MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

5.17: PHARMACY ROOM REQUIREMENTS

General

The following guidelines are provided for designing spaces where sterile and nonsterile pharmaceutical drugs are compounded and/ or stored.

Design Process

Engage pharmacy staff stakeholders early during the design process. Pharmacy staff will be responsible for defining the types and risk categories for all drug compounding that will be performed within the pharmacy per United States Pharmacopeia Convention (USP) definitions.

Sterile compounding is routinely performed within a Primary Engineering Control (PEC). Pharmacy staff determine the number of PECs.

The following USP types and risk categories will be defined by the pharmacy stakeholders:

1. Type - Sterile and/or Non Sterile Drug Compounding
2. Type - Hazardous and/or Non Hazardous Drug Compounding
3. Risk Categories (For Compounded Sterile Preparations and radiopharmaceuticals)
    a. Category 1 (BUD 12 Hours or Less)
    b. Category 2 (BUD greater than 12 Hours)
4. Drug Storage Rooms

See attached sample room type layouts, sheets SK-1 & 2.

Codes and Guidelines

The following codes/guidelines are to be complied with:

- USP 659 Packaging and Storage Requirements
- USP 795 Pharmaceutical Compounding - Nonsterile Preparations
- USP 797 Pharmaceutical Compounding - Sterile Preparations
- USP 800 Hazardous Drugs - Handling in Healthcare Settings
- USP 825 Radiopharmaceuticals Compounding
- USP 1066 Physical Environments that Promote Safe Medication Use
- USP 1079.2 Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products
- State of Michigan Healthcare Code
- ASHRAE Standard 170 Ventilation of Health Care Facilities
- The Joint Commission Medication Compounding Certification Standards
- National Association of Boards of Pharmacy Verified Pharmacy Program (VPP)
- US Federal Drug Quality and Security Act Section 503a
- FDA Guidance Documents for Hospitals and 503a Pharmacies:
    - “Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act”
    - “Insanitary Conditions at Compounding Facilities”
    - “Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act”
- NRC (Nuclear Regulatory Commission) For Radiopharmaceutical Compounding Only
- FDA (Food and Drug Administration) For Radiopharmaceutical Compounding Only
- UM Environment, Health and Safety (EHS): "Placement of Biological Safety Cabinets"

A/E shall reference the following related Michigan Medicine Design Guidelines for additional compliance requirements: SBA 5.16 - Requirements for Critical Pressure Sensitive Rooms.

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

Terminology

BSC: Biological Safety Cabinet - Device (PEC) used for hazardous CSPs. Requires external exhaust for units being used to prepare hazardous drugs. Exhausted cabinets do not contribute to air changes per hour (ACPH) of the buffer room. Michigan Medicine has standardized to use Class II A2 BSCs for all hazardous pharmaceutical compounding.

BUD: Beyond-Use Date. Date or time after which a Compounded Sterile Preparation (CSP) may not be stored or transported from the date or time of compounding.

CSP: Compounded Sterile Preparation.

C-PEC: Containment - Primary Engineering Control for hazardous CSPs. Examples include biological safety cabinets and containment isolators.

C-SEC: Containment - Secondary Engineering Control for hazardous CSPs. This type of room is designed with negative pressure to the adjacent anteroom to prevent spill contaminated air from exiting the room.

C-SCA: Containment- Segregated Compounding Area (Category 1 Risk Category Only): An unclassified area allowed for hazardous CSPs that are defined as risk Category 1 (BUD of 12 hours or less). C-SCAs have a requirement to be negative pressure and have a minimum of 12 air changes per hour and be externally exhausted.

Controlled Compounding Environment: A dedicated compounding space within which people must follow handwashing practices and be garbed. All materials passed into the controlled space must be disinfected. Controlled pharmacy space must be separated from general pharmacy/office space by either physical separation (walls/door) or a line of demarcation. Types of controlled pharmacy spaces include SCA, C-SCA, and clean room suites.

Drug Storage Location: A location where medications (a.k.a. drugs) will be stored. This space may have shared usage for operational processes and workstations. Access to a drug storage location requires restricted access (e.g., card readers). The location must also have continuous temperature and humidity monitoring. Locations where hazardous drugs will be handled may require remote security monitoring (Refer to Policy 170.00 Appendix A: Controlled Substances Security Principles). Hazardous drug storage locations require negative pressure containment (i.e. differential pressure of <0”wc from adjoining rooms).

HMI: Human Machine Interface. Typically, a wall mounted touchscreen used to display room environmental data. See UM masterspec 230905.

ISO Class: An air quality classification from the International Organization for Standardization

LAFW: Laminar Airflow Workbench - Device (PEC) used for nonhazardous CSPs. Does not require external exhaust and can contribute air changes per hour (ACPH) to buffer room total.

