PART 1 - GENERAL

1.1 OVERVIEW

A. This document provides design and construction criteria for individual rooms and their suites used for the compounding of non-hazardous and hazardous pharmaceuticals at The University of Texas MD Anderson Cancer Center (Owner).

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. Design shall be in accordance with:

1. The United States Pharmacopeia Chapter <797>, Pharmaceutical Compounding-Sterile Preparations (CSP)
2. The United States Pharmacopeia Chapter <800>, Hazardous Drugs - Handling in Healthcare Settings.
3. Texas State Board of Pharmacy (TSBP) Texas Administrative Code, Title 22, Part 15.

PART 2 - DESIGN CRITERIA

2.1 GENERAL

A. Design shall allow sterile compounding to be performed within an ISO Class 7 Buffer room that may be part of a larger compounding suite.

1. Facilities shall be designed to be in operation twenty-four (24) hours/day, seven (7) days/week, 365 days/year.
2. A rectilinear footprint, without offsets, is preferred for its relative design advantage in achieving uniformity of air flow.

B. Designed Environmental Air conditions for Compounding room(s) and Anteroom shall be at or below sixty-eight (68) degrees Fahrenheit and at or below sixty (60) percent relative humidity at all times (USP 797).

C. Basic design for the compounding space shall consist of an ISO Class 5 Primary Engineering Control (PEC) located within an ISO Class 7 Hazardous or Non-Hazardous Compounding Rooms (USP 797).
1. Access to these rooms shall be through an ISO Class 7 Anteroom and restricted to authorized personnel only. All other exits from Compounding suite shall be for emergency use only (USP 800).

2. The PEC function shall be satisfied using nominal width: five (5) foot or six (6) foot Class II-B2 Biological Safety Cabinet (BSC).

3. Provide a minimum of two BSCs in each compounding room. Overall design shall enable one or more BSCs to remain in use should the other(s) become inoperable.

D. Separate “clean” and “dirty” store rooms, receiving/break-down rooms for drugs that are neutral/normal or negative pressure relative to the surrounding areas, pump room, housekeeping, and workroom support areas shall typically be provided. These spaces are located outside the ISO Class 7 environment; however, requirements shall be confirmed with Owner’s Project Manager and the Facility Program.

E. Emergency power shall be provided, where available, to storage spaces, lighting, and equipment as required to maintain proper temperature and humidity of critical pharmaceuticals. Confirm requirements with the Facility Program.

F. Access to the Compounding Suite, which includes the support spaces, shall be through secured doors with keyed entry and card access control hardware.

G. For security, provide video coverage at locations where pharmaceuticals are mixed, dispensed, and distributed, and at locations approved by the Owner’s Project Manager and UTPD. Refer to Owners Design Guideline Element D5038 for additional information.

2.2 ARCHITECTURAL REQUIREMENTS

A. 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:

1. Doors: 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).

a. 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) rooms shall swing into the room, and doors at positive pressure Non-Hazardous Buffer rooms 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.
3) Access to these rooms shall be through an ISO Class 7 Anteroom and restricted to authorized personnel only. All other exits from Compounding suite shall be for emergency use only (USP 800 pg. 3).

2. The PEC function shall be satisfied using nominal width: five (5) foot or six (6) foot Class II-B2 Biological Safety Cabinet (BSC). Refer to below for placement requirements within the room.

3. Provide a minimum of two BSCs in each compounding room. Overall environmental design shall enable one or more BSCs to remain in use should the other(s) become inoperable.

4. Doors between rooms shall be designed to interlock such that no two doors in any room can be open at the same time to maintain pressure differential.

5. 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 (USP 800).

6. 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 window sill (USP 797).

7. Partitions shall be constructed of gypsum board with epoxy paint finish and color to be approved by MD Anderson Facilities Interiors Team. Provide integral cove trim (with approximately one-inch radius) at intersection with the ceiling and at inside corners of walls (USP 797).
   a. Anteroom 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 epoxy paint above.

8. Ceiling shall be smooth and impervious suspended gypsum ceiling painted with epoxy coated paint (USP 797).
   a. Junctures of ceiling to walls shall be coved or caulked to avoid dirt accumulation (USP 797).
   b. Provide gasketed access doors (2'-0" x 4'-0" or larger) for all above-ceiling items requiring access.
   c. Where gypsum suspended ceiling is not possible, a smooth, durable, washable, suspended 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).

