

105 CMR 127.000 LICENSING OF MAMMOGRAPHY FACILITIES

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127.001: Purpose

105 CMR 127.000 sets forth standards for the maintenance and operation of mammography facilities.

127.004: Scope and Application

(A) 105 CMR 127.000 applies to all facilities in the Commonwealth, whether stationary or mobile, that offer breast cancer screening or diagnosis or procedures through mammography including, but not limited to, facilities owned or operated by any health care provider, including those which are part of a clinic or a hospital licensed under M.G.L. c. 111, § 51, a health maintenance organization licensed pursuant to M.G.L. c. 166G, a radiology practice, or office of a physician, or other person.

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(B) 105 CMR 127.000 applies to the licensure of all persons who seek to or currently own and operate mammography facilities in the Commonwealth of Massachusetts.

127.005: Definitions

The following terms as used in 105 CMR 127.000 shall be interpreted as follows, unless the context or subject matter clearly requires a different interpretation:

Annual means a period of time that does not exceed 12 months.

Applicant means any person who applies to the Department for a license to operate a mammography facility. In the case of an applicant which is not a natural person, the term "applicant" shall also mean any shareholder owning 5% or more; any officer and any director of any corporate applicant; any limited partner owning 5% or more and any general partner of any partnership applicant; any trustees or any trust applicant; any sole proprietor of any applicant which is a sole proprietorship; any mortgagee in possession; and any executor or administrator of any applicant which is an estate.

Asymptomatic means without signs or symptoms of breast disease.

Automatic Exposure Control means a device which automatically controls one or more technique factors in order to obtain at a preselected location or locations a required quantity of radiation.

Central Ray means the ray of the x-ray beam that is perpendicular to the plane of the image receptor.

Charged Coupled Device (CCD) Based Mammography means a method of Digital Mammography in which a light sensitive integrated circuit is used to capture and convert the image to electronic format.

Coefficient of Variation means the ratio of the standard deviation to the mean value of a population of observations.

Commissioner means the Commissioner of the Massachusetts Department of Public Health or his or her designee.

Compression Device means a rigid apparatus that compresses the breast to immobilize the breast and provide uniform thickness during mammography.

Computed Radiography (CR) Based Mammography means a type of digital mammography in which a light sensitive phosphor is used to capture the image and then convert to electronic format.

Cranio-caudal means a mammographic projection where the image receptor is placed inferior to the breast and the x-ray beam is directed superior to inferior, through the breast.

Department means the Massachusetts Department of Public Health.

Diagnostic Mammography means the mammographic examination of the breast of a patient with signs or symptoms of breast disease, a possible abnormality detected on screening mammography or other imaging, or who has prior mammography findings requiring imaging follow-up.

Diagnostic Physics means the branch of medical physics that deals with the diagnostic applications of ionizing radiation and the equipment associated with its production and use.

Digital Breast Tomosynthesis (DBT) (also known as 3-Dimensional (3D) Mammography) means a Digital Mammography (DM) modality where the breast is imaged at multiple angles and digital image slices are created.

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Digital Mammography (DM) means mammography in which the image is captured on a digital detector, converted into electronic format and displayed either on a softcopy workstation or as a hardcopy laser printout. Digital mammography includes, but is not limited to, Full Field Digital Mammography (FFDM), Computed Radiography (CR) Based Mammography, and Charged Coupled Device (CCD) Based Mammography.

Direct Supervision means:

- (1) For a physician during joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised; and
- (2) For a mammography technologist, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination; and
- (3) For the medical physicist, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is conducting the survey.

Focal Spot means the area of the target on the anode of an x-ray tube that is struck by electrons emitted from the cathode. The effective focal spot is the actual focal spot observed from the direction of the central ray of the x-ray tube.

Full Field Digital Mammography (FFDM) means a type of Digital Mammography in which the field of view is large enough to image the entire breast.

Grid means a device used to control scattered radiation that is composed of alternating strips of lead and low x-ray absorption spacer material encased in a protective cover.

Half-value Layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent that the exposure rate is reduced to ½ of its original value.

Image Receptor means any device which transforms incident x-ray photons into a visible image or into another form which can be made into a visible image by further transformation.

Interpreting Physician means a licensed physician who interprets mammograms and meets the requirements of 243 CMR 2.07(24).

Licensee means any person holding a license to operate a mammography facility. In the case of a licensee that is not a natural person, the term "licensee" shall also mean any shareholder owning 5% or more of any class of the outstanding stock of a privately-held corporation; any limited partner owning 5% or more of the partnership interests and any general partner of a partnership licensee; any trustee of any trust licensee; any sole proprietor of any licensee that is a sole proprietorship; any mortgagee in possession; and any executor or administrator of an estate of a licensee.

Machine means a radiation machine designed specifically for mammography.

Mammogram means the resulting radiographic image (on a digital soft copy format or hard copy laser printout) produced when mammography is performed.

Mammography means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast.

Mammography Facility means any facility, whether stationary or mobile, that offers diagnostic or screening mammography services in the Commonwealth to any person.

Mammography Modality means a technology for radiography of the breast that requires specialized training for image generation, interpretation, and quality control. Modalities include, but are not restricted to, digital mammography, digital breast tomosynthesis, and stereotactic breast biopsy.

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Mammography Phantom means a test object used to stimulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

Mammography Radiologic Technologist means an individual licensed as a Radiologic Technologist in both Radiography and Mammography under the provisions of M.G.L. c. 111, § 5L and 105 CMR 125.000: *Licensing of Radiologic Technologists*.

Mammography Unit or Units means an assemblage of components for the production of x-rays for use during mammography, including at a minimum: an x-ray generator, an x-ray control, an x-ray housing assembly, a beam limiting device, and the supporting structures for these components.

Medical Physicist means an individual who meets the qualifications of 105 CMR 127.013.

Mobile Mammography means diagnostic mammography services offered by transporting a mammography unit to a site for the purpose of performing mammography. Mobile mammography also includes mammography units used in mobile vans.

Optimization means the initial selection of operating parameters and equipment set-up process within the mammography facility in which a balance between the minimum patient dose and the maximum diagnostic information is achieved. This process involves the selection and evaluation of all the equipment in the mammographic system through a joint undertaking by the Responsible Physician, the Medical Physicist, the Mammography Radiologic Technologist and the Interpreting Physician. Such equipment includes, but is not limited to: digital image receptors, image processing, and image display systems, grids, kilovolt peak (kVp), exposure time and filtration.

Person means any natural person, corporation, partnership, firm, association, society, trust, estate, public or private institution, group, agency, political subdivision of this Commonwealth, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

Physician means an individual registered by the Board of Registration in Medicine under M.G.L. c. 112 § 2 as a qualified physician.

Quality Assurance Procedures Manual (QAPM) means a written document containing the site specific procedures for the mammography facility for the purpose of assuring high quality services for consumers including, but not limited to: procedures for optimization, equipment quality assurance, techniques, policies, and clinical quality assurance.

Radiation Control Program means the Radiation Control Program of the Massachusetts Department of Public Health.

Radiological Physics means that branch of medical physics which includes diagnostic physics, and medical nuclear physics.

Responsible Physician or Lead Interpreting Physician means a physician designated by the licensee to be responsible for the overall quality assurance of the facility.

Screening Mammography means the periodic mammographic examination of asymptomatic women to detect unsuspected breast cancer in its earliest stage.