PEC: Primary Engineering Control - A zone or device that provides an ISO Class 5 environment, e.g. laminar airflow workbench or biological safety cabinet.

PPE: Personal Protective Equipment.

SCA: Segregated Compounding Area (Category 1 Risk Category Only). An unclassified area allowed for CSPs that are defined as risk Category 1 (BUD of 12 hours or less)

SRPA: Segregated Radiopharmaceutical Processing Area. A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for radiopharmaceutical preparation,

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

dispensing, and repackaging only. If the SRPA is used to elute radionuclide generators it must have an ISO Class 8 air quality.

SEC: Secondary Engineering Control - The area where the PEC is placed (e.g., a clean room suite, SCA or SRPA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

USP: United States Pharmacopeia

Pharmacy Room Types

Refer to attached sample room layouts (SK-1 &2) for Category 1 and Category 2 compounding area requirements.

Ante Rooms (Required for Category 2 CSPs Only): An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels are performed. The ante-room is the transition room between the unclassified area of the facility and the buffer room. Required for CSPs that have a beyond use date (BUD) greater than 12 hours.

Buffer Rooms (Required for Category 2 CSPs Only): An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the ante room. Required for CSPs that have a BUD greater than 12 hours.

- Non Hazardous drug buffer rooms should be positively pressurized above 0.02" W.C.
- Hazardous drug buffer rooms should be negatively pressurized between 0.01-0.03" W.C., and be externally exhausted.

Hazardous Drug Buffer Room: A type of buffer room required for hazardous CSPs.

Nonhazardous Drug Buffer Room: A type of buffer room used for nonhazardous CSPs.

Radiopharmaceutical Buffer Room: A type of buffer room used for compounding radioactive drugs.

Unclassified Area: Any space not required to meet particle and microbial level classification based on the International Organization for Standardization. Segregated Compounding Areas are considered unclassified. Defined as any area that does not require an ISO Classification.

Hazardous Drug Storage: Storage room dedicated for hazardous (high hazard drugs that require manipulation) drug storage only. Required to be negative pressure, a minimum of 12 air changes per hour and be externally exhausted.

Drug Storage: Storage room for non-hazardous and hazardous (hazardous drugs not requiring negative pressure) drug storage. It can be an independent, dedicated storage room, or part of other pharmacy room types (i.e. Pharmacy Workroom).

Pharmacy Workroom: Workspace needed adjacent to the controlled compounding environment. Space requirements must be discussed with pharmacy staff during the space programming stage of the project. Office space must be separated from controlled pharmacy compounding spaces and non-hazardous, non-sterile compounding area through a physical barrier (walls and door) or a line of demarcation is allowable in a SCA or non-hazardous, non-sterile compounding area. Pharmacy workrooms commonly also function as drug storage locations.

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

Requirements for Controlled Compounding Environments (SCA, SRPA & Category 2 Classified Spaces)

All classified buffer and ante rooms shall meet ISO class 7 requirements. Exceptions:

- Integrated vertical laminar flow zones (IVLFZ) is a designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. IVLFZ's may be specified for smaller classified areas, but the increased cost of the mechanical building systems, maintenance and functional use must be reviewed with pharmacy staff for applicability.
- Ante rooms adjacent only to positive pressure buffer rooms may be designed and classified as ISO 8. Review with pharmacy staff for applicability.

Room finishes for Category 1 Segregated Compounding Areas (SCA) and Segregated Radiopharmaceutical Processing Areas (SRPA) shall be consistent with Category 2 areas.

Room finishes for Non-Sterile Compounding Areas shall be consistent with Category 1 SCA's. Non-Sterile Compounding shall be performed in a dedicated space.

Unnecessary walls/partitions within the buffer rooms should be avoided as they inhibit room air circulation and may affect particle counts and viable sample results.

Square footage shall be adjusted upwards from minimum values stated on sample room layouts to provide adequate work clearances for multiple PECs and other equipment planned within space. AE shall review additional space needs for future growth and flexibility.

Sink and eyewash drench hose should be easily accessible and located outside of the compounding area. Sink must be a minimum of 1 meter from compounding room entrance, and a minimum 1 meter from any PEC or C-PEC. Sink shall be scrub sink grade, all SS, large enough to facilitate washing of hands to the elbow while preventing water from splashing on adjacent walls. Provided with fully encased piping and hands free faucet. Faucet & sink shall conform to requirements under design guideline "220010-H: SUPPLEMENTAL PLUMBING SPECIALTIES" (no aerators, faucets shall not terminate directly over grid strainer, no overflow on sink, etc).

All epoxy paint shall be 2-part, non-pre-catalyzed marine grade epoxy, similar to Benjamin Moore Waterborne Corotech V440.

