Hazardous Drugs
Proposed 247 CMR 19.00

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19.01: Authority and Purpose

247 CMR 19.00 is promulgated under the authority granted the Board by M.G.L. c. 112, §§ 39G, 39H, 39I, and 42A. The purpose of 247 CMR 19.00 is to establish minimum professional standards pertaining to hazardous drugs (“HD”) in order to safeguard the public health and welfare. 247 CMR 19.00 applies to all pharmacies licensed by the Board that dispense hazardous drugs.

19.02: General

(1) A pharmacy shall comply with 29 CFR § 1910.1200.

(2) A pharmacy shall comply with 29 CFR § 1910.132.

(3) 247 CMR 19.00 does not apply to the counting, repackaging, and dispensing of medications that are in a solid, final dosage form and ready for patient administration.

(4) Notwithstanding 247 CMR 19.02(3), a pharmacy may not place any HD capsule or HD tablet into an automated counting or packaging machine.

(5) Any drug or active pharmaceutical ingredient (“API”) that appears on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare settings, , shall be considered a hazardous drug (“HD”).

(6) Any drug or API that is designated as a hazardous drug by the Board in written guidance shall be considered a hazardous drug for the purposes of Board regulations, 247 CMR 2.00 et seq.
Any drug identified by a licensee as posing a health hazard shall be considered a hazardous drug for the purposes of Board regulations, 247 CMR 2.00 et seq.

19.03: Facilities and Engineering Controls – General

(1) A pharmacy shall have designated areas for the receipt, unpacking, and storage of HDs that are not under positive pressure.

(2) A pharmacy shall restrict access to HD areas to authorized persons.

(3) A pharmacy shall locate HD areas away from breakrooms and refreshment areas.

(4) A pharmacy may not remove a HD from a shipping container in an ISO classified area.

(5) Storage of HDs

(a) A pharmacy shall store HDs and HD API in an externally vented negative-pressure room with at least 12 air changes per hour (ACPH).

(b) A pharmacy may not store HDs for sterile compounding in a negative pressure buffer room.

(c) A pharmacy shall store HDs requiring refrigeration in a refrigerator dedicated to HDs and located in a negative pressure area with at least 12 ACPH.

(6) A pharmacy may not compound non-sterile HDs in a negative pressure buffer room used for sterile HD compounding.

(7) Sterile and nonsterile HDs must be compounded within a C-PEC located in a containment secondary engineering control (C-SEC).

(8) A pharmacy shall continuously operate C-PECs used for HD compounding.

(9) A pharmacy may not utilize a closed system transfer device (CSTD) as a substitute for a C-PEC when compounding HDs.

(10) A pharmacy shall ensure a C-PEC is decontaminated:

(a) at least each day it is used;

(b) at the end of each shift;

(c) any time a spill occurs;
(d) before and after certification;

(e) after any voluntary interruption or situation where the C-PEC is powered off;

(f) after any loss of power;

(g) if the C-PEC or ventilation components are moved; and

(h) at other intervals as required by work flow to minimize HD contamination.

(11) A pharmacy shall ensure that areas under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly.

(12) A pharmacy without uninterrupted power sources (“UPS”) that maintains negative pressure ventilation shall contain HDs, decontaminate, and validate engineering controls in the event of a power loss.

19.04: Facilities and Engineering Controls – Non-sterile Compounding

(1) Containment primary engineering controls (C-PECs) shall be either externally vented or have redundant–HEPA filters in series. C-PECs shall be properly certified in accordance with 247 CMR 18.00.

(2) A pharmacy compounding non-sterile HDs shall utilize a containment primary engineering control (“C-PEC”) such as a Class I Biological Safety Cabinet (“BSC”) orContainment Ventilated Enclosure (“CVE”). A Class II BSC or a compounding aseptic containment isolator (“CACI”) may also be used provided that the BSC or CACI is installed in accordance with manufacturer specifications and is properly vented and certified.

(3) A C-SEC shall be externally vented, have at least 12 ACPH, and maintain a constant negative differential pressure between -0.01 and -0.03 inches of water column relative to adjacent areas.

(4) A pharmacy may not compound non-sterile, non-HD preparations in a C-PEC that is used for non-sterile, HD preparations.