Source-image Receptor Distance (SID) means the distance from the source to the center of the input surface of the image receptor.

Stereotactic Breast Biopsy (SBB) means a mammography modality used to precisely identify and biopsy an abnormality within the breast.

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Transfer of Ownership means the following transfers:

- (1) A transfer of a majority interest in the ownership of a mammography facility;
- (2) In the case of a privately-held for profit corporation, transfer of a majority of any class of the stock thereof;
- (3) In the case of a partnership, transfer of a majority of the partnership interest;
- (4) In the case of a trust, change of the trustee or a majority of trustees; or,
- (5) In the case of a non-profit corporation, such changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control of the clinic.

Transfer of Ownership also means any change in the ownership interest or structure of the clinic or the clinic's organization or parent organization(s) that the Commissioner determines to effect a change in control of the operation of the clinic. A transfer of ownership shall also be deemed to have occurred where foreclosure proceedings have been instituted by a mortgagee in possession. The Commissioner may, in his or her discretion, determine a proposed transaction does not rise to the level of a transfer of ownership.

127.006: Compliance with Requirements

Unless otherwise provided, all mammography facilities licensed under 105 CMR 127.000 shall meet the requirements set forth in 105 CMR 127.000.

127.007: Compliance with Other Laws and Regulations

The mammography facility shall be in compliance with all applicable federal, state, and local laws and regulations pertaining to radiological services and screening mammography services, including:

- (1) Licensure or registration of supplier;
- (2) Licensure or registration of personnel;
- (3) Licensure or registration of equipment; and
- (4) Health and safety requirements.

127.008: Waiver

(A) The Commissioner or his or her designee may waive the applicability of one or more of the requirements imposed on the facility by 105 CMR 127.000 upon the finding that:

- (1) compliance would cause undue hardship to the facility;
- (2) the facility is in substantial compliance with the spirit of the requirement; and
- (3) the facility's non-compliance does not jeopardize the health or safety of its patients and does not limit the facility's capacity to provide the service.

(B) The facility shall provide the Commissioner or his or her designee written documentation supporting its request for a waiver.

127.010: Requirements of the Licensee

(A) Licensee Qualifications. A licensee is qualified to operate a mammography facility if he or she:

- (1) Is the owner of the mammography facility, and
- (2) Has demonstrated that the facility meets all applicable requirements of 105 CMR 127.000, and
- (3) Has demonstrated to the satisfaction of the Department that he or she is responsible and suitable to operate a mammography facility in compliance with applicable federal, state, and local laws and regulations. In determining whether an applicant is responsible and suitable to be granted a mammography facility license, the Department shall consider all relevant information including, but not limited to, the following:
  - (a) The proposed licensee's history of statutory and regulatory compliance for mammography facilities in Massachusetts. Assessment of this factor shall include the ability and willingness of the proposed licensee to take corrective action when notified by the Department of any regulatory violations;

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- (b) The proposed licensee's history of statutory and regulatory compliance for mammography facilities in other jurisdictions, including proceedings in which the proposed licensee was involved which resulted in or led to a limitation upon, suspension, revocation, or refusal to grant or renew a mammography facility license or certification for Medicaid or Medicare to the proposed licensee; and,
- (c) The history of criminal conduct of the proposed licensee and the mammography facility administrator, officers and directors as evidenced by criminal proceedings against those individuals which resulted in convictions, or guilty pleas, or pleas of *nolo contendere*, or admission of sufficient facts.
- (B) Licensee Duties. The licensee or applicant shall be responsible for insuring that:
- (1) The facility maintains adequate staffing to meet the health and safety needs of the patients including, but not be limited to:
    - (a) A qualified Responsible Physician designated to be responsible for patient services and the overall operation of the facility;
    - (b) A qualified Mammography Radiologic Technologist;
    - (c) A qualified Medical Physicist; and
    - (d) A qualified Interpreting Physician;
 each of whom meets the training and qualifications specified in 105 CMR 127.000.
  - (2) No individual operates or allows to be operated a radiation machine for mammography unless the individual meets the standards established by the Department.
  - (3) Radiation machines for mammography are specifically designed to perform mammography.
  - (4) The mammography facility allows inspection of its operation by the Department at any reasonable time and makes available to the Department at the time of inspection all records required pursuant to 105 CMR 127.000.
  - (5) A *Quality Assurance Procedures Manual* is developed and provided to all staff: Responsible and Interpreting Physicians, Mammography Radiologic Technologists and Medical Physicists.
  - (6) An annual review and updating of the *Quality Assurance Procedures Manual* is conducted and documented.
  - (7) All required training documents are maintained at the facility or are reasonably accessible.
  - (8) All mammographic x-ray machines are registered with the Radiation Control Program.
  - (9) All mammographic x-ray equipment has been inspected and quality assurance tests are performed as required by 105 CMR 127.019(C).
  - (10) Current Department licenses and certificates are prominently posted in the mammography facility: mammography facility license, certificate of inspection, and Mammography Radiologic Technologist license(s).
  - (11) Quality assurance test devices are provided at the facility.
    - (a) Each facility shall maintain on-site quality assurance test devices referenced in 105 CMR 127.019(C)(1), (2) and (4).
    - (b) The quality assurance test devices referenced in 105 CMR 127.019(C)(1) and (4) may be shared by and utilized at more than one facility.

127.011: Requirements of the Responsible Physician

- (A) Responsible Physician Qualifications A physician shall be qualified to be designated as a Responsible Physician if he or she holds a current Massachusetts license issued by the Board of Registration in Medicine and is in compliance with applicable regulations issued by the Board of Registration in Medicine, including 243 CMR 2.07(24)(g).
- (B) Responsible Physician Duties The Responsible Physician shall be responsible for:
- (1) Establishing and maintaining an ongoing quality assurance program in accordance with 105 CMR 127.018;
  - (2) Establishing a *Quality Assurance Procedures Manual* as specified in 105 CMR 127.018(B);
  - (3) Conducting and documenting an annual review of the *Quality Assurance Procedures Manual*;

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- (4) Ensuring that test equipment and materials as specified in the *Quality Assurance Procedures Manual* are available to perform quality control tests and to record and interpret results;
- (5) Ensuring that staffing and scheduling are arranged so that adequate time is available to perform quality assurance tests and to record and interpret results;
- (6) Ensuring that a designated individual oversees the radiation protection program for employees, patients, and other individuals in the surrounding area;
- (7) Ensuring that records concerning employee qualifications, mammography technique and procedures, quality assurance, safety, and protection are properly maintained and updated in the *Quality Assurance Procedures Manual*;
- (8) Evaluating the Mammography Radiologic Technologist's performance during the first three months of employment and annually thereafter;
- (9) Ensuring that:
  - (a) Mammography Radiologic Technologists meet mammography training and continuing education standards as defined in 105 CMR 127.012; and,
  - (b) A Mammography Radiologic Technologist is selected to be the quality assurance technologist, who is personally responsible for maintaining mammography quality and performing the quality assurance tests defined in 105 CMR 127.019(C)(1) through (4), and (10), the results of which are reviewed at least quarterly by the Responsible Physician;
- (10) Ensuring that:
  - (a) All Medical Physicists meet mammography training and education standards of 105 CMR 127.013;
  - (b) A designated Medical Physicist establishes and evaluates the equipment quality assurance program; and
  - (c) All Medical Physicist's reports and results are reviewed by the Responsible Physician within a reasonable time of completion of the tests however in any case no longer than 30 days of completion of the tests;
- (11) Ensuring that the Responsible Physician and Interpreting Physician meet mammography training and education standards outlined in 105 CMR 127.011 and 127.014;
- (12) Ensuring that an ongoing program to assess the quality of mammographic interpretation is implemented; and
- (13) Ensuring that the Interpreting Physician is complying with the reporting requirements of 105 CMR 127.020(B).