9. Floor shall be seamless homogeneous sheet vinyl with heat welded seams with a smooth surface. Flooring with hard-to-clean textured surfaces is not acceptable (USP 797 & USP 800).
a. Anteroom shall have two distinct colors and/or shade of same color provided at
the entrance to form a demarcation line between “clean” and “dirty” areas of the
space (USP 797). Color to be approved by MD Anderson Facilities Interiors
Team.

10. Base shall be coved (radiused), seamless homogeneous sheet vinyl integral with floor
finish and flush with wall surface. Use of projecting trim at top of base is not acceptable
(USP 797).

11. 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-through refrigerators shall not be used. Other methods of containment (such as
sealed containers) may be used if needed.

12. Compounding suite shall provide a comfortable and well-lighted working environment
(USP 797).

a. Light fixtures shall be designed for clean room application, flush with the surface of
the ceiling, and have smooth lenses. Fixture perimeter and any openings shall be
sealed to ceiling (USP 797).

13. All fixed work cabinets shall be epoxy painted steel frame casework with stainless steel work
surface. Modular and mobile components are preferred when possible (USP 797).

14. Compounding Buffer room(s) shall not contain sinks or floor drains. Anteroom(s) shall
contain a handwashing sink near the entry door when possible. The handwashing sink
must be a minimum of 1 meter from the entrance of a Compounding Buffer room (USP
797, USP 800).

a. Fixture size should be larger than 144 square inches with a minimum of ten (10)
inches from faucet discharge to drain and shall be of adequate dimensions to allow
for washing up to the elbows. Recommend knee operated scrub sink (USP 797).

b. 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 (100) degrees Fahrenheit maximum.

c. A dual eyewash shall be located at the handwashing sink with ability to be used in sink
or detached for emergency shower use.

d. Locate sink and eyewash station on wall opposite entry to compounding rooms if
possible.

15. Acoustical design for noise from building systems shall be a maximum of NC 40.
16. Space in Anteroom(s) for donning and doffing PPE, package receiving, handling, and storage shall be provided unless separate rooms are provided for these functions.

17. 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.

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

a. The pump 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.

b. 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.

c. Provide handwashing sink, dual eyewash, PPE storage, and display of proper hazardous signage to rooms and/or locations (USP 800).

2.3 ENGINEERING CONTROLS AND AIR DISTRIBUTION REQUIREMENTS:

2.3.1 USP800

<table>
<thead>
<tr>
<th>Containment Secondary Engineering Control (C-SEC)</th>
<th>Non-Sterile HD Room</th>
<th>Sterile HD Room</th>
<th>Containment Segregated Compounding Areas (C-SCA)</th>
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</thead>
<tbody>
<tr>
<td>Air Rate Change Per Hour</td>
<td>At least 12 ACH</td>
<td>Minimum of 30 ACH Hepa Filtered Supply Air</td>
<td>Minimum of 30 ACH Hepa Filtered Supply Air</td>
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<tr>
<td>Room Ventilation</td>
<td>C-PEC must be placed inside a Buffer room (C-5EC), and the room be externally vented. The C-PEC must also be Externally Ventilated or have redundant HEPA Filters.</td>
<td>N/A</td>
<td>Room and C-PEC must be Externally Ventilated</td>
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<tr>
<td>Room Pressure</td>
<td>Negative .01&quot; - .03&quot; water with respect to adj areas</td>
<td>Maintain a positive pressure of at least .02&quot; water column relative to adjacent areas</td>
<td>Negative .01&quot; - .03&quot; water with respect to adj areas</td>
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<tr>
<td>Air Class</td>
<td>N/A</td>
<td>ISO 7</td>
<td>ISO 7</td>
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<tr>
<td>Compounded Sterile Preparations (CSPs)</td>
<td>Not Allowed</td>
<td>Not Allowed</td>
<td>Category 1 and 2 CSPs</td>
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</table>

2.3.1 USP797

A. Refer to Owner's Design Guideline Element D304104 for additional information and requirements.

B. Non-Hazardous and Hazardous Buffer rooms and Anterooms shall be designed for a minimum of thirty (30) air changes/hour. 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. BSC(s)
C. The following pressure relationships shall be maintained:

1. Non-Hazardous Compounding Buffer Rooms shall maintain a 0.01-inch w.c. to 0.03-inch w.c. positive air pressure with respect to their anterooms, with an operational design objective of 0.02-inch air pressure (USP 797, & USP 800).

