105 CMR 120.000 – The Control of Radiation

Informational Briefing on Proposed Amendments

Jack Priest
Director, Radiation Control Program

James Ballin, Esq.
Deputy General Counsel

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I. Regulatory Overview

- The U.S. Nuclear Regulatory Commission (NRC) has sole regulatory authority over all producers of radioactive material
- "Agreement States"
  - NRC relinquishes some authority over certain radioactive material to the state agency responsible for radiation control
  - The NRC evaluates Agreement States’ staffing and operational protocols on a routine basis to ensure standards are maintained
- MA became an Agreement State in 1997
  - Massachusetts Department of Public Health’s Radiation Control Program (DPH/RCP) regulates most non-federal entities in the Commonwealth that possess, use, transfer, receive, or distribute radioactive material.
  - RCP must operate in accordance with nationally accepted standards and is required by federal requirements to adopt regulations that are compatible with NRC regulations on a schedule established by the NRC
  - Failure to comply with NRC requirements could jeopardize Massachusetts’ Agreement State status.
II. Background

105 CMR 120.000: The Control of Radiation

• This presentation provides an informational briefing on proposed amendments to 105 CMR 120.000: *The Control of Radiation*. These amendments are being proposed to maintain compatibility between Massachusetts regulations and the regulations of the U.S. Nuclear Regulatory Commission (NRC) as required under an agreement between the Commonwealth of Massachusetts and the NRC.

• These proposed amendments have been reviewed by NRC and all comments made by NRC have been addressed. No fiscal impacts upon licensees are expected.
Decommissioning planning: 105 CMR 120.100, 120.200 are revised to alter requirements regarding decommissioning planning related to terms and conditions of licenses and financial assurance for decommissioning.

- An application for transfer of a license must now include identity, technical and financial qualifications of the proposed transferee.

- A licensee using a Parent Company Guarantee for assurance of funds for decommissioning must have a tangible net worth of at least $21 million instead of $10 million. The three licensees currently using a Parent Company Guarantee are not expected to be affected by this change.
III. Proposed Amendments

Distribution and use of byproduct material: 105 CMR 120.005, 120.100 are revised to be compatible with U.S. NRC’s 10 CFR Parts 30, 31 and 32.

• Specific Licenses: Applicant may be granted license for sealed sources and devices even though it may not be feasible for the applicant to identify each source/device individually with the manufacturer and model number. Includes constraints on amounts and conditions of use as approved by the Agency;

• General Licenses: Certain devices containing small amounts of byproduct materials are exempt from licensing instead of being generally licensed;

• Clarification is made that NRC, not Agreement State, is responsible for issuing specific licenses that authorize for distribution of products containing byproduct materials to persons exempt from licensing.
III. Proposed Amendments

**Distribution and use of source material:** 105 CMR 120.005 and 120.100 are amended to revise the definition for Unrefined and Unprocessed Ore and altering certain licensing requirements related to distribution and use of source material.

- **Specific License:** New specific type license is offered for persons that may want to initially transfer source material to persons generally licensed;

- **General licenses:** Limitation is placed upon amount of dispersible forms (e.g., gaseous, liquid, powder, etc.) of source material that may be possessed and used;

- **Exemptions:** Clarification is made that NRC, not Agreement State, is responsible for issuing specific licenses that authorize for distribution of products containing source materials to persons exempt from licensing.
Transportation Safety: 105 CMR 120.005, 120.016 and 120.770 are revised to update relevant definitions, include a shipment record retention policy and make changes to quality assurance programs for transportation.

- Record Retention: Shipment Records to be maintained by licensees for a period of three years after shipment showing applicable information such as identification of the packaging by model number and serial number, type and quantity of materials in each package, date of shipment, and address to which the shipment was made.

- Quality Assurance: Provides greater flexibility to make changes (as long as not considered reductions in commitments). Added requirements establishing corrective action measures to assure that conditions adverse to quality are promptly identified and corrected and audits carried out to verify compliance and determine effectiveness of the licensee’s quality assurance program.
IV. Next Steps

– Following this initial presentation, a public hearing and comment period will be held.

– Approval of the proposed amendments, along with a review of public comments, will be requested at a subsequent meeting of the Public Health Council.

– Following final approval, this regulation will be amended.
Questions?