127.012: Requirements of the Mammography Radiologic Technologist

- (A) Mammography Radiologic Technologist Qualifications. A Mammography Radiologic Technologist is qualified to be employed in a mammography facility if he or she holds a current Massachusetts license in Radiography and Mammography issued under 105 CMR 125.000: *Licensing of Radiologic Technologists.*
- (B) Mammography Radiologic Technologist Duties. The Mammography Radiologic Technologist shall be responsible for:
  - (1) Prominently posting his or her license at the facility;
  - (2) Ensuring that the radiographs meet the technical and diagnostic quality standards of the Interpreting Physician;
  - (3) Performing mammographic duties in accordance with established policies specified in the *Quality Assurance Procedures Manual*; and
  - (4) Ensuring that safe operating conditions of the unit are maintained in accordance with the *Quality Assurance Procedure Manual.*
- (C) New Mammography Modality Training. Mammography Radiologic Technologists must complete eight hours of training in a mammography modality prior to independently performing mammography examinations using such a modality, unless he or she has been previously trained in that modality.
- (D) Required Examinations. Mammography Radiologic Technologists must perform at least 200 mammography examinations every 24 months. Mammography Radiologic Technologists who fail to perform the required number of examinations shall perform a minimum of 25 mammography examinations under direct supervision of a qualified Radiologic Technologist before resuming the performance of independent mammography examinations.

127.013: Requirements of the Medical Physicist

(A) Medical Physicist Initial Qualifications. A Medical Physicist is qualified to be employed in a mammography facility if he or she:

- (1) Is currently registered with the Department as a Medical Physicist; and
- (2) Is certified by one of the following:
  1. the American Board of Radiology in Diagnostic Radiological Physics, Diagnostic Medical Physics, Imaging Physics, or Radiological Physics;
  2. the American Board of Medical Physics in Diagnostic Radiological Physics, Diagnostic Medical Physics, Imaging Physics, or Radiological Physics; or
  3. another certifying body in an equivalent specialty area acceptable to the Department; and
- (3) Holds a master's degree or higher in a physical science with no less than 20 semester hours in physics. Appropriate fields include those physical sciences accepted by the American College of Radiology, American Board of Radiology, and the American Board of Medical Physics; and
- (4) Has 20 contact hours of specialized training in conducting mammography facility surveys; and
- (5) Has conducted surveys of at least one mammography facility and at least ten mammography units under the direct supervision of a qualified medical physicist.
- (6) If the Medical Physicist was qualified under the FDA interim regulations prior to April 28, 1999, the Medical Physicist may be considered qualified to be employed if the physicist:
  - (a) Has a bachelor's degree or higher in a physical science with no less than ten semester hours in physics;
  - (b) Has completed 40 contact hours of documented specialized training in conducting surveys of mammography facilities; and
  - (c) Has conducted surveys of at least one mammography facility and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement specified in 105 CMR 127.013(A)(6)(a).

(B) Medical Physicist Duties. The Medical Physicist shall be responsible for:

- (1) Ensuring that the equipment meets the standards set forth in 105 CMR 127.017;
- (2) Establishing and conducting the ongoing quality assurance program for the equipment as specified in 105 CMR 127.019(C); and
- (3) Verifying in writing that the mammography x-ray equipment is in safe operating condition and is being operated at optimum performance criteria to yield the highest quality mammograms:
  - (a) When the equipment is first installed;
  - (b) After any major changes or replacement of parts;
  - (c) At least annually during use; and
  - (d) When quality assurance tests indicate that calibration is needed.

(C) Medical Physicist Continuing Qualifications. To continue to be employed at a mammography facility, a Medical Physicist shall:

- (1) Have obtained or taught at least 15 hours of documented continuing medical education in mammography physics in the last three-year period;
- (2) Have surveyed at least two mammography facilities and at least six mammography units in the last two-year period; and
- (3) Maintain a valid Massachusetts registration.

(D) Medical Physicist Re-establishing Qualifications. Medical Physicists who fail to maintain the required continuing qualifications in 105 CMR 127.013(C) may not perform mammography surveys without the supervision of a qualified medical physicist. Before independently surveying a facility, the medical physicist must re-establish their qualifications, as follows:

- (1) Medical Physicists who fail to meet the continuing education requirements shall obtain a sufficient number of CEU's to bring their total up to the required 15 hours in the previous three years.
- (2) Medical Physicists who fail to survey enough facilities or units shall, under the direct supervision of a qualified medical physicist, complete a sufficient number of surveys so that they have surveyed at least two mammography facilities and six mammography units in the previous 24 months.

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(E) New Mammography Modality Training. Medical Physicists must receive at least eight hours of training in surveying units of the new mammographic modality.

127.014: Requirements of the Interpreting Physician

(A) Interpreting Physician Initial Qualifications. An Interpreting Physician is qualified to be employed in a mammography facility if he or she:

- (1) Is licensed to practice under M.G.L. c. 112, § 2;
- (2) Is in compliance with applicable regulations issued by the Board of Registration in Medicine including 243 CMR 2.07(24)(a) through (c).

(B) Interpreting Physician Duties. The Interpreting Physician shall be responsible for:

- (1) Ensuring that an ongoing program to assess the quality of mammographic interpretation is operating;
- (2) Complying with the reporting requirements of 105 CMR 127.020(B);
- (3) Providing a copy of the written report and the mammograms to the patient's mammography facility for inclusion in the patient's medical record;
- (4) Providing prompt feedback to the Mammography Radiologic Technologist on the quality of the mammograms received;
- (5) Providing prompt feedback to the Responsible Physician of any suboptimal quality of mammograms; and
- (6) Ensuring that he or she is readily available to the staff at the mammography facility.

(C) Continued Experience and Education. The interpreting physician shall interpret 960 mammographic examinations over a 24-month period, and shall take at least 15 hours of Category 1 CME in mammography in a 36-month period while performing the duties of an Interpreting Physician.

(D) New Mammographic Modalities. Before an Interpreting Physician may independently interpret mammograms produced by a new mammographic modality, *i.e.*, a mammographic modality in which the physician has not previously been trained, the Interpreting Physician shall have at least eight hours of training in the new mammographic modality.

(E) Re-establishing Qualifications. Interpreting Physicians who fail to maintain the required continuing experience or continuing education requirements shall re-establish their qualifications before resuming the independent interpretation of mammograms.

