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Board of Registration in Pharmacy

Advisory: Failed HEPA Filters in ISO-Classified Environments

I. Required Board Notification: Disclosure of Failed Certification

Every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall report the failure of certification of **primary and / or secondary engineering controls in any sterile compounding or institutional sterile compounding pharmacy licensed by the Board**, as applicable. Reporting forms are located here: <https://www.mass.gov/lists/reporting-forms-for-the-board-of-registration-in-pharmacy>

II. General

Based on recommendations from the Advisory Committee to the Board of Registration in Pharmacy, guidance has been developed regarding proper response and remediation of HEPA filter failures in ISO classified environments.

A failed HEPA (High Efficiency Particulate Air) filter is defined as a filter that has failed a required certification performance test (such as a filter integrity test) or demonstrates other adverse conditions (such as the presence of visible contamination) that may negatively impact the state of control of a sterile compounding facility.

The pharmacy should work with a qualified vendor in developing a maintenance and replacement plan for HEPA filters and pre-filters.

Compounding personnel should visually inspect the external portion of PEC filters at least daily for signs of filth, residue, or other contamination and, if present, contact a qualified vendor for an evaluation.

III. Pharmacy Response to Failed HEPA Filter(s)

A. Remediation Steps

The pharmacy shall immediately remediate a failed HEPA filter by:

- i. properly repairing or replacing the HEPA filter;
- ii. recertifying the affected ISO classified area; and
- iii. performing environmental monitoring (non-viable air, viable air and surface, bacterial and fungal) in **at least** the affected ISO classified area according to the environmental monitoring sampling map. The pharmacy should justify and document its rationale for the scope and frequency of environmental monitoring (“EM”) conducted based on its risk assessment. It is recommended that a qualified microbiologist, infection control professional, industrial hygienist, or other qualified professional be consulted.

B. Pharmacies should perform a risk assessment of compounded products based on the location and scope of the failed HEPA filter(s) and take appropriate action.

In accordance with the “*Advisory on Pharmacy Requirement to Maintain a Defective Drug Log*”, the pharmacy shall recall a compounded drug preparation¹ if it knows, or should have reason to know, that a compounded drug preparation is, or may be defective in any way.

<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/advisories/defective-drug-prep-log.pdf>

IV. Recommended Conditions for Sterile Compounding Following Identification of Failed HEPA Filters in ISO Classified Spaces

After initiation of remediation steps and conducting a risk assessment, the pharmacy may resume sterile compounding activities, depending on the location of the failed HEPA filter(s), according to the conditions below.

The pharmacy should not batch CSPs prepared under these conditions until failed HEPA filter(s) are properly remediated.

In the event the pharmacy suspends compounding activities, their continuity of care plan must be implemented to ensure patient needs are met until remediation has been completed.

¹ A defective drug preparation is defined as any out of specification result such as the potency, pyrogenicity, stability, improper composition, contamination, mislabeling, or sterility of a compounded sterile product (CSP) or the potency, purity, quality, mislabeling, or stability of a simple, moderate, or complex compounded non-sterile preparation (CNP).

A. ISO-5 Primary Engineering Control (“PEC”):

The pharmacy shall shut off and discontinue use of the affected PEC until the failed HEPA filter is remediated. If the pharmacy’s design is an ISO Class 7 buffer room with multiple ISO Class 5 PECs, the pharmacy may continue to compound in the unaffected PEC(s) provided that the buffer room is able to maintain the required minimum air changes per hour (“ACPH”) with the affected PEC removed from service.

B. Other ISO Classified Spaces (ISO-7 Non-Hazardous Drug Buffer Room, ISO-7 Ante Room, ISO-8 Ante Room, or Other ISO-8 Classified Space):

The pharmacy should limit the beyond use dates (“BUDs”) for compounded sterile preparations (“CSPs”) to 12 hours or less until the failed HEPA filter(s) are remediated and the repeat EM demonstrates results within acceptable levels.

If an ISO-8 classified space does not immediately precede an ISO-7 non-hazardous buffer room (e.g., air lock, prep room, etc.), limit the BUDs to no more than 24 hours room temperature or 72 hours refrigerated until the failed HEPA filter(s) are remediated and the repeat EM demonstrates results within acceptable levels.

C. HEPA Filtered Pass-Throughs:

A pharmacy with a failed HEPA filter in a pass-through should determine if continued utilization of the unit is appropriate based on a risk assessment accounting for factors such as its specific location, nature and volume of compounding conducted, and other operational factors.

V. Documentation

All reports and documentation related to the failed HEPA filter(s), including risk assessment and subsequent remediation activities, must be maintained in the pharmacy’s records and available for Board inspection.

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