Caulk all dissimilar materials within segregated compounding and classified areas. All caulking shall be similar to GE SCS 1700 Silicone sealant. Caulk should be applied after general cleaning of the areas is completed. Caulk should be free of dust and debris.

All surfaces shall be easily cleanable and sealed to prevent accumulation of dust and debris.

All materials and sealants must withstand aggressive cleaning solutions.

All exposed fasteners should be stainless steel.

Eliminate horizontal surfaces wherever possible including door frames, pass thru cabinets, window sills, above hoods, etc. Horizontal surfaces should be reduced by multiple means including the following: flush mounting, vertical soffit, vertical enclosure, or sloped top when vertical surface is not possible.

Room envelope should be designed to adequately maintain the required room pressurization. All room penetrations must be sealed.

Provide smooth, seamless flooring with integral cove base and embedded demarcation lines.

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

Walls:

- Provide monolithic, smooth, cleanable, hard surface walls without seams or loose trim joints. AE shall base wall finish on Crane Composites FRP board with smooth finish & flush-tooled polyurethane sealant joints.
- Provide stainless steel corner guards on all outside wall corners.

Ceilings:

- Provide epoxy painted, drywall ceilings.
- Junctures of ceiling to walls shall be sealed with caulking to avoid cracks or crevices where dirt can accumulate.
- Cleanroom ceiling grids with “drop in” panels are not allowed by Michigan Medicine.
- Specify stainless steel gasketed and sealed access panels, diffusers and lighting fixtures that are designed for cleanroom use. Minimum access panel size is 24”x24”. Call for device trim to be caulked to the ceiling.
- Provide 9'-6" (min 9'-0") ceiling in HD compounding rooms to accommodate BSC's.

Doors:

- Doors shall be waterproof, completely encased, seamless hinged or sliding aluminum, or stainless steel door with matching welded frame material.
- Provide automatic door operators with touchless door actuators, e.g. hand wave.
- Provide with concealed closer, hospital tip hinges & hospital stops on frame.
- Door sweeps are NOT allowed.
- Interlock to prevent simultaneous opening of doors to connected spaces.
- Consider the need for frosted glass on door lights on anteroom door to obscure garbing. Review with pharmacy staff if needed.

Pass-thrus between classified compounding rooms and non-classified (Workroom) spaces:

- Seamless stainless steel construction
- Utilize tempered glass (not acrylic) doors
- Utilize an integral, packaged HEPA filtered purge
- Include interlocking mechanisms to prevent doors on both sides from being opened simultaneously
- Refrigerator passthrus are NOT allowed.

Shedding devices and objects, such as corrugated boxes, shall not be located within classified areas and/or segregated compounding areas. Printers, where required, should have low wall returns adjacent to the printer location to control dust.

No floor drains or water sources are allowed in ante rooms, buffer rooms or within the perimeter of an SCA or SRPA.

HD drugs must be stored under negative pressure with a minimum of 12 air changes in a space that is externally exhausted in the C-PEC or HD storage room (negative pressure, unclassified air). HD storage will require space for both room temperature and refrigerated storage locations.

AE shall coordinate BSC & LAFW placement and required clearances with UM EHS "Placement of Biological Safety Cabinets"

Requirements for Radiopharmaceutical Rooms

The radiopharmaceutical compounding PEC must be located in a SEC, which may be either a buffer room with ante-room or an SRPA (Segregated Radiopharmaceutical Processing Area).

Radiopharmaceutical buffer rooms are required to be Positive pressure (≥0.02”wc), with a Positive pressure anteroom (≥0.02”wc) and a Negative pressure pharmacy workroom (directional airflow, no min differential pressure). All other requirements apply.

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

In addition to the room pressure monitor requirements for buffer rooms stated elsewhere in this guideline, provide a room pressure monitor for all Radiopharmaceutical Workrooms, to monitor & alarm the negative pressure requirement noted above.

These buffer rooms are preferably placed in areas that are adjacent to the clinical functions that they serve (i.e. nuclear imaging and oncology departments).

Any compounding involving blood cell tagging needs to be done in a dedicated buffer room.

If the SRPA is used to store and elute radionuclide generators it must meet an ISO Class 8.

Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA. The SRPA must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC. An SRPA must not be located adjacent to environmental control challenges (e.g., restrooms, warehouses, or food preparation areas). A visible perimeter must establish the boundaries of the SRPA. Access to the SRPA must be restricted to authorized personnel and required materials.

Mechanical

Because of the difficulty in accessing ceiling utilities as well as the risks of leaks, utilities located above the ceilings of classified spaces shall be only those that directly serve the classified space.

All equipment/ devices needing service (i.e. valves, dampers, terminal VAV boxes, etc) shall be located outside of the classified space, in an accessible location.

Provide dedicated temperature control zone for each classified room, non-sterile compounding area, SCA, and SRPA.