(5) A pharmacy preparing non-sterile, non-HD compounds in the same C-SEC used for non-sterile HD compounding shall ensure HDs do not contaminate non-HDs or preparations.

(6) A pharmacy shall monitor the pressure differential between the non-sterile C-SEC and adjacent areas with a pressure gauge at least daily and shall document the results.
(7) A pharmacy shall review differential pressure logs or continuous monitoring device reports daily and shall document the review and response to any out of range pressure.

(8) A pharmacy shall ensure that water sources and drains in the C-SEC used for non-sterile HD compounding are located at least one meter away from the C-PEC.

(9) The containment secondary engineering control (C-SEC) used for non-sterile HD compounding shall comply with all requirements for a dedicated compounding room as specified in 247 CMR 18.03.

(10) A pharmacy shall ensure that the C-SEC used for HD compounding has surfaces that are smooth, seamless, impervious, free from cracks and crevices, and non-shedding to facilitate cleaning HD contamination.

19.05: Facilities and Engineering Controls – Sterile Compounding

(1) A C-PEC may not serve as the sole source of exhaust for a negative pressure buffer room.

(2) A C-PEC shall be externally vented and provide ISO Class 5 or better air quality.

(3) A pharmacy may not utilize a positive pressure primary engineering control for compounding sterile HDs.

(4) A pharmacy shall suspend compounding in any C-PEC used for sterile HD compounding in the event a pressure alarm has been activated and may not resume sterile compounding in that C-PEC until the alarm condition has been properly remediated.

(5) A pharmacy shall locate a C-PEC in an ISO Class 7 negative pressure buffer room that:

   (a) is physically separated from the non-HD buffer room; and

   (b) is preceded by an ISO Class 7 ante-room.

(6) A pharmacy may not conduct sterile HD compounding in a segregated compounding area that is not ISO classified.

(7) A pharmacy shall conduct sterile compounding of HDs in a negative pressure buffer room that:

   (a) is externally vented; and

   (b) is under a constant negative pressure between -0.01 and -0.03 inches of water column relative to adjacent positive pressure ISO Class 7 ante-areas.
8) A pharmacy shall ensure that the ante-room used for entry into the ISO Class 7 HD negative pressure buffer room maintains a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas.

9) The ante-room shall contain a hand-washing sink that is located at least one meter away from the entrance to the HD buffer room. Floor drains in the ante room are prohibited.

10) A pharmacy may not have a non-HD positive pressure buffer room precede a negative pressure HD buffer room.

11) A pharmacy may not compound sterile non-HD preparations in a C-PEC that is used for the preparation of sterile HDs unless the non-HD preparation is an adjunct medication for the same patient and is placed into a protective outer wrapper during removal from the C-PEC.

12) Negative pressure buffer rooms used for sterile HD compounding built after January 1, 2018 shall be at least 72 square feet and comply with all other facility requirements specified in 247 CMR 17.00.

13) A pharmacy may not compound non-sterile HDs in a containment primary engineering control (C-PEC) located in a negative pressure buffer room used for sterile HD compounding.

19.06: Handling Hazardous Drugs

1) A pharmacy shall deliver HDs to the HD storage area immediately after unpacking.

2) Personnel shall ensure that the compounding processes, handling, labeling, and transport of HDs do not introduce contamination to non-HD (handling) areas.

3) A pharmacy may not use equipment for both HD compounding and non-HD compounding.

4) Personnel shall carefully count or repackage HDs utilizing clean equipment dedicated for use with HDs and decontaminate said equipment after every use.

5) A pharmacy shall ensure that HDs and HD APIs are handled in a C-PEC during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).

6) A pharmacy shall ensure that all areas where HDs are handled and all reusable equipment and devices are deactivated, decontaminated, and cleaned.
(7) A pharmacy shall ensure that spills are immediately contained and cleaned by qualified personnel.

(8) A pharmacy shall ensure that spill kits are readily available in all areas where HDs are routinely handled.

19.07: Labeling, Packaging, Transport, and Disposal

(1) Personnel shall select and use packaging containers and materials that will maintain the physical integrity, stability, and sterility (if applicable) of the HDs during transport.

(2) A pharmacy may not utilize pneumatic tubes to transport any liquid HDs or any antineoplastic HDs.