- (1) Interpreting Physicians who fail to meet the continuing experience requirements shall interpret or multi-read at least 240 mammographic examinations under the direct supervision of an Interpreting Physician, or interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an Interpreting Physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.
- (2) Interpreting Physicians who fail to meet the continuing education requirements shall obtain a sufficient number of additional Category I CME's in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

127.015: Physical Facility Requirements

(A) Each mammography facility shall:

- (1) Maintain its physical facilities in good repair in a safe, comfortable and sanitary state;
- (2) Provide adequate space and equipment for reception and waiting areas, for administrative and staff offices, and for storage of patient records;
- (3) Provide consultation, examination, and dressing areas appropriate to the services provided by the facility. Each facility shall furnish and arrange such areas in a manner that is consistent with their use and that safeguards the personal dignity and privacy (in terms of both sight and sound) of the patient during interview and examination;
- (4) Provide conveniently located hand washing and toilet facilities adequate for patient and personnel, as appropriate to the services provided at the facility. A hand washing facility shall be immediately available and convenient to each examination area for staff use;

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- (5) Provide secure/locked location not accessible to unauthorized persons for storage of reports and records;
- (6) Provide all rooms which do not have direct access to the outside, including toilets and utility areas, with satisfactory mechanical ventilation;
- (7) Be accessible to individuals with disabilities and comply with applicable federal, state, and local requirements for accessibility;
- (8) Maintain supplies and equipment appropriate in quantity and type to the specific services which the facility offers its patients;
- (9) Keep supplies and equipment safe, sanitary and in good working condition as necessary for the services offered by the facility;
- (10) Disinfect diagnostic and therapeutic equipment after each use in accordance with recognized standards of practice;
- (11) Establish and enforce a preventative maintenance program to ensure all equipment is in safe working order. A maintenance check shall be regularly performed on all mechanical and electronic medical equipment. Electrified equipment shall be properly grounded and calibrated consistent with manufacturer's recommendations; and
- (12) Develop and maintain a written fire safety plan and make a copy of this plan available to all staff members.

127.016: Optimum Exposure Ranges

For mammographic examination of a 4.5 centimeter (cm) thick, compressed breast, consisting of 50% glandular and 50% adipose tissue, the average glandular dose shall be no more than 3mGy as measured using mammography phantom accepted by the U.S. Food and Drug Administration.

127.017: Equipment Standards

- (A) Initial optimization of operating parameters shall be performed on all equipment used in producing mammograms. The process undertaken to perform the optimization and the results shall be documented.
- (B) The image acquisition and image receptor systems and their individual components shall be specifically designed for digital mammography.
- (C) The x-ray system must have the capability of providing kilovolt peak (kVp)/target/filter combinations appropriate to image receptor systems meeting the requirements of 105 CMR 127.017(B).
- (D) The x-ray machine shall be equipped with the following:
  - (1) a means of immobilizing and compressing the breast so that a constant force of a minimum of 25 to a maximum of 45 pounds is achievable; and
  - (2) a means of maintaining this compression throughout the period of exposure.
- (E) A mammographic x-ray unit shall have automatic exposure control.
- (F) X-ray systems shall indicate, or provide the means of determining, the milliamperes-seconds (mAs) resulting from each exposure made with automatic exposure control for new units installed after 1994.
- (G) Special Attachments for Mammography. When special attachments for mammography are in service, the x-ray system upon which they are used shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than one percent of the SID. This evaluation shall be performed at the maximum SID.

127.018: Quality Assurance Program

- (A) General Provisions. The quality assurance program must include the following:
- (1) The Responsible Physician of each facility in which mammographic x-ray procedures are performed shall establish and maintain an ongoing quality assurance program specific to mammographic imaging, covering all components of the mammography facility, to ensure consistently high-quality images with minimum patient exposure.
  - (2) The Responsible Physician shall conduct a review, at least annually, of the effectiveness of the quality assurance program and maintain a written report of such review. The most recent copy of such reports shall be available for inspection by Department inspectors at the machine use location.
  - (3) The Medical Physicist has the responsibility for establishing and conducting the ongoing equipment quality assurance program, as specified in 105 CMR 127.019(C), including:
    - (a) Conducting the initial setup optimization procedures on all the equipment used in producing mammograms prior to use on patients;
    - (b) Conducting or training others to conduct equipment performance monitoring functions;
    - (c) Conducting or training others to perform the analysis of the monitoring results to determine if there are problems requiring correction; and
    - (d) Carrying out or arranging for the necessary corrective actions, prior to continuing mammographic operations, when quality assurance test results indicate the need.
  - (4) The Medical Physicist shall routinely perform the equipment quality assurance measurements, when equipment is initially installed, after major changes or replacement of parts, and according to the frequency specified in 105 CMR 127.019.
  - (5) The licensee is responsible for ensuring that the mammographic x-ray equipment under his or her jurisdiction has been inspected and that quality assurance tests are performed by an individual as indicated:
    - (a) Quality assurance tests outlined in 105 CMR 127.019(C) may be performed by a Medical Physicist;
    - (b) Quality assurance tests outlined in 105 CMR 127.019(C)(1) through (4) and (10) may be performed by a licensed Mammography Radiologic Technologist.
  - (6) Any individual who performs the quality assurance tests required in 105 CMR 127.019(C) shall verify in writing that the mammographic x-ray equipment is in safe operating condition, and is being operated at optimum performance criteria to yield the optimal quality mammogram that is adequate for clinical requirements:
    - (a) Prior to initial use of the equipment; and
    - (b) At least yearly after the initial verification.
- (B) Quality Assurance Procedures Manual. Each mammography x-ray facility shall have a *Quality Assurance Procedures Manual*. The *Quality Assurance Procedures Manual* shall include at least the following:
- (1) List of names and qualifications of individuals responsible for:
    - (a) Supervision;
    - (b) Performance of each of the quality assurance tests; and
    - (c) Repairing or servicing of mammographic x-ray equipment.
  - (2) Control limits or parameters of acceptability for each quality assurance test.
  - (3) Brief description of the quality assurance tests to be performed.
  - (4) Frequency of each quality assurance test.
  - (5) Forms to be used for each quality assurance test.
  - (6) A protocol for correcting each quality assurance finding that does not fall within the acceptable limits as specified in 105 CMR 127.017.
  - (7) A list of equipment to be used for performing quality assurance tests.

127.019: Equipment Quality Assurance

- (A) Quality Assurance Records for Mammography X-ray Equipment.
- (1) Records of all quality assurance tests shall be maintained for mammographic x-ray equipment and shall include at least the following:
    - (a) The mammographic x-ray equipment performance evaluation and optimization, including initial acceptance testing (to be completed before patients are exposed with the machine) and subsequent evaluations and testing;

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- (b) Verification that mammographic x-ray equipment is in safe operating order;
  - (c) Subsequent quality assurance test results;
  - (d) Notes regarding changes in operating conditions shall be recorded on the appropriate control charts;
  - (e) Operating levels and control limits for all quality assurance tests shall be indicated on the appropriate control chart;
  - (f) All records shall bear the date the procedure was done and the initials or name of the individual performing the test;
  - (g) Quality assurance tests on the Radiologist workstation monitors shall be done in accordance with manufacturer's requirements;
  - (h) Quality assurance tests on laser hardcopy printers shall be done in accordance with manufacturer's requirements.
- (2) Records or written logs of maintenance and/or repairs of mammographic x-ray equipment shall be kept for at least three years. All records for a machine shall be kept in a single file at the machine use location. Repair records shall be referenced to quality assurance test results, if applicable.
- (3) All quality assurance records shall be maintained for a minimum of 24 months and readily available at the use location for review by representatives of the Department.

(B) Quality Assurance Records and Requirements for Test Equipment and Mammography Systems.