For Drug Storage locations, the preference is dedicated temperature control for the space. Drug Storage spaces shall not share HVAC zoning with rooms whose HVAC load is based on occupancy (i.e. offices). In the absence of the availability of dedicated temperature control, and when the controlling thermostat is not located within the drug storage room, AE shall call for the thermostat adjustment to be restricted in the DDC system so that adjustment is only within the acceptable drug storage range.

AE shall provide a dedicated HVAC system for each Category 2 pharmacy, in order to maintain ISO cleanliness and environmental compliance. Review needs with AHU zoning and pharmacy emergency power requirements.

HVAC systems serving classified spaces shall be fully ducted, no plenum circulation (SA or RA) is allowed.

All airflow serving classified spaces shall utilize HEPA filtration at the point of entry into the room, either through HEPA filtered diffusers or HEPA fan filter units (FFUs), utilizing HEPA type C or J filters. FFU shall be:

- Fully accessible/maintainable from room side
- Utilize stainless steel screen and frame
- Provide with airflow measurement
- Local/packaged controls and room-side display of FFU airflow (CFM), status and alarm
- Mount FFU in plaster frame to allow easy removal of FFU
- Monitor FFU general alarm thru BMS

AE shall review with pharmacy the anticipated staff traffic and the storage of any shed-able material within the pharmacy workroom, immediately outside of the Category 2 anteroom. High traffic and shed-able material storage immediately in front of the anteroom door has shown to be detrimental to proper

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

pressure control of the anteroom and results in failed environmental testing. Design should limit traffic and storage in front of the anteroom. Where unavoidable, consider the need for a second unclassified anteroom and/ or a FFU located immediately outside the Cat 2 anteroom doorway to provide environmental containment to maintain control of adjacent room pressures and air quality.

Provide external aerosol injection ports in ductwork upstream of FFU's/HEPA filtered diffusers. Injection ports should be clearly labeled. Pipe injection ports to aerosol injection port assembly mounted in a stainless steel panel mounted in the ceiling of the unclassified pharmacy workroom. Injection ports by CEPA Operations, Inc.

Provide a high speed modulating air control valve to supply air into the HD compounding room. Valve to modulate supply airflow to maintain negative pressure requirement.

Provide pressure monitoring of all Category 2 pharmacies, as shown on attached schematic SK-2.

- Locate pressure pickup ports in the ceiling, as far away from doors as possible, so as to limit room pressure fluctuations from doors opening & closing.
- Local DDC room pressure monitor shall be integrated into the hospital BMS

Additional air changes (ie 60ACs) beyond the minimum 30 AC's requirement for ISO-7 compliance may be required to reduce microbial counts, see Table 1: Pharmacy Space Environmental Requirements. Recirculation is allowed thru HEPA FFU within the Ante Rm and Non-HD Compounding Rooms as long as a minimum of 15 AC's of ventilation air is provided. No recirculation is allowed within HD Compounding.

Provide ducted exhaust from BSCs to a hazardous exhaust system with 10'-0" high discharge stack designed to discharge at 3,000 FPM (high plume exhaust). Locate exhaust termination minimum 30' away from any supply air intakes. Room air exhaust from C-SEC also needs to be externally vented with no re-circulation. Provide 10'-0" high discharge stack on all exhaust fans serving C-SEC.

Airflow within classified buffer and ante rooms shall utilize a minimum of two low, stainless steel, heavy duty return air grilles. Ceiling return or exhaust grilles are not allowed in buffer rooms & ante rooms. Ceiling return grilles are allowed in SCA's/ SRPA's. Grilles shall be easily cleanable utilizing parallel blades. Provide additional return/exhaust grille inlets adjacent to all sinks and printer locations, as well as behind all refrigerators within classified areas, mounted adjacent to compressors. Where compressors are on top of the refrigerator, provide a high wall return grille adjacent to the compressor location.

BSCs within HD compounding rooms shall be provided with a local alarm for loss of central exhaust airflow via a pressure switch in the exhaust air duct connection to the BSC. Provide a gas-tight bubble point damper (if room height is 10' or higher) or an iris style damper (if ceiling height is <10') immediately downstream of the pressure switch to test alarm and commission the BSC.

Provide temperature and humidity sensors in all SCA's, SRPA's and Category 2 buffer rooms for continuous monitoring thru MM BMS. Sensors/data points for Pharmacy drug storage and compounding locations need to be tied into pharmacy BMS trend views.

All temperature & humidity sensors in Category 2 rooms shall be mounted in the return ductwork and not via wall sensors which are prone to damage and clean-ability issues. Locate duct sensors so that they are accessible outside of the classified space.

All equipment identification labels shall utilize a high-bond adhesive and a thin poly-carbonate overlaminate.

Sprinklers shall be fully recessed, gasketed and concealed.

