Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding

The Massachusetts Board of Registration in Pharmacy (“Board”) would like to advise licensees of the process of conducting repairs or service to facilities engaging in sterile compounding or complex non-sterile compounding.

Such facilities may conduct required repairs and / or service without submitting an Application for Remodeling, Change in Configuration, or Change in Square Footage (Renovation / Expansion) provided that the repair and / or service:

a. Is in response to the need for an urgent repair (e.g. damage from a broken pipe, storm-related repairs, etc.) and Board staff has been notified;
b. Is in response to a deficiency cited during an inspection and has been detailed in a submitted plan of correction;
c. Is designed to improve or maintain the compounding facility;
d. Does not involve remodeling;
e. Does not change the configuration or square footage of any secondary engineering control or complex non-sterile dedicated compounding room;
f. Does not involve the moving, removing, adding, modifying, or replacing of any secondary engineering control or complex non-sterile dedicated compounding room;
g. Does not involve the moving (permanent relocation), removing, adding, modifying, or replacing of any primary engineering control;
h. Does not involve a major repair and / or major service¹; and
i. Is conducted in accordance with this advisory.

A written strategy to mitigate the effects of the work and maintain quality assurance during the work period must be in place.

The Board advises that facilities engaged in sterile and complex non-sterile compounding suspend compounding activities during the period of work and until

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¹ Major Repair / Major Service is defined as significant modifications, repairs, or service to the compounding pharmacy that may not affect the floor plan but may result in changes to airflow dynamics and / or the generation of environmental contaminants. Requires submission of Application for Remodeling, Change in Configuration, or Change in Square Footage (Renovation / Expansion).

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environmental monitoring (EM) reports demonstrate results within acceptable levels, if applicable (e.g. sterile compounding facilities).
The pharmacy’s continuity of care plan should be implemented to meet patient needs during the work period and subsequent testing period, as required.

The compounding facility should determine, based on a risk assessment\(^2\), when it is safe to resume compounding.

If, after performing a risk assessment, the **sterile compounder** chooses to continue production during the work period and subsequent testing period, the Board advises that beyond use dates (BUDs) be limited to 24 hours room temperature or 3 days refrigerated until environmental monitoring (EM) reports demonstrate results within acceptable levels.

Similarly, the pharmacy should not freeze or batch any compounded sterile products (CSPs) until environmental monitoring (EM) reports demonstrate results within acceptable levels.

The pharmacist Manager of Record must assure that all certifications and EM testing after repairs or service were conducted in accordance with USP Standards, applicable statutes, regulations, and policies of the Board. All documentation related to the repair or service event, including risk assessment, must be maintained in the pharmacy’s records and available for Board inspection.

Repairs and / or services that fall outside of the scope of this advisory require submission of an Application for Remodeling, Change in Configuration, or Change in Square Footage (Renovation/ Expansion):

**Please direct any questions to:** Pharmacy.Admin@MassMail.State.MA.US

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\(^2\) A qualified microbiologist, infection control professional, industrial hygienist, and certification professional should be consulted.

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