The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

250 Washington Street, Boston, MA 02108-4619



**Sterile Compounding Compliance Checklist**

If the proposed design meets the listed requirement, please indicate by placing “Y” (yes) or “N” (no) and include comments as to the reason for the non-compliance and plans to mitigate. If not applicable, indicate with “NA”.

Please note that this is not an all-inclusive list of proposed standards in [Draft 247 CMR 17.00](https://www.mass.gov/lists/draft-regulations-for-the-board-of-registration-in-pharmacy) or the requirements of USP. At a minimum, applicants are required to adhere to the standards set forth in the most recent version of USP <797> and USP <800>. It is the responsibility of the applicant to be familiar with the requirements set forth in USP chapters and the Board’s regulations.

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| **Draft 247 CMR 17.00** | **Citation** | **Y/N** | **Comments** |
| **Miscellaneous** |  |  |  |
| A pharmacy may not compound non-sterile preparations in any Primary Engineering Control (PEC) or Secondary Engineering Control (SEC) used for sterile compounding. | 17.03(8) |  |  |
| A pharmacy shall have a dedicated changing area for sterile compounding personnel. | 17.04(2) |  |  |
| **Primary Engineering Controls (PECs)** |  |  |  |
| A pharmacy shall utilize only commercially manufactured PECs. | 17.06(1) |  |  |
| **All Secondary Engineering Controls (SECs)** |  |  |  |
| The doors leading into and between ISO Classified SECs shall be constructed with an interlocking design or utilize an alternative method to ensure that doors are not opened simultaneously. | 17.07(1)(c) |  |  |
| Unless prohibited by local building or fire code, an SEC may not have more than one door to immediately adjacent areas. | 17.07(1)(b) |  |  |
| Each newly constructed SEC shall allow for visual observation through windows or technology. | 17.07(1)(a) |  |  |
| SECs may not contain windows to the outdoors. | 17.07(1)(k) |  |  |
| A pharmacy shall ensure that any pass-through chambers:1. have an interlocking door design; and
2. are not refrigerator units.
 | 17.04(1) |  |  |
| Walls shall be made of solid surface materials such as locking sealed panels or epoxy-coated gypsum board. | 17.07(1)(j) |  |  |
| Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter. | 17.07(1)(h) |  |  |
| SECs shall utilize light fixtures designed for sterile compounding areas (i.e., cleanroom grade) that have an exterior surface that is smooth, mounted flush with the ceiling, and sealed. | 17.07(1)(g)  |  |  |
| Sprinkler heads shall be recessed, covered, and easily cleanable. | 17.07(1)(i) |  |  |
| Floors shall be composed of wide sheet vinyl that is heat sealed at the seams, or other solid, smooth surface, and coved at the wall or appropriately sealed. | 17.07(1)(l) |  |  |
| SECs may not contain floor drains. | 17.07(1)(f) |  |  |
| A pharmacy may not locate a refrigerator in any ISO Classified SEC. | 17.07(1)(e) |  |  |
| A pharmacy may not use ISO Classified areas for drug storage. | 17.04(3) |  |  |
| **Ante Rooms** |  |  |  |
| A newly constructed ante room shall be at least 72 square feet.  | 17.07(3)(a)  |  |  |
| For hand hygiene, an anteroom shall have a stainless-steel sink that is located on the clean side of the line of demarcation at least one meter away from the buffer room door. | 17.07(3)(b)  |  |  |
| The stainless-steel sink shall:1. be equipped with hands-free controls for water and soap dispensing;
2. have proper depth and capacity for hand washing up to the elbows;
3. minimize splashing and dripping of water;
4. be designed to prevent standing water; and
5. have a faucet that does not have an aerator mechanism on the nozzle.
 | 17.07(3)(c) |  |  |
| An ante room shall have low-lint, disposable towels located in close proximity to the sink. | 17.07(3)(d)  |  |  |
| **Buffer Rooms** |  |  |  |
| A newly constructed **non-hazardous drug** buffer room shall be at least 100 square feet.  | 17.07(2)(a) |  |  |
| A newly constructed **hazardous drug** buffer room shall be at least 72 square feet. | 17.07(2)(b) |  |  |
| Buffer room doors shall be hands-free.  | 17.07(2)(c) |  |  |
| **HVAC** |  |  |  |
| Newly constructed ISO Classified SECs shall utilize a closed loop ducted system, a sealed plenum system, or equivalent HVAC design. | 17.05(1)  |  |  |
| Supply air provided for each ISO Classified SEC shall be provided exclusively through ceiling mounted HEPA filters. | 17.05(3) |  |  |
| Air returns in ISO Classified SECs shall be mounted low on the walls | 17.05(4)  |  |  |
| If utilized, relief air vents shall be mounted low on the wall and designed to prevent the ingress of less clean air or contaminants from adjacent areas.  | 17.05(5)  |  |  |
| **Temperature/Humidity** |  |  |  |
| A pharmacy shall have a system to continuously measure the temperature and humidity of each SEC. The quantitative results shall be reviewed and documented at least daily on all days the pharmacy is open. | 17.10(3) |  |  |
| SECs shall maintain a temperature of 68 degrees Fahrenheit (20 degrees Celsius) or lower. | 17.10(1) |  |  |
| SECs shall maintain relative humidity of 60% or lower. | 17.10(2) |  |  |

**Please direct any questions to: Pharmacy.Admin@mass.gov**