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

All “Non-Sterile Compounding” rooms shall be provided with a RO/ DI rinse at the handwashing sink located in the Pharmacy Workroom. The exception is Radiopharmaceutical Non-Sterile Compounding, which does not require a RO/ DI rinse.

Electrical

Lighting:

- Follow all USP 1066 illumination requirements. Lighting level recommendations are summarized below in Table 2.
    - Consult IESNA reference RP-29: “Lighting Hospitals and Healthcare Facilities” for more details about lighting medication areas.
    - Refer to UMH DG 265100-H: Supplemental Interior Lighting for additional info.
- Color temperature of 4000K and color rendering index (CRI) of 90+ for all LED light fixtures.
- Utilize basic lighting controls (i.e. no occupancy sensing, etc.) to eliminate lighting level variances in these spaces.
- Dimming controls are not allowed in sterile compounding and preparation areas (e.g., buffer, chemo, and ante rooms). Dimming controls are allowed in non-sterile compounding and preparation areas.
- Provide clean room rated, flush-mounted light fixtures incorporating gasketed smooth lenses, sealed around the frame to the ceiling. Fixture type shall be 2'x4', 2'x2' or 1’x4’ LED. Mount lights in a plaster frame to allow for future maintenance.

Review emergency power needs with pharmacy staff. At a minimum, provide adequate emergency power receptacles for all drug storage refrigerators and all PEC’s and their associated exhaust systems. When emergency power is deemed necessary for a functioning, compliant pharmacy, consider the need to provide additional emergency power to the pharmacy HVAC system (fan filter units, supply and exhaust fans, heating and cooling), faucet controls, door operators and monitoring controls.

Generally, pharmacy operations Loss of power can tolerate a loss of utility power for 30 seconds or less; therefore, UPS backup for emergency generators is not needed. The exception is the need to maintain continuous monitoring of Category 2 cleanroom spaces. Provide UPS power for all Category 2 DDC controllers.

Provide an intercom system within each room (Ante Room, HD, and Non-HD Compounding Rooms, Hazardous SCA and Pharmacy Work Room) to allow communication between occupants, e.g. Stentofon “IP OR Master”. Intercom vendors shall provide an 8 or 16 port POE switch and interconnecting Cat 6 cable as required for intercom connectivity. Switch shall reside in a MM designated Telecom Room. Intercom POE switch shall not be connected to the hospital network. Review with pharmacist need for wall mounted vs desktop intercom. Where wall mounted, mount at standing height, unobstructed access.

All equipment identification labels and circuit identification labels shall utilize a high-bond adhesive and a thin poly-carbonate overlaminate.

Provide a 30-amp circuit for each 6' laminar flow workstation with auxiliary receptacle. Confirm amperage requirements of each PEC/C-PEC location.

Provide stainless steel covers for outlets and switches. Seal to wall.

Provide key-lockable disconnect switches for 120V and 208V fan filter units, e.g. Leviton 1222-2KL.

Provide pilot light switches for all classified spaces, e.g. Hubbell HBL1221PL.

Automatic doors to be equipped with door monitored contact. Magnetic lock and emergency exit button are not required.

All airlock door controls shall be located above the accessible ceiling in the Pharmacy Workroom.

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

Requirements for Drug Storage Rooms

Requirements

- Easily cleanable flooring, carpet is not allowed.
- Should not have windows to the outside to prevent UV light damage to drugs. Where windows are unavoidable, provide automated window shades and/ or UV protection on windows.
- Provide security cameras for locations with controlled substance storage.
- Provide card reader access if distinct from a Pharmacy location.
- 68-77 deg F, <60%RH, no pressure requirement. HVAC zoning shall be dedicated or with other similar non-normally occupied spaces to prevent temperature excursions due to human preference.
- Provide monitoring of temperature and humidity, integrated into the UMH BMS.
- Provide emergency power, if available, for drug storage refrigerators. If emergency power is not available, consider battery backup solutions.
- Follow electrical requirements under Controlled Compounding Environment section. Dimmable lighting is allowed.

Activation Requirements

Compliance requires Category 2 pharmacy cleanrooms undergo cleanroom certification testing prior to activation of the cleanroom. This testing consists of:

- Environmental testing validating ISO compliance including particle counts, airflow, pressurization, temperature and humidity readings.
- Environmental sampling to validate levels of surface and airborne bacteria are below ISO standards.

Cleanroom certification is managed by the MM pharmacy department.

All project testing and balancing should be performed prior to cleanroom certification.

Cleanroom certifier shall be provided a copy of the HVAC design specifications and final test & balance report. Prior to clean room certification, the project shall provide a minimum 72 hour trend of the cleanroom environment (airflow, temperature, humidity & pressure) to validate compliance with design.

