Commonwealth of Massachusetts
Department of Public Health

Helping People Lead Healthy Lives In Healthy Communities

105 CMR 127.000 – Licensing of Mammography Facilities

Final Regulatory Amendment Presentation

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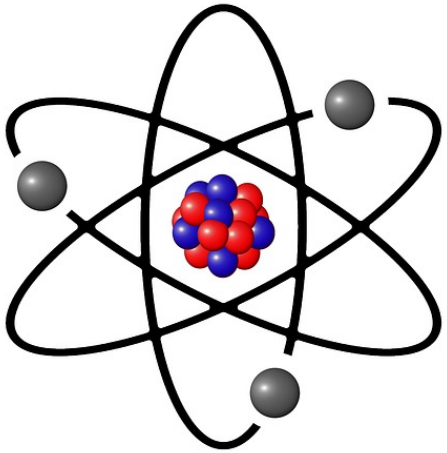

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I. Regulatory Overview

- **Mammography Facilities:**
  - The U.S. Food and Drug Administration (FDA) regulates mammography facilities and requires certification by an accreditation body.
  - The American College of Radiology (ACR) is the only accreditation body in Massachusetts, and facilities must meet their standards to be accredited.
  - M.G.L. c. 111, § 5Q charges DPH's Bureau of Environmental Health / Radiation Control Program (RCP) with regulating the licensure of mammography facilities within the Commonwealth.

- **Mammography Providers**:
  - The FDA sets minimum standards for Interpreting Physicians, Responsible Physicians, Radiologic Technologists and Medical Physicists.
  - The Massachusetts Board of Registration in Medicine (BORIM) regulates licensure of all Interpreting and Responsible Physicians

II. Background (cont.)

- 105 CMR 127.000: Licensing of Mammography Facilities
  - Sets forth standards for the operation of mammography facilities that offer breast cancer screening or diagnosis through mammography.
  - Last updated in 1994. Technological and national standards have evolved.

- Initial proposed amendments encompassed current practices in mammography, reflected advances in mammography technology, and incorporated language from regulations promulgated by the Massachusetts Board of Registration in Medicine (BORIM) and the U.S. Food and Drug Administration (FDA).

- A public hearing was held on December 1, 2016 and the public comment period closed on December 2, 2016.

III. Proposed Amendments

- **Definitions**: Definitions added to clarify terms in the regulation, including 'Direct Supervision', 'Mammographic Modality' and 'Interpreting Physician,' and clarifying that "Lead Interpreting Physician" and "Responsible Physician" are synonymous to align with FDA language.

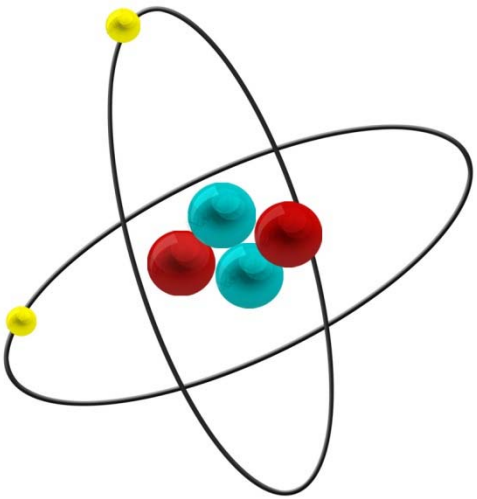
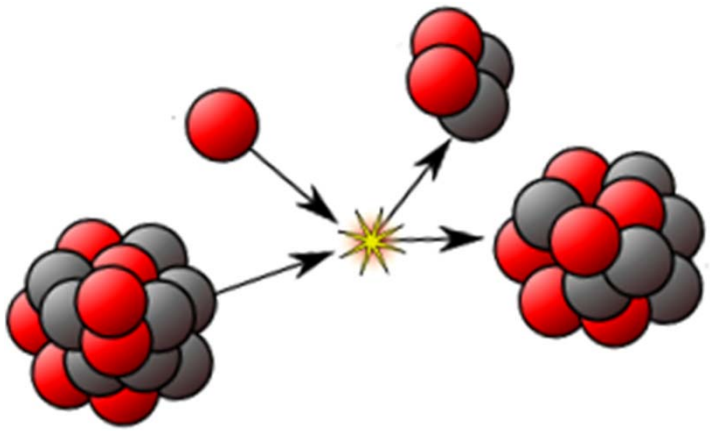
- **Quality Control Standards:** The initial draft required that all Digital Mammography screening follow manufacturer's recommendations for Quality Control. In response to comment, RCP proposes that alternatively, American College of Radiation (the accreditation body for all Massachusetts mammography facilities) standards could be utilized.

III. Proposed Amendments

- **Alignment with Current ACR, FDA or BORIM Standards**: In response to comments, changes were made to ensure that American College of Radiology (ACR) Standards for facilities, FDA standards for mammography facilities and staff, and BORIM standards for physicians, were aligned with this regulation. These are current standards which facilities must be in compliance with, and no additional obligations were imposed.

- **Removal of References Outdated, Obsolete Technology:** In response to comments, RCP recommends the removal of references to Film Screen imaging and other outdated technology throughout the regulation to eliminate confusion, and prohibition of film screen mammography (no registered facility is using Film Screen imaging and have all transferred to digital).

IV. Next Steps

- Staff requests the Public Health Council approve the proposed regulations for promulgation.
- Following Public Health Council approval, the Department will file the amended regulation with the Secretary of the Commonwealth for final enactment.
- RCP will develop training and guidance materials to assist with implementation.

Questions?