- (1) The quality assurance test equipment shall be in good operating order.
- (2) Records of each repair and/or calibration of quality assurance test equipment shall include the date of repair and/or calibration.
- (3) Records of each repair and/or calibration of quality assurance test equipment shall be kept for at least three years.
- (4) Quality assurance tests shall be performed in accordance with manufacturers' recommendations after the repair and/or replacement of any component of the mammographic x-ray system, prior to using the equipment.

(C) Quality Assurance Tests for Equipment.

- (1) Laser Hardcopy Printer. Quality assurance tests for laser printers, if used by the mammography facility for clinical diagnosis, shall be performed in accordance with the manufacturer's recommendations.
- (2) Mammography Phantom.
  - (a) Quality assurance tests for image quality in fixed mammography facilities shall be performed weekly.
  - (b) Quality assurance tests for image quality in mobile mammography facilities shall be performed each time the machine has been moved, before beginning examinations of patient at least weekly.
  - (c) Each facility shall utilize a mammography phantom approved or accepted by ACR for performing quality assurance tests for image quality. The following image quality requirements shall be met, for different mammography modalities:
    - 1. For Digital Mammography, manufacturer's specifications or specifications stated in the *2016 ACR Digital Mammography Quality Control Manual*, or its revisions.
    - 2. For Digital Breast Tomosynthesis, manufacturer's specifications.
    - 3. For stereotactic breast biopsy, manufacturer's specifications or specifications stated in the *1999 ACR Stereotactic Breast Biopsy Quality Control Manual*, or its revisions.
  - (d) Each facility shall take corrective action in the event that quality assurance tests for image quality do not meet the requirements in 105 CMR 127.019(C)(2)(c).
- (3) Retake Analysis.
  - (a) Quality assurance tests for retake analysis shall be performed as specified by the mammography system manufacturer or at least quarterly.
  - (b) The test tools for performing quality assurance tests on retake analysis are records of rejected images.
  - (c) When performing quality assurance tests for retake analysis, the total number of images and the total number of rejected images used during the test period shall be evaluated for ascertaining the reason for rejection. The rejected images shall be identified in at least the following categories:

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1. Technique;
  2. Motion;
  3. Positioning error;
  4. Digital imaging processing; and
  5. Clinically significant artifacts (dead pixel clusters on digital detector arrays, shifts of masked spots, *etc.*).
- (4) Compression in the Manual and/or Power Modes
- (a) Quality assurance tests for compression in the manual and/or power modes in fixed mammography facilities shall be performed semi-annually.
  - (b) Quality assurance tests for compression in the manual and/or power modes in mobile mammography facilities shall be performed each time the machine has been moved, but not less than semi-annually.
  - (c) Each facility shall use a push-pull force gauge or a flat bathroom type scale method with accuracy of  $\pm 2\%$  of full scale for performing quality assurance tests.
  - (d) When performing the quality assurance test for compression, the maximum compression force shall range from a minimum of 25 to a maximum of 45 pounds in both the manual and power drive modes and shall remain consistent throughout the period of exposure. The compression release mechanism shall be tested at the same interval.
- (5) Automatic Exposure Control.
- (a) Quality assurance tests for automatic exposure control (phototiming) at fixed mammography facilities shall be performed at least annually.
  - (b) Quality assurance tests for automatic exposure control (phototiming) at mobile mammography facilities shall be performed at least semi-annually.
- (6) Kilovolt Peak (kVp) Accuracy.
- (a) Quality assurance tests for kVp accuracy at fixed mammography facilities shall be performed at least annually.
  - (b) Quality assurance tests for kVp accuracy at mobile mammography facilities shall be performed at least semi-annually.
  - (c) Each facility shall use a non-invasive kVp meter with appropriate calibration procedures or an oscilloscope and voltage divider network to perform quality assurance tests.
  - (d) When performing quality assurance tests for kVp accuracy, the actual (measured) versus indicated kVp shall be maintained as specified by the x-ray equipment manufacturer, but shall not vary from the indicated kVp by greater than 5% from the indicated.
- (7) Glandular Tissue Dose.
- (a) Quality assurance tests for glandular tissue dose at fixed mammography facilities shall be performed at least annually.
  - (b) Quality assurance tests for glandular tissue dose at mobile mammography facilities shall be performed at least semi-annually.
  - (c) Each facility shall use an ion chamber or solid state detector calibrated at the energy ranges used in mammography for performing quality assurance tests.
  - (d) When performing quality assurance tests for glandular tissue dose, the technique setting shall be those used for imaging a 4.5 cm compressed breast in the cranio-caudal projection and the measurement point shall be 4.5 cm from the surface of the breast support as appropriate.
  - (e) For mammographic examination of a 4.5 centimeter (cm) thick, compressed breast, consisting of 50% glandular and 50% adipose tissue, the average glandular dose shall be no more than 3 mGy per view.
- (8) Spatial Resolution.
- (a) Quality assurance tests for spatial resolution at fixed mammography facilities shall be performed at least annually.
  - (b) Quality assurance tests for spatial resolution at mobile mammography facilities shall be performed at least semi-annually.
- (9) Half-value Layer (HVL)
- (a) Quality assurance tests for half-value layer at fixed mammography facilities shall be performed at least annually.
  - (b) Quality assurance tests for half-value layer at mobile mammography facilities shall be performed at least semi-annually.

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- (c) When performing quality assurance tests for half-value layer, the HVL shall be measured with the mammography x-ray unit's compression paddle in place over the ionization chamber or solid state detector.
- (10) All mammography facilities shall follow the manufacturer's recommendations or the *ACR Digital Mammography QC Manual* for quality control of all components used for digital image acquisition, digital image processing and digital image display.

127.020: Clinical Quality Assurance/Recordkeeping

(A) Responsible Physician Reports: The Responsible Physician, or his or her designee, shall maintain a recordkeeping system for each patient, with a record of the mammography services the facility provides, including:

- (1) The date the mammography procedure was performed;
- (2) The name, address, and date of birth of the patient;
- (3) A description of the procedures performed;
- (4) The name and business address of the referring physician or other person to whom mammogram(s) (images) are loaned or otherwise transferred on a temporary basis; the date the mammograms are sent; and the date the mammograms are expected to be retrieved by the mammography facility.

(B) Interpreting Physician Reports: The Interpreting Physician shall:

- (1) Review the patient's previous mammograms, when available, in the process of interpreting the current mammogram(s);
- (2) Prepare and sign a written report on his or her interpretation of the mammogram(s);
- (3) Provide a copy of the written report and the images to the patient's mammography facility for inclusion in the patient's medical record;
- (4) Provide a written statement to the patient, either through a referring physician or his or her designate, or, if a referring physician is not available, directly to the patient, by mail, secure electronic submission, or secure web-based access. This statement:
  - (a) Shall be written in clear plain language that a lay person can understand. The facility shall use reasonable means to communicate the required information to patients who are not proficient in reading English or are blind or visually impaired.
  - (b) Shall describe the test results and the importance of mammography to the patient's ongoing health (including, if her results suggest other than routine mammographic follow-up, a description of the next steps), as well as the patient's responsibility to share with any new physician or facility performing her next mammography procedure the date and place of her previous mammography procedure;
  - (c) Shall record the following information:
    1. Date of the procedure;
    2. Name and address of the facility providing the procedure;
    3. Name of the physician (if any) to whom the patient wants a copy to be sent; and
    4. Indication that images are being provided to the mammography facility for inclusion in the patient's medical record.
- (5) Communicate all reports that suggest other than routine mammographic follow-up to the patient and/or the referring physician or his or her designated representative by telephone, certified mail, or other means of communication in such a manner that receipt is assured and documented;
- (6) Provide written notification to a patient if an interpreting physician determines, based on standards set by the American College of Radiology, that the patient has dense breast tissue. This written notification shall be in terms easily understood by a lay person and include, at a minimum, the following information:
  - (a) That the patient's mammogram shows dense breast tissue;
  - (b) That the degree of density is apparent and an explanation of that degree of density;
  - (c) That dense breast tissue is common and not abnormal but that dense breast tissue may increase the risk of breast cancer;
  - (d) That dense breast tissue can make it more difficult to find cancer on a mammogram and that additional testing may be needed for reliable breast cancer screening;

