925	Revisions and Inclusion of USP <797> and USP <800>	EYP
Rev. 2	20181023	Include additional smoke testing, HEPA seals and sink-eyewash	EYP
Rev. 3	20190301	Reissued with Owner Design Guideline Renewal 2019	FPDC
Rev. 4	20231129	Updated for changes to USP 797/800 taking effect Nov. 1st 2023	EBSM
Rev. 5	20250204	Update additional requirements to match current guidelines and practices	EBSM

END OF ELEMENT Z4075