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/

TABLE 1: Pharmacy Space Environmental Requirements

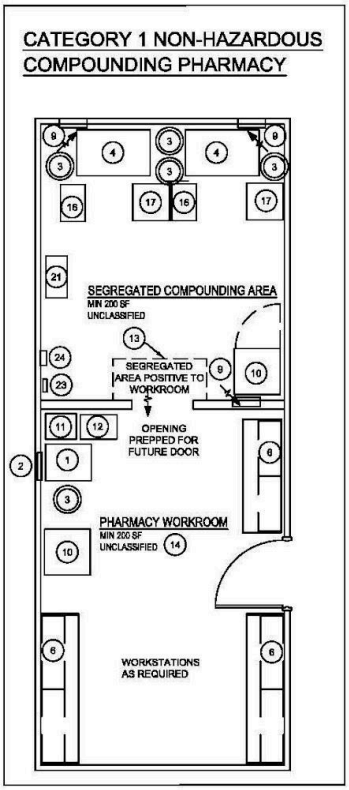
Space Type	Minimum Code Criteria				Environmental Design Criteria				Notes
	Temperature	Humidity (3)	Room Pressurization	Airchange Rate (Total/ Recirc)	Temperature (1)	Humidity (2)(3)	Room Pressurization	Airchange Rate (Total/ Recirc)	
Pharmacy Workroom	Max 72 deg F	<60%RH	NA	NA	≤72 deg F	<60%RH	NA	NA	(5)
Segregated Compounding Area- Non Hazardous	Max 72 deg F	<60%RH	NA	NA	≤72 deg F	<60%RH	NA	NA	(5)
Segregated Compounding Area- Hazardous	Max 72 deg F	<60%RH	-0.01"wc to -0.03"wc	12/0	≤72 deg F	<60%RH	-0.02"wc	12/0	(4), (5), (6)
Ante-Room	Max 68 deg F	<60%RH	≥ +0.02"wc	30/15 (7)	≤66 deg F	<60%RH	+0.04"wc to +0.06"wc	70/55	(4), (5), (6)
Non-Hazardous Compounding	Max 68 deg F	<60%RH	≥ +0.02"wc	30/15 (7)	≤66 deg F	<60%RH	+0.04"wc to +0.06"wc	30/15	(4), (5), (6)
Hazardous Compounding	Max 68 deg F	<60%RH	-0.01"wc to -0.03"wc	30/0 (7)	≤66 deg F	<60%RH	-0.02"wc	60/0	(4), (5), (6)
Hazardous Storage	Max 76 deg F	<60%RH	Negative	12/ (8)	≤72 deg F	<60%RH	-0.02"wc	12/ (8)	(4), (5), (6)
Non- Sterile Hazardous Compounding	Max 72 deg F	<60%RH	-0.01"wc to -0.03"wc	12/0	≤66 deg F	<60%RH	-0.02"wc	12/0	(4), (5), (6)
Non-Sterile Non- Hazardous Compounding	Max 72 deg F	<60%RH	Neutral	NA	≤72 deg F	<60%RH	NA	NA	(5)

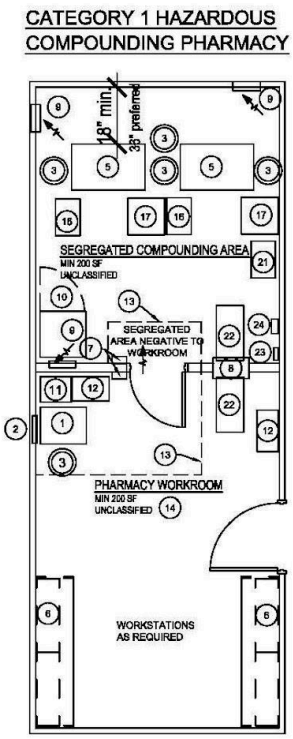
Notes 1) Via wall mounted temperature sensor mounted in flush wall box, adjustable thru room pressure monitor touchscreen
2) Via return duct mounted sensor, accessible location
3) USP requires <60%RH. When located within Inpatient or Ambulatory Surgery Centers, state healthcare code requires minimum 30%RH.
4) Room Pressure shall be locally alarmed at respective RPM's. All criteria also locally alarmed at RPM HMI in Pharmacy Workroom
5) All criteria also alarmed at BMS frontend
6) Mechanical Controls Contractor shall coordinate with Systems Integrator for all local device alarm definitions
7) Per minimum requirements for ISO 7
8) Recirculation is allowed for supplemental cooling airflow in excess of 12 ACs

TABLE 2: Lighting Level Recommendations for Healthcare Settings (from USP 1066)