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, with an operational design objective of 0.02-inch w.c. negative air pressure (USP 797, & USP 800).

3. Anterooms shall maintain at least a 0.02-inch w.c. positive air pressure with respect to adjoining circulation/workroom spaces (USP 800).

4. A separate area from compounding rooms shall be provided for storage and break down of hazardous pharmaceuticals. 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. Hazardous Compounding Buffer Rooms shall be hard ducted and externally exhausted (USP 800).

D. 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).

E. 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.

F. Air distribution grilles at Non-Hazardous and Hazardous Compounding Buffer Rooms and Anterooms:

1. 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).

   a. Downward, unidirectional air flow for supply air is preferred, provided an overall laminar flow design, without turbulence, can be achieved (USP 797).

   b. Supply air grilles shall not be located directly over, or at the front of BSCs (USP 797).

   c. 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).
2. In-suite air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions, prior to substantial completion during construction (USP 797).

   a. Smoke study shall include leakage testing of all ceiling and wall penetrations including but not limited to light fixtures, devices, access panels, etc.

G. Provide an exhaust adjacent to the compressor for each refrigerator and/or freezer located in a negative pressure Compounding Buffer Room.

H. Air flow at BSCs shall be monitored through tie-in to the BAS.

### 2.4 EQUIPMENT AND FURNISHINGS

A. BSCs used for hazardous drug preparation must be externally vented and should be HEPA filtered exhaust for environmental protection. Use of another type PEC in Hazardous or Non-Hazardous Compounding rooms, such as a laminar airflow work station, is not acceptable.

1. Where possible provide a closure panel between the top of the BSC and the ceiling and in accordance with the manufacturer recommendations and requirements.

2. The BSC shall be located out of traffic patterns and away from circulating air currents (USP 797).

3. The following minimum clearances shall be provided around the individual BSC:
   a. Forty (40) inches by the full length of BSC, as work space, in front.
   b. Twelve (12) inches to nearest side wall or column.
   c. Eighty (80) inches clear floor area from face of BSC.
   d. Forty (40) inches to stationary items at perpendicular walls.

4. 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.

5. 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.

6. Where a BSC is exhausted to the exterior, the fan shall be: dedicated to the unit, HEPA filtered and provided with emergency power.

7. HEPA filters on BSC units shall not utilize gel-type seals.
B. Provide standard refrigerators, ultra-low refrigerators, rolling shelving units, and movable work stations 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.

C. A housekeeping closet or cabinet that is cleanable and impermeable, a stainless steel fixed-to-floor bench, and storage facilities for personnel garbings shall be provided in Anteroom.

D. All carts, shelving, mobile work stations, 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).

E. Automated systems to be supported include BD Cato, Pyxis, and Barcode scanning for inventory receipt.

1. Provide data connections and electrical power to equipment as required by the Facility Program.

2. Pyxis equipment shall be provided with emergency power.

F. The status board requirements are to be satisfied through use of large-format monitors mounted to the walls.

G. Trash bins, when provided, should have lids.

H. Spill kits counting all the materials needed to clean hazardous drug spills shall be readily available in all areas where hazardous drugs are routinely handled (USP 800).

I. All surfaces of fixtures, shelving, and cabinets/work stations, etc. shall be smooth, impervious, and without cracks, crevices or other design which would make cleaning and infection control difficult. Plastic laminate (PLAM) is not an acceptable solution. Stainless steel counters and shelves are preferred. In cases of epoxy painted steel frame components, color shall be approved by the MD Anderson Facilities Interiors Team (USP 797).

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 - DOCUMENT REVISION HISTORY

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<td></td>
<td>20151021</td>
<td>Initial Adoption of Element</td>
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<tr>
<td>Rev. 1</td>
<td>20180925</td>
<td>Revisions and Inclusion of USP &lt;797&gt; and USP &lt;800&gt;</td>
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<tr>
<td>Rev. 2</td>
<td>20181023</td>
<td>Include additional smoke testing, HEPA seals and sink-eyewash</td>
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<td>Rev. 3</td>
<td>20190301</td>
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END OF ELEMENT Z4075