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- (e) That additional screening may be advisable and that the patient should discuss the results of the mammogram with the patient's referring physician or primary care physician;
  - (f) That the patient has the right to discuss the results of the patient's mammogram with the interpreting radiologist or the referring physician;
  - (g) That a report of the patient's mammogram has been sent to the referring physician and will become part of the patient's medical record; and
  - (h) Where the patient can find additional information about dense breast tissue.
- (C) Health Questionnaire. Before the initial procedure at the facility, the patient shall fill out a health questionnaire specific to breast cancer risk factors. The questionnaire shall be placed in the patient's medical record at the facility. The questionnaire shall require information on at least the following:
- (1) Past history of breast cancer;
  - (2) Family history of breast cancer;
  - (3) Age of onset of menses and menopause;
  - (4) Hormones;
  - (5) Surgery;
  - (6) Time and place of previous mammogram; and
  - (7) Child bearing history.
- (D) Record Management.
- (1) The facility shall develop and implement policies and procedures for record management.
  - (2) All mammograms (images), reports and other related patient medical records are confidential and shall not be disclosed without the written authorization of the patient or his or her representative except in response to a court order.
- (E) Record Retention.
- (1) All records required under 105 CMR 127.020(A) and (B) must be retained in the patient's permanent medical records at the mammography facility for a period of ten years following the date of service or, for hospitals and clinics, the records retention period specifies in M.G.L. c. 111, § 70; or
  - (2) Until such time as the patient should request that the patient's medical records be forwarded to a medical institution or a healthcare provider designated by the patient; and,
  - (3) If the facility should cease to operate before the end of the ten year period, the records must be retained in a manner which provides security and which permits former patients or their healthcare provider access to them for the remainder of the ten year period.

127.021: Patient Protection

- (A) Rights of Patients.
- (1) Each mammography facility shall protect patients' rights and shall develop a patients' rights statement ensuring that each patient shall:
    - (a) Be treated with dignity and respect;
    - (b) Be informed, at the time of scheduling the appointment, that the patient should either arrange for the patient's most recent prior mammogram (images) to be sent to the facility before the appointment, or bring it to the facility at the time of the appointment;
    - (c) Not be denied service or otherwise discriminated against solely because the patient is self-referred;
    - (d) Be provided with an opportunity, upon request, to discuss any radiation safety concerns with the Responsible Physician and/or the Mammography Radiologic Technologist before undergoing a mammography examination at the facility;
    - (e) Be informed, upon request, of the proposed or actual glandular dose of radiation;
    - (f) Receive a written statement describing the test results and, if results suggest other than routine mammographic follow-up, the next steps for the patient to pursue promptly after undergoing a mammogram at the facility;
    - (g) Be informed of the patient's right to discuss the results of the mammogram with the Responsible or Interpreting Physician;

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- (h) Be entitled to inspect and copy the patient's medical record, upon request, during normal business hours at the facility;
  - (i) Be entitled, upon request, to receive the images; and
  - (j) Be provided with the name and address and telephone number of the Radiation Control Program as the agency to which complaints can be made.
- (2) Each mammography facility shall have visibly posted a notice which has the heading "NOTICE OF PATIENTS' RIGHTS" and which contain all the rights provided by 105 CMR 127.021(A)(1). The notice shall be posted in at least one central area where all patients are likely to see it. In addition, each patient, upon request to the mammography facility, shall be given a written document containing all the rights provided by 105 CMR 127.021(A)(1).

(B) Educational Materials. The mammography facility shall have available educational material for each patient.

(C) The patients' rights statement and educational materials shall be written in clear plain language that a lay person can understand. The facility shall use reasonable means to communicate the required information to patients who are not proficient in reading English or are blind or visually impaired.

127.022: Licensure

(A) No person shall maintain or operate a mammography facility unless he or she is the holder of a valid license granted by the Department.

(B) The Department shall issue two types of licenses to operate mammography facilities in the Commonwealth. The types of licenses shall be known as "Full" and "Provisional."

(1) Full License:

(a) A full license shall be issued to any facility that has been determined to meet all of the requirements of 105 CMR 127.000.

(b) A full license is valid for a period not to exceed 12 months.

(2) Provisional License:

(a) A provisional license may be issued to a facility as an interim measure if the Department determines that the facility does not meet, but is in substantial compliance with, all requirements for a full license; provided that the facility has demonstrated to the Department's satisfaction the capability to correct deficiencies and conform to all requirements; provided further that the Department finds that the facility provides satisfactory mammography services and presents satisfactory evidence that the requirements for full licensure can and will be met within a reasonable period not to exceed a six-month period.

(b) In order to be issued a provisional license, the applicant shall submit, on a form prescribed by the Department, a written plan for meeting the appropriate requirements and the plan must be approved by the Department.

(c) A provisional license is valid for a period not to exceed six months and may be renewed once for no more than six months.

(d) The Department may incorporate in the license at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession and use of the license to operate a mammography facility as it deems appropriate or necessary.

(C) Each mammography facility's license shall be displayed in a conspicuous place in the mammography facility so as to be clearly visible to the patients.

127.023: Application for a License

Mammography facilities shall apply for a license to operate the facility issued pursuant to M.G.L. c. 111 § 5Q.

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(A) Applications for licensure shall be made on forms prescribed by and available from the Department. Each applicant shall submit all the information required by the form and the accompanying instructions. The term "application" as used herein shall include original and renewal applications.

(B) The applicant shall provide at least the following information in order to be issued a license to operate a mammography facility:

(1) Name, address and telephone number of the following:

(a) The mammography facility; and,

(b) The prospective licensee of the mammography facility, including a statement of ownership of the facility that discloses the name and addresses of all owners or in the case of a corporation, the officers;

(2) The manufacturer, model number, model year, serial number (if available) and type of each mammography machine located within the facility;

(3) The geographic areas to be serviced, if the facility is mobile;

(4) The name and address of the mammography machine supplier, installer, date of installation of each mammography machine, and service agent; and

(5) A signed and dated certification that the applicant has read, understood, and complies with the requirements of 105 CMR 127.000.

(C) Each applicant shall provide such additional information as the Department may reasonably require.

(D) Each applicant shall submit with his or her application for a license a check payable to the Commonwealth of Massachusetts. The fee for a license is specified in 801 CMR 4.00: *Rates*.

127.024: Application for Renewal of a License

(A) An applicant for license renewal must submit completed application forms and a check payable to the Commonwealth of Massachusetts to the Department no later than 60 days prior to the expiration of the current license, whereupon the licensee's existing license shall not expire until the renewal application status has been finally determined by the Department. The fee for a license renewal is specified in 801 CMR 4.00: *Rates*.