WORK AREA	ILLUMINATION LEVEL
Computer order entry	100fc
Handwritten order processing	100fc
Medication filling and checking (pharmacy)	90-150fc
Patient counseling (pharmacy)	90-150fc
Sterile compounding and preparation (e.g., buffer, chemo, ante rooms)	100-150fc
Non-sterile compounding and preparation (e.g., buffer, chemo, ante rooms)	90fc
Pharmacy medication storeroom	50fc
Medication preparation area (e.g., nursing station)	100fc
Medication administration work area (e.g., cart surface, patient room)	100fc

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/





9/13/22 mcintyre, thomas c:\users\thommcin\onedrive - michigan medicine\ld-plan-standards\cad\mechanical\details

KEYNOTE LEGEND

1. 1- COMPARTMENT STAINLESS STEEL SCRUB SINK WITH ELECTRONIC SENSOR FAUCET, NO AERATOR, WITH FLOW CONTROL IN THE BASE OF THE SPOUT, NON-SHEDDING WIPES. SIMILAR TO ELKAY EWSF 13026, 30" W x 26" D WITH STAINLESS STEEL SHROUD COVERING ALL PIPING AND INTEGRAL DECK MOUNTED DRENCH HOSE EYEWASH.
2. MIRROR
3. WASTE BASKET
4. PEC: LAMINAR AIRFLOW WORK BENCH, ISO CLASS 5, ON LOCKABLE CASTERS.
5. PEC: BIOLOGICAL SAFETY CABINET, ISO CLASS 5, DUCTED EXHAUST.
6. SOLID SURFACE OR STAINLESS STEEL WORKSTATION, EASILY CLEANABLE. PROVIDE WITH WALL HUNG MAGNETIC, CERAMIC MARKERBOARDS BETWEEN COUNTER AND BINDER BINS.
7. ROOM PRESSURE MONITOR WITH TEMPERATURE ADJUSTMENT
8. NON-HEPA PURGE PASS THRU WITH INTERLOCKING DOORS
9. LOW INTAKE GRILLE, HEAVY DUTY STAINLESS STEEL. LOCATE LOW RETURNS BEHIND ALL PARTICLE GENERATORS (SINK, REFRIGERATORS, PRINTERS, ETC)
10. DEDICATED REFRIGERATOR WITH TEMPTRACK WIRELESS MONITORING
11. PPE STORAGE
12. STAINLESS STEEL STOOL OR BENCH WITH OPEN (NON-ENCLOSED) LEGS AND/OR SHELF.
13. LINE OF DEMARCATION, INSET INTO FLOORING
14. ROOM FINISHES IN UN-CLASSIFIED WORKROOM:
    - PAINTED WALLS
    - SHEET FLOOR W/RUBBER BASE
    - CLEANABLE CEILING TILES
16. 24" L x 16" W STAINLESS STEEL CART
17. STAINLESS STEEL MOBILE WORKSTATION WITH COMPUTER
21. SUPPLY CART
22. 18 X 36 CART
23. MOP HOLDER
24. LADDER

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

TERMS & CONDITIONS FOR DOCUMENT USE
PROPERTY OF THE UNIVERSITY OF MICHIGAN
SUBJECT TO RESTRICTIONS

These plans are the confidential property of the University of Michigan. These plans have been provided to you for the limited purpose of bidding and/or providing construction work at the University of Michigan. You acknowledge that these plans are the confidential property of the University of Michigan. You will keep the plans confidential and will not discuss with or provide these plans to any third party, other than those employees, subcontractors, or consultants who are essential to completing your bid and/or work. Unless your company is selected to perform a part of the work, you will destroy all copies of the plans within 90 days of the bid due date.

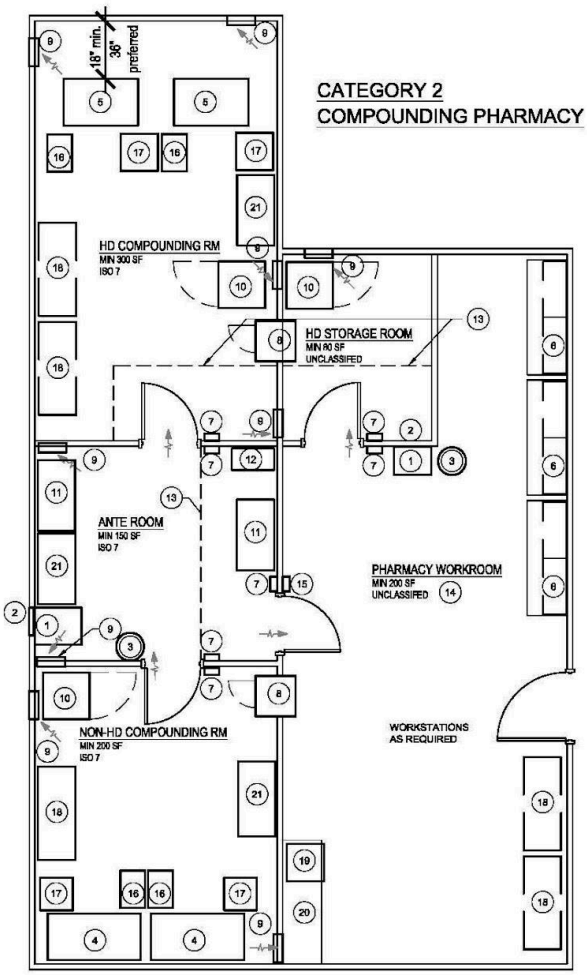
Project
MICHIGAN MEDICINE - REQUIREMENTS FOR PHARMACEUTICAL DRUG COMPOUNDING AREAS CATEGORY 1

