

# Amendments to 105 CMR 127.000: Licensing of Mammography Facilities.

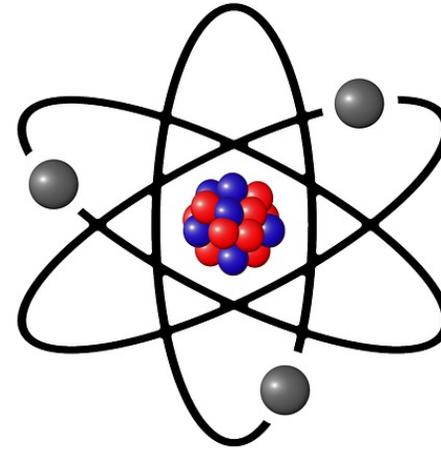
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# I. Background

- 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.
- 105 CMR 127.000, promulgated under this authority, has not been updated since 1994.
- Proposed amendments encompass current practices in mammography, reflect advances in mammography technology, and incorporate statutory requirements and language from regulations promulgated by the Massachusetts Board of Registration in Medicine (BORIM) and the U.S. Food and Drug Administration (FDA).

## II. Proposed Amendments

### **Modality training and proficiency requirements:**

- **Existing:**
  - No requirement for new modality training or number of exams that must be completed to establish ongoing proficiency for Mammography Radiologic Technologists
  - No requirements for new modality training or continuing qualifications for Medical Physicists
- **Proposed:**
  - Mammography Radiologic Technologists must complete new modality training and perform 200 exams every 24 months
  - Clarifies definitions and academic requirements, requires new modality training, and sets continuing qualifications for Medical Physicists.
- **Rationale:**
  - Updates regulations to meet FDA requirements

## II. Proposed Amendments

### Proficiency Requirements for the Responsible Physician:

- **Existing:**
  - Requires a Responsible Physician to have read/interpreted an average of 10 or more mammograms per work week for the prior 6 months.
  
- **Proposed:**
  - Responsible physicians exam interpretation proficiency timeline extended to 960 read and interpreted over a 24 month period
  
- **Rationale:**
  - Aligns with MA Board of Registration in Medicine (BORIM) regulations

## II. Proposed Amendments

### Breast Density Notification

- **Existing:**
  - No regulatory requirement to provide patient notification if a mammography reveals dense breast tissue.
  
- **Proposed:**
  - Adds a requirement that the interpreting physician provides written notification to patients after a mammography reveals dense breast tissue. This notification must be verified as part of the Clinical Quality Assurance/Recordkeeping requirements in 127.020.
  
- **Rationale:**
  - This inclusion meets the requirements of Chapter 150 of the Acts of 2014 (codified in M.G.L. c. 111, § 5Q).

## II. Proposed Amendments

### Other Proposed Amendments:

- Updates to definitions to reflect current terminology and clarify existing provisions
- Streamlining and re-ordering the regulations to make them more efficient, coherent and consistent
- References updated to reflect correct MA regulations and statutes
- These changes align terminology and definitions in accordance with Massachusetts Executive Order NO. 562

### III. 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. Training and guidance materials will be developed to assist with implementation.