(B) A license to operate a mammography facility shall not be renewed if there are any outstanding civil penalties issued pursuant to M.G.L. c. 111, § 5O and 105 CMR 127.000.

127.025: Acceptance of Application

The Department shall not accept an application for an original or renewal license unless:

(A) The application includes all information required by the Department;

(B) The application and all required attachments and statements submitted by the applicant meet the requirements of 105 CMR 127.000; and,

(C) The applicant has paid all required fees.

127.026: Processing of Applications

(A) The Department will process applications for original licensure upon receipt of the completed forms and fees required. A license shall be issued to those applicants meeting all the requirements of 105 CMR 127.000.

(B) The Department will process renewal licenses upon receipt of the applicant's submission of completed forms. A renewal application shall be submitted at least 60 days prior to expiration. In the event that the Department is unable to act on a timely submitted renewal application prior to license expiration, the mammography facility may continue to operate until the Department takes action on the application. If, however, an application for renewal is not submitted within 60 days of expiration of the current license, then the license shall automatically expire and the mammography facility may not continue to operate without written permission by the Department.

127.027: Non-transferability of License

No license shall be transferable from one person to another or from one mammography facility or location to another.

127.028: Change of Name, Ownership or Location

(A) The licensee shall notify the Department immediately, and in writing, of any proposed change in location, name or ownership of the mammography facility.

(B) A licensee who intends to change the location of a mammography facility shall submit a completed application for licensure at the new site at least 30 days prior to the intended date of relocation.

(C) Within 48 hours of a change in ownership, the new owner(s) of the mammography facility shall file an application for licensure. This application shall have the effect of a provisional license until such time as the Department acts upon the application.

(D) In the case of the transfer of ownership of a mammography facility, the application of the new owner for a license shall not have the effect of a provisional license when the application is not filed within 48 hours of a change of ownership or is not in accordance with 105 CMR 127.023.

(E) Any notice of hearing, order or decision which the Department or the Commissioner issues for a mammography facility prior to a transfer of ownership shall be effective against the former owner prior to such transfer and, where appropriate, the new owner, following such transfer unless said notice, order or decision is modified or dismissed by the Department or by the Commissioner.

127.029: Collection and Updating of Information

(A) Each mammography facility shall file with the Department such data, statistics, schedules or information as the Department may require for the purposes of licensing and/or monitoring and evaluating the facility.

(B) All information submitted under the requirements of 105 CMR 127.000 or otherwise required by the Department shall be kept current by each licensee. Any document which amends, supplements, updates or otherwise alters a required document must be filed with the Department within 30 days of the change.

(C) Ownership and control information submitted under the requirements of 105 CMR 127.000 or otherwise required by the Department shall be kept current by each licensee. Any document which amends, supplements, updates or otherwise alters any ownership and control document required to be filed shall be filed with the Department within 30 days of the execution thereof.

(D) The licensee shall notify the Department in writing immediately but in any event no later than within 30 days of the initiation of any legal or disciplinary action or proceeding against the licensee or any person employed by the facility by any other licensing jurisdiction (State, United States or foreign), any health care institution, any professional society or association, any government agency, any law enforcement agency or any court for acts or conduct which would constitute grounds for suspension, denial, modification, limitation, revocation or refusal to renew a license under 105 CMR 127.000, *see* 105 CMR 127.035 or 127.036 (A), or which would in any way relate directly or indirectly to his or her fitness to be licensed under 105 CMR 127.000, to the care of patients at the facility, or to the continued operation of the facility.

127.030: Inspection

(A) Authorized personnel of the Department shall be permitted to inspect mammography facilities at any reasonable time without prior notice. All parts of the mammography facility, all staff, all activities, all equipment, all supplies and all records are subject to inspection.

(B) The Department shall inspect each mammography facility annually.

127.031: Reports to the Board of Registration in Medicine

Whenever the Department finds that a physician is practicing in violation of the requirements of M.G.L. c. 112 § 5 and 243 CMR 2.07(24): *Standards for Reading and Interpreting Mammography* regarding the reading and/or interpretation of mammography, the Department shall forthwith provide written notification to the Board of Registration in Medicine. In the case where the Interpreting Physician is practicing out of the State, this notification shall be made to the appropriate agency within the state in which the physician is licensed.

127.032: Certificate of Inspection

(A) No person shall operate a mammography facility unless licensed to do so and unless a certificate of inspection has been issued by the Department.

(B) Prior to issuing or renewing a license, the Department shall inspect each mammography facility for which application is made.

(C) A certificate of inspection shall be issued by the Department only if the mammography facility is found to be in substantial compliance with 105 CMR 127.000.

(D) No certificate of inspection shall continue in force after the expiration of the license under which it is issued.

(E) No certificate of inspection shall continue in force after the Department has suspended, revoked or refused to renew the license under which it is issued.

(F) No certificate of inspection shall be valid for any building premise other than for those for which the certificate was originally issued.

(G) Each licensee issued a certificate of inspection by the Department shall display the certificate on or near the mammography unit in full public view.

127.033: Complaints

The Department shall investigate every complaint received about practices or acts which may violate M.G.L. c. 111, §§ 5N through 5Q or any provision of 105 CMR 127.000.

(A) If the Department finds that an investigation is not required because the alleged act or practice is not in violation of M.G.L. c. 111, §§ 5N through 5Q or 105 CMR 127.000, the Department shall notify the complainant of this finding and the reasons on which it is based.

(B) If the Department finds that an investigation is required, because the alleged act or practice may be in violation of M.G.L. c. 111, §§ 5N through 5Q or 105 CMR 127.000, the Department shall investigate and if a finding is made that the act or practice is in violation of M.G.L. c. 111, §§ 5N through 5Q or 105 CMR 127.000, then the Department may apply whichever enforcement procedure as provided in 105 CMR 127.000 is appropriate to remedying the situation and the Department shall notify the complainant of its action in this matter.

(C) Investigation of complaints may lead to enforcement actions including an order to cease an activity; denial, revocation, suspension or refusal to renew a license registration or certificate; modification or limitation of a license by the Department; and/or imposition of civil or criminal penalties.

(D) All oral or written complaints about mammography facilities shall be addressed to the Complaint Specialist, Radiation Control Program.

127.034: Availability of Reports; Disclosure of Information

(A) Disclosure of Information While Investigation Is Pending. Upon request by any person, the Department shall provide the following information about a complaint pending investigation.

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- (1) The date on which Department staff received the complaint;
  - (2) The estimated date on which the Department expects to complete its investigation and issue the final complaint investigation report; and,
  - (3) Information about any actions taken by the Department to protect and ensure the health and safety of patients, employees or the public.
- (B) Availability of Final Complaint Investigation Report. Upon written request, a copy of the final complaint investigation report containing the Department's findings and recommendations may be made available, however, any materials or data which would permit identification of the reporting individual, a patient or any person whose right of privacy pursuant to M.G.L. c. 66A would be abridged by the disclosure, shall be redacted from the copy of the final complaint investigation report.

127.035: Grounds for Suspension of a License or Immediate Cessation of Activity

In accordance with M.G.L. c. 111, § 5O, the Commissioner may summarily suspend a license or order immediate cessation of an activity, pending a hearing, whenever the Commissioner finds that public health, safety or the environment would be threatened by delay in issuance of an order. A mammography facility may not operate during the period of a suspension of its license or conduct a prohibited activity after notification of an order of immediate cessation of said activity.