UM Design Manager:	-
Designed:	
Drawn:	
Checked:	
Approved:	-
Issued:	- 12/11/2019
Revised:	7/27/2022
Issued:	:
Issued:	:

Project Number

Sheet Number
SK-1

2101 Commonwealth Blvd, Suite B
Ann Arbor, MI 48105-5759
www.med.umich.edu/facilities/plan/



9/13/22 mcintyre, thomas c:\users\thommcin\onedrive - michigan medicine\ld-plan-standards\cad\mechanical\details

KEYNOTE LEGEND

1. 1- COMPARTMENT STAINLESS STEEL SCRUB SINK WITH ELECTRONIC SENSOR FAUCET, NO AERATOR, WITH FLOW CONTROL IN THE BASE OF THE SPOUT, NON-SHEDDING WIPES. SIMILAR TO ELKAY EWSF 13026, 30" W x 26" D WITH STAINLESS STEEL SHROUD COVERING . ALL PIPING AND INTEGRAL DECK MOUNTED DRENCH HOSE EYEWASH.
2. MIRROR
3. WASTE BASKET
4. PEC: LAMINAR AIRFLOW WORK BENCH, ISO CLASS 5, ON LOCKABLE CASTERS.
5. PEC: BIOLOGICAL SAFETY CABINET, ISO CLASS 5, DUCTED EXHAUST. LOCATE PEC A MINIMUM 18" (36" PREFERRED) FROM THE WALL TO ALLOW CLEANING BEHIND.
6. WORKSTATION, EASILY CLEANABLE
7. ROOM PRESSURE MONITOR
8. PASS THRU WITH INTERLOCKING DOORS
9. LOW INTAKE GRILLE, HEAVY DUTY STAINLESS STEEL. LOCATE LOW RETURNS BEHIND ALL PARTICLE GENERATORS (SINK, REFRIGERATORS, PRINTERS, ETC)
10. DEDICATED REFRIGERATOR WITH TEMPTRACK WIRELESS MONITORING
11. PPE STORAGE
12. STAINLESS STEEL STOOL OR BENCH WITH OPEN (NON-ENCLOSED) LEGS AND/OR SHELF.
13. DEMARCATION LINE INTEGRATED WITH FLOORING.
14. ROOM FINISHES IN UN-CLASSIFIED WORKROOM:
    - EPOXY PAINTED WALLS
    - SHEET FLOOR W/RUBBER BASE
    - CLEANABLE CEILING TILES
15. ROOM PRESSURE MONITOR DISPLAYING ENVIRONMENTAL DATA & ALARMS (TEMPERATURE, HUMIDITY, DIFFERENTIAL PRESSURE, FFU ALARMS) FOR EACH CLASSIFIED SPACE: ANTE RM, HD COMPOUNDING RM, NON-HD COMPOUNDING RM
16. 24" L x 15" W STAINLESS STEEL CART
17. STAINLESS STEEL MOBILE WORKSTATION WITH COMPUTER
18. MSC SUPPLY CART
19. UNDERCOUNTER REFRIGERATOR (24" X 24")
20. STAINLESS STEEL WORK COUNTER
21. WORK CART

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

TERMS & CONDITIONS FOR DOCUMENT USE
PROPERTY OF THE UNIVERSITY OF MICHIGAN
SUBJECT TO RESTRICTIONS

These plans are the confidential property of the University of Michigan. These plans have been provided to you for the limited purpose of bidding and/or providing construction work at the University of Michigan. You acknowledge that these plans are the confidential property of the University of Michigan. You will keep the plans confidential and will not discuss with or provide these plans to any third party, other than those employees, subcontractors, or consultants who are essential to completing your bid and/or work. Unless your company is selected to perform a part of the work, you will destroy all copies of the plans within 90 days of the bid due date.

Project
MICHIGAN MEDICINE - REQUIREMENTS FOR PHARMACEUTICAL DRUG COMPOUNDING AREAS
CATEGORY 2

UM Design Manager:	-
Designed:	-
Drawn:	
Checked:	
Approved:	-
Issued:	- 5/29/2019
Revised:	7/27/2022
Issued:	:
Issued:	:

Project Number

Sheet Number
SK-2