



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Bureau of Public Health
 Bureau of Health Professions Licensure
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 Commissioner

Board of Registration in Pharmacy

Disclosure of Failed Certification

Name of Pharmacy _____	MA License Number _____
Pharmacy Address _____	
City/Town _____	Zip Code _____
Tel. No. _____	Fax No. _____
E-mail _____	

In accordance with 247 CMR 6.15 (7), every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall report within **7 business days** all abnormal results, 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 *United States Pharmacopeia General Chapter 797* standards or criteria. **This form is intended to disclose failed certification of primary and / or secondary engineering controls in any sterile compounding or institutional sterile compounding pharmacy licensed by the Board.**

Note: Above action level environmental monitoring results shall be reported using the Above Action Level Environmental Monitoring (EM) Results form: (<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/em-intial-reporting.pdf>).

Any defective drug preparation shall be reported using the Pharmacy Report of Defective Drug Preparation form: (<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/defective-drug-prep-log.pdf>).

	Date of Occurrence	Description
Failed Certification of Primary and / or Secondary Engineering Controls		

Attach a copy the Corrective Action Plan (CAP) used to address the failed certification you are reporting as well as a copy of related documentation provided by the certification vendor.

Review the Board’s advisory on how a Pharmacy should respond to Failed HEPA Filters:
<https://www.mass.gov/files/documents/2018/02/16/Failed-hepa-filter.pdf>

Please direct any questions regarding this reporting form to:
abnormalresults@MassMail.State.MA.US

The FAILURE of any Massachusetts pharmacy or pharmacist to make a report required by 247 CMR to the Board within the timeframe stated in 247 CMR will be grounds for discipline under 247 CMR 10.03(q).

Print Name Licensee/Registrant: _____

Title: _____

MA License Number: _____

Signature of Licensee: _____

Date: _____

A signed copy of this report and related documentation must be scanned and emailed to
abnormalresults@MassMail.State.MA.US