The Commonwealth of Massachusetts

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To: Commissioner Margret Cooke and Members of the Public Health Council

From: Nalina Narain, Bureau Director, Bureau of Environmental Health

Date: June 8, 2022

RE: Informational Briefing on Proposed Amendments to 105 CMR 120.000, *The Control of Radiation*

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**I. Introduction**

The purpose of this memorandum is to provide the Public Health Council (PHC) with information about proposed amendments to 105 CMR 120.000, *The Control of Radiation.* This regulation grants the Department’s Radiation Control Program (RCP) exclusive regulatory authority and responsibility in the Commonwealth for protecting people from the harmful aspects of radiation, pursuant to M.G.L. c. 111, § 5N.

In 1997, Massachusetts signed an agreement with the U.S. Nuclear Regulatory Commission (NRC), whereby the NRC delegated much of its regulatory authority regarding radiation safety to the Department/RCP. In exchange, RCP’s regulations must maintain conformance with NRC regulations. Massachusetts is among 39 “Agreement States” under the NRC.

From 2018 through 2019, the U.S. NRC notified the Massachusetts RCP about five categories of amendments to federal regulations that it has made, and under the agreement, Massachusetts must promulgate compatible regulations. In response, RCP has prepared these proposed regulatory amendments, which conform to NRC’s five federal regulation amendments. These regulatory changes are required to maintain Agreement State status.

These proposed amendments are not expected to generate extensive comments nor be controversial, as the NRC has already involved stakeholders nationally through its process of amending its regulations, including soliciting for and resolving comments as published in the Federal Register prior to NRC issuing final regulations. The final NRC regulations have now been implemented nationally, in areas where NRC maintains jurisdiction, for two or more years.

All proposed amendments have been reviewed by NRC and all comments made by NRC have been addressed. No fiscal impacts on licensees are expected.

**II. Summary of Proposed Changes**

There are five categories of proposed amendments required to align with the federal updates. All appear in numerous places throughout the regulation, and prominent instances are noted below:

1. **Licensing of Radioactive Materials (105 CMR 120.100 and .500):** Amends specific terms and conditions of certain licenses (generator elution, preparation of technetioum-99m and rubidium-82 radiopharmaceuticals) to require reporting of an exceedance of permissible concentrations of breakthrough or contaminate solutions of specific materials.
2. **Radiation Safety Requirements of Industrial Radiographic (105 CMR 120.300)**: The amended language requires advance notification of each location of radiographic operations, prior to exceeding 180 cumulative days of radiographic operations in a calendar year, for any location not listed on the license.
3. **Use of Radionuclides in the Healing Arts (105 CMR 120.500):** Numerous sections have been revised to be compatible with U.S. NRC’s 10 Code of Federal Regulations (CFR) Parts 30, 32 and 35.The amended language addresses:
* Medical event definitions and reporting/notification requirements
* Certification, training and appointing requirements for Associate and Radiation Safety Officers
* Documentation requirements for implantation brachytherapy procedures and use of sealed sources in brachytherapy
* Safety, experience, and training requirements for use of sealed sources for ophthalmic treatments
* Certification and training requirements for medical uses of byproduct materials
* Allowances for certain uses of byproduct material
* Training, experience, and safety requirements for authorized use of sealed and unsealed radioactive materials
1. **Transportation of Radioactive Material (105 CMR 120.700):** Amended to reference 105 CMR 120.016(L) (Deliberate Misconduct)regarding compliance with the general license and the contact information for submitting first use of package information to the NRC. This means that the licensee must contact NRC in writing prior to first use of an NRC-approved package containing radioactive material.
2. **Miscellaneous Corrections and Organizational Amendments (105 CMR 120.000):** Updates the online address (URL) of RCP’s website, updates oath and affirmation requirements, updates the contact information regarding fingerprint checks, and clarifies general security program requirements.

**III. Next Steps**

The Department intends to conduct a public comment hearing and will then return to the PHC to report on testimony and any recommended changes to the proposed amendments. Following final action by the PHC at a future meeting, the Department will be able to file the final amendments with the Secretary of the Commonwealth.

The proposed amendments to 105 CMR 120.000 are attached to this memorandum.