

**COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY**

**Enforcement Policy 16-04**

<b>Title</b>	<b>Staff Action to Handle Above Action Level Results</b>
<b>Purpose</b>	The Board of Registration in Pharmacy (“Board”) adopts this policy to authorize Board staff to effectively manage above action level results from environmental monitoring (EM) reported by licensees pursuant to 247 CMR 6.15(7).
<b>Date Adopted</b>	November 1, 2016
<b>Regulatory Guidelines</b>	<b>247 CMR 6.15(7)</b> “Every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall <b>report within seven business days all abnormal results</b> , including failure of certification as required pursuant to 247 CMR 6.01(5)(c), and identification of environmental contaminants or improper potency in that pharmacy inconsistent with Board Regulations or USP <797> standards or criteria.”
<b>Definitions:</b>	<p><b>Successful remediation of an above action level environmental monitoring result</b> means: (1) the pharmacy implemented a remediation plan upon receipt of above action level environmental monitoring result; (2) the pharmacy conducted a Root Cause Analysis; (3) the pharmacy implemented a Corrective Action / Preventative Action plan; and (4) repeat environmental monitoring results were below USP &lt;797&gt; action levels.</p> <p><b>Triage Team</b> <u>means</u> a team that reviews newly received complaints, notifications, and emergent issues on a regular basis. The Triage team consists of at least four of the following individuals: (1) the Executive Director of the Board of Registration in Pharmacy; (2) the Associate Executive Director for the Board of Registration in Pharmacy; (3) Board Counsel; (4) the Director of Pharmacy Compliance; (5) Quality Assurance Pharmacist; (6) the Director of Pharmacy Investigations; or (7) Pharmacy Compliance Officer.</p>
<b>Authorization to Approve</b>	<p>The Board authorizes designated Board staff to review and process above action level environmental monitoring results as follows:</p> <ol style="list-style-type: none"> <li>1. Above Action Level Reports will be reviewed for compliance and risk assessment by a Quality Assurance pharmacist.</li> <li>2. A triage file will be opened for each Above Action Level Report and assigned to an Investigator.</li> <li>3. Triage files are reviewed by Investigators for reporting compliance, and successful remediation (i.e. within USP &lt;797&gt; action levels).</li> <li>4. Above Action Level Reports will be entered into a database by the Quality Assurance team to maintain a history for each pharmacy.</li> </ol>

<p><b>Authorization to Approve</b></p>	<p>5. Above Action Level triage files will be reviewed by the triage team:</p> <ul style="list-style-type: none"> <li>a. The Board authorizes the triage team to close a triage file and take no further action if the pharmacy demonstrated successful remediation and was compliant with reporting requirements.</li> <li>b. The Board authorizes the triage team to open a staff assignment or complaint if the pharmacy did not demonstrate successful remediation or did not comply with reporting requirements.</li> </ul> <p>6. Staff Assignments and Complaints involving Above Action Level Reports shall be reviewed at scheduled Board meetings.</p>
<p><b>Report to Board</b></p>	<p>Board Staff shall submit a report of above action level statistics to the Board on a monthly basis.</p>