The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
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Board of Registration in Pharmacy

Action Level Environmental Monitoring Result Disclosure

Pharmacy Name _____MA License Number_____
Pharmacy Address _____
City/Town _____State_____ Zip Code _____
Pharmacy Tel. No. _____
Name of Manager of Record (MOR) / Designated Pharmacist-in-Charge (PIC)
(print)_____
MOR / PIC MA License Number_____
Pharmacy / MOR / PIC Email_____

Within 1 (one) business day of receipt of the microbiology report, a signed copy of this form must be scanned and emailed to: AbnormalResults@mass.gov Specify the name of the pharmacy and license number in the subject line.
Date report was received: _____

Have there been any other action level reports within the last 60 days?
If yes, date of report: _____

Confirm that BUDs for compounded preparations dispensed into, within, or from Massachusetts will be limited, or compounding suspended in accordance with Policy 2023-09: *Action Level Environmental Monitoring Results* **MOR/PIC initials:**_____

If the action level occurred in an **ISO 5 PEC**, provide the date that it was removed from service.
Date:_____

If the pharmacy has ceased <u>all</u> sterile compounding, indicate the effective date: _____

*All documentation (microbiology reports, RCA, CAPA, disclosure forms, etc.) must be kept on site and available upon Board request.

ISO Classification (e.g., 5, 7, 8)	Positive / Negative Pressure?	Air / Surface Result?	Organism Identification	CFU Count	Non-Viable Particle Count (only report if action level)

Additional Questions	Yes, No, N/A, or provide requested information
1. If there has been a significant loss of control **(>15 CFU)** in the ISO 5 PEC, did/will the pharmacy recall any CSP that are within their BUDs, perform adverse event surveillance, contact prescribers, and engage a qualified microbiology professional?	
2. If the action level was associated with non-viable particles in any ISO classified area, did/will compounding be suspended until successfully remediated and all classified areas are recertified?	
3. Did/will the continuity of care plan [as required by 247 CMR 9.19(15)] to meet patient needs be instituted in the event compounding must be suspended?	
4. Have/will remedial cleaning activities been initiated with the appropriate cleaning agents based on the organism(s) identified?	
5. Has/will a risk assessment/risk mitigation plan been initiated to determine whether it is appropriate to compound during remediation in accordance with Policy 2023-09: *Action Level Environmental Monitoring Results*?	
6. For action levels identified in ISO Class 5 PECs, was/will all compounding be transitioned to unaffected PECs until proper remediation has been completed?	
7. If only one ISO Class 5 PEC is available for compounding, will BUDs be limited to **"immediate use only"** until proper remediation has been completed?	
8. For action levels identified in ISO Class 7 areas, will BUDs for all CSPs be limited to **24 hours room temperature or 4 days refrigerated** until proper remediation has been completed?	
9. Until proper remediation has been completed for action levels identified in ISO Class 8 areas, will BUDs be limited to: a. **24 hours room temperature or 4 days refrigerated** if prepared from one or more **nonsterile** starting component(s); or b. **4 days room temperature or 10 days refrigerated** if prepared from **sterile** starting component(s)?	**Describe:**
10. Has repeat environmental monitoring (EM) of the **entire affected classified area (air and surface samples)** based on the pharmacy's EM sampling plan been scheduled?	**Date scheduled:**
11. Has a root cause analysis (RCA) investigation been initiated?	
12. Has a Corrective Action and Preventative Action plan (CAPA) been initiated and actions documented?	

See guidance to help ascertain root cause and develop a remediation plan.

Non-Viable Air Sample Action Levels:

ISO Class 5	>3520 particles 0.5 µm or larger per cubic meter of air
ISO Class 7	>352,000 particles 0.5 µm or larger per cubic meter of air
ISO Class 8	>3,520,000 particles 0.5 µm or larger per cubic meter of air

Viable Air Sample Action Levels (cumulative count):

ISO Class 5	> 1 CFU
ISO Class 7	> 10 CFU
ISO Class 8	> 100 CFU
Highly pathogenic microorganisms as determined by a qualified microbiology professional	≥ 1 CFU

Viable Surface Sample Action Levels (cumulative count):

ISO Class 5	> 3 CFU
ISO Class 7	> 5 CFU
ISO Class 8	> 50 CFU
Highly pathogenic microorganisms as determined by a qualified microbiology professional	≥ 1 CFU

Attestation:

I, _____ (MOR / PIC), of _____(pharmacy name), attest that all steps for response and remediation will be completed according to the standards set forth in the current USP <797>, Board regulations and policies (including Policy 2023-09: *Action Level Environmental Monitoring Results*), and that all ISO classified spaces shall have repeat environmental sampling results within action levels prior to resuming the facility's standard sterile compounding activities**.**

MOR/PIC Signature: _____ Date: _____