MINNESOTA
BOARD OF PHARMACY

# Sterile Compounding Area Remodel Guidance – Pharmacy

Pharmacies should consider the following when remodeling their current sterile compounding area.

*Minnesota Rule 6800.0800 requires pharmacies to submit proposed remodel plans to the Board at a minimum of 60 days before the project is to begin. Depending on the scope of the project, it may take additional time. Consideration should be given to variance and/or policy approvals and allow additional time as applicable.*

*Minnesota Department of Health (MDH) is responsible for the enforcement of state and federal rules and regulations relating to a healthcare facilities physical plant. You or your facility are advised to contact them prior to initiating any new construction or modification of existing space. E-mail address is healthcareengineers@state.mn.us or go to the Minnesota Department of Health (MDH) website for "Engineering Services" Construction Plan Process.*

## Following Must Be Completed With Any Remodeling Proposal

- A completed new application noting that the pharmacy will have "dimension/layout changes." The application can be found on the Board's website under License and Registration, Application for Registration as a Pharmacy.
  As noted on the application, include at a minimum the following information:
  - The overall floorplan identifying all pharmacy department boundaries and the location of the remodel within the licensed pharmacy space.
  - An enlarged floorplan of the compounding spaces/areas and HD storage if provided. This plan shall identify all required components. An electronic version is preferred.
    - Provide details related to the proposed space including:
      - Types of primary engineering controls (PECs)
      - Placement of the PECs
      - Whether the PEC is vented to the outside
      - Location and ISO classification of all secondary engineering controls (e.g. ante, buffer/clean rooms)
      - Location of pressure monitors and pressure differentials between ISO classified spaces
      - Indication and location of any pass-through with specifications (e.g. interlocking, HEPA filtered)
      - Type of surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets. These surfaces in classified areas shall be smooth, impervious, free from cracks and crevices and non-shedding. The surfaces shall be resistant to damage by disinfectant agents (USP <797>):
        - Walls may be constructed of flexible material or of epoxy coated gypsum board.
        - Lighting fixtures should be smooth, mounted flush and sealed.
        - Penetrations through the ceiling or walls shall be sealed.
          - Fire sprinklers
          - Pressure monitors
        - Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic.
        - Storage shelving, counters, and cabinets shall be smooth, impervious, and free from cracks and crevices, non-shedding, cleanable and disinfect-able.
          - Wood doors, particle board cabinets and counter tops laminated onto particle board are best avoided unless all surfaces can be made smooth, impervious, and free from cracks and crevices.
        - Ceiling panels shall be impervious, hydrophobic and caulked around each perimeter to seal them to the support frame.
        - Floors should be overlaid with wide sheet vinyl flooring with heat-sealed seams and coving to the side wall.
        - Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction and cleanable casters.

- Include a cover letter that explains the scope of the work and whether you are remodeling an existing space or creating a new space within the building. Provide a timeline of the scope of the work.
- If you are remodeling an existing space, explain how you will continue operations during the phases of the remodeling. Options may include:
    - Designating an area as a temporary cleanroom which would need to meet USP 797 requirements. Include plans for the temporary space which must have primary and secondary engineering controls certified under dynamic operating conditions to meet USP 797, prior to use. The Board will need to inspect and approve the space prior to use.
    - Compounding in an existing approved satellite space, as applicable. Consideration should be given to space being adequate for volume of compounding that will occur.
    - Designating space as a segregated compounding area (SCA) by relocation of a compounding aseptic isolator (CAI) within the licensed pharmacy space. Segregated Sterile Compounding Area (SCA or S-SCA) means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three-foot perimeter) or in a separate room.
        - Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding.
        - The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation.
        - The segregated sterile compounding area shall not have a sink other than an emergency eye-washing station, located within one meter of a PEC.
        - The segregated sterile compounding area shall be restricted to preparation of sterile to the sterile compounded preparations.
        - Include plans for SCA noting the location of the CAI, the type of CAI, and show that it meets the SCA definition and allowances within USP 797. Insanitary conditions such as proximity of the SCA to the construction area must be mitigated. Product preparation is limited to Low Risk preparations as defined in USP 797. Beyond use dates (BUDs) are limited to 12 hours or less. Work practices such as hand hygiene and garbing, must be addressed by compounding personnel to limit the risk of microbial contamination.
    - Compounding can be outsourced to another Minnesota licensed pharmacy, or compounding could be completed within another licensed compounding space within a health system or in close proximity. Consideration should be given to how the other licensed pharmacy will share time or space. Variances or central service approvals may be required if utilizing staff from both locations for processing and compounding orders. Delivery and storage conditions of the completed CSPs should also be described.
    - Compounding under a central service arrangement with another Minnesota licensed pharmacy. This would require central service policy approval from the Board and possibly a variance depending on the proposal. Consider the timeframe for variances and submit documents well ahead of the Variance and Policy Meeting cutoff date to allow time for the Board's consideration.
    - Utilization of a mobile unit located onsite at the pharmacy location. This will require a variance to MR 6800.0700 Subp 1D. The variance committee meeting dates are listed on the Board website. The variance request form can be found on the Board's website under the Forms tab, "Variance Request" form.
      **If a mobile unit is proposed, the pharmacy must include the following additional information with the variance request:**
        - Documentation of the unit to show that it will conform to the applicable requirements, including controlled temperature and monitoring, types of finishes confirming that they are non-porous and cleanable, location of the sink and fridge, and all other aspects related to USP 797/800 (e.g. certification to CETA standard, environmental monitoring, staff training, etc.).

- Diagram indicating the proposed location of the unit and the proximity to the current pharmacy.
- Diagram showing the interior design of the mobile unit.
- Explanation of proposed work plan and intended duration of use. Include whether you plan to store drugs in the unit and whether controlled substances would be included in the storage.
- Security parameters including alarms, limited access, key control policy, and any other applicable elements.
- Staffing of the unit, including proposed pharmacist to technician ratio and how the immediate and direct technician supervision will occur (if applicable).
- Include emergency procedures in the event of the mobile unit becoming inoperable or unsafe to operate (power failure, severe weather, etc.).

It is the responsibility of each facility to ensure that each source of ISO Class 5 environment is properly located, operated, maintained, monitored, and verified. If you continue operating in close proximity to a construction area during the renovation, indicate all workflow adjustments including limited beyond use dating, cleaning plans, environmental monitoring, and/or sterility.

## Related Regulations

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| Pharmacy, Space, and Security | https://www.revisor.mn.gov/rules/6800.0700/ |
| Location, Dimension, or Security Changes | https://www.revisor.mn.gov/rules/6800.0800/ |
| Compounding Standards | https://www.revisor.mn.gov/rules/6800.3300/ |
| USP <797> and USP <800> | http://www.usp.org/compounding |
| Variances | https://www.revisor.mn.gov/rules/6800.9900/ |