The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Bureau of Public Health

Bureau of Health Professions Licensure

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[www.mass.gov/dph/boards](http://www.mass.gov/dph/boards)



**Board of Registration in Pharmacy**

MARYLOU SUDDERS

Secretary

MONICA BHAREL, MD, MPH Commissioner

CHARLES D. BAKER

Governor

KARYN E. POLITO

Lieutenant Governor

 **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**