127.036: Grounds for Denial, Modification, Limitation, Revocation or Refusal to Renew a License

- (A) Specific Grounds. The Department may issue an order denying, revoking, modifying, limiting, or refusing to renew a license sought or issued under 105 CMR 127.000 for any one of the following reasons:
- (1) The applicant or licensee failed to submit the information required for licensure under 105 CMR 127.000.
  - (2) The applicant failed to meet the requirements for licensure as specified in M.G.L. c. 111, § 5Q and/or 105 CMR 127.000.
  - (3) The applicant or licensee is not suitable and responsible to operate a mammography facility.
  - (4) The applicant or licensee obtained or attempted to obtain or maintain a license by fraud, misrepresentation, or by the submission of incorrect, false or misleading information.
  - (5) The applicant or licensee failed to pay licensure and/or registration fees.
  - (6) The applicant or licensee failed to pay civil penalties or criminal fines levied in accordance with of M.G.L. c. 111, § 5P or 5O and/or 105 CMR 127.000.
  - (7) (a) The applicant or licensee failed to allow duly authorized agents of the Department to conduct inspections.  
 (b) The applicant or licensee attempted to impede the work of duly authorized representatives of the Department or the enforcement of any provisions of M.G.L. c. 111, §§ 5N through 5Q or 105 CMR 127.000.
  - (8) The facility has been denied a certificate of inspection by the Department.
  - (9) The applicant or licensee has been convicted of, pleaded guilty to, or has, in a judicial proceeding, admitted facts sufficient for a finding that he or she is guilty of, any criminal violation relating directly or indirectly to his or her fitness to be licensed under 105 CMR 127.000 including, but not limited to:
    - (a) Medicare or Medicaid fraud;
    - (b) a crime relating to the operation of mammography services;
    - (c) rape, assault or other violent crimes against persons; and
    - (d) a drug related crime.
  - (10) A mammography facility owned or operated by the applicant or licensee has been the subject of proceedings which resulted in the suspension, denial, modification, limitation, or revocation of the license or refusal of renewal of the license or has been the subject of proceedings which resulted in the denial, cancellation, or revocation of the Medicaid/Medicare certification of the facility.

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- (11) A mammography facility owned or operated by the applicant or licensee has been the subject of proceedings which were ultimately resolved by settlement agreement but which were initiated to suspend, deny, modify, limit, or revoke or refuse renewal of a license or to deny, cancel, or revoke the Medicaid/Medicare certification of the facility.
- (12) (a) The applicant or licensee has been disciplined in another jurisdiction in any way by a licensing authority for reasons substantially the same as those set forth herein.  
 (b) The applicant or licensee failed to report to the Department, within the time period provided by law or regulation, any legal or disciplinary action or proceeding initiated against the licensee or any person employed by the facility by another licensing jurisdiction (United States or foreign), any health care institution, any professional society or association, any government agency, any law enforcement agency, or any court for acts or conduct substantially the same as acts or conduct which would constitute grounds for suspension, denial, modification, limitation, revocation or refusal to renew a license under 105 CMR 127.000, *see* 105 CMR 127.035 and 127.036(A), or which would in any way relate directly or indirectly to his or her fitness to be licensed under 105 CMR 127.000, to the care of patients at the facility, or to the continued operation of the facility.
- (13) The applicant or licensee operated a mammography facility after the expiration of the license.
- (14) The applicant or licensee failed to remedy or correct a cited violation by the date specified in the written notice from the Department under M.G.L. c. 111, § 5O or by the date specified in the plan of correction accepted or modified by the Department, unless the applicant or licensee demonstrates to the satisfaction of the Department that such failure was not due to neglect of duty and occurred despite his or her good faith attempt to make corrections by the specified time.
- (15) The applicant or licensee engaged in or aided in the falsification of mammography results including, but not limited to, the reporting of such false results to any patient.
- (16) The applicant or licensee operated or maintained a mammography facility in a manner which endangers public health, safety, or the environment.

(B) Other Grounds. Nothing herein shall limit the Department's adoption of policies and grounds for discipline through adjudication as well as through rule-making.

#### 127.037: Enforcement Procedures

(A) Notice of Violation. Whenever the Department finds upon inspection, investigation of a complaint or through information in its possession that an applicant or licensee is not in compliance with provisions of M.G.L. c. 111, §§ 5N through 5Q or a regulation promulgated thereunder, the Department shall notify the applicant or licensee of such violation or deficiency. The notice shall include a statement of the violations or deficiencies found, the provision of the law relied upon, and a reasonable period of time for correction. A violation or deficiency may result in denial, suspension, revocation or refusal to renew a license or certificate of inspection; a modification or limitation of a license; a cease and desist order; and/or the imposition of a civil penalty and/or criminal sanctions.

(B) Plan of Correction.

- (1) The applicant or licensee shall within ten days of receipt of the notice, file with the Department a written plan of correction. The plan shall clearly identify the licensee, state the date, reference the violation or deficiency cited, state specific corrective action(s) and timetable(s) and date(s) for completion for each deficiency cited, and shall be signed by either the applicant or licensee or his or her designee.
- (2) The Department may reinspect a facility in order to determine whether the corrections have been made. If upon review of plan of correction and/or reinspection the Department finds that the applicant or licensee is in compliance with 105 CMR 127.000 and/or that the applicant or licensee has submitted an acceptable plan of correction, the Department shall notify the applicant or licensee of its findings of compliance and/or its acceptance or modification of the plan of correction.

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(3) If upon review of plan of correction and/or reinspection the Department finds the plan of correction is unacceptable, the Department may request that the applicant or licensee amend and resubmit the plan of correction with five days of the date of notice or such other time as the Department may specify for resubmission.

(4) If upon review of the plan of correction and/or reinspection the Department determines that an applicant or licensee remains noncompliant with applicable laws and regulations regarding licensure, the Department may initiate enforcement procedures as set forth in 105 CMR 128.037(C).

(C) Notice of Department's Intent to Issue an Order.

(1) Prior to the Department issuing an order to modify, limit, deny, revoke or refuse to renew a license, and/or to require a person to cease and desist any activity, and/or to impose civil penalties, the applicant or licensee shall be notified in writing of the grounds for the Department's action, the provision(s) of law relied upon, the amount of any civil penalty, and his or her right to request an adjudicatory proceeding and/or judicial review.

(2) If a license is to be denied, modified, limited, revoked or refused renewal or if an activity is to be ceased or a civil penalty imposed by the Department, then the aggrieved applicant or licensee may request an adjudicatory hearing within 21 days of receipt of notification of the Department's Intent to Issue an Order. Said request shall be filed in accordance with Standard Adjudicatory Rules of Practice and Procedures, 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

(D) Administrative Hearings: Procedure.

(1) Suspension of a License or Immediate Cessation of Activity.

(a) The Department shall give the licensee written notice stating the reason(s) for the suspension or immediate cessation of an activity and the provisions of law relied upon. The suspension or order of immediate cessation of an activity shall take effect immediately upon issuance of the notice.

(b) The Department shall provide for a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures* promptly after the issuance of an order of suspension or order of immediate cessation of an activity.

(c) In cases of suspension of a license or immediate cessation of an activity, the Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that there existed, immediately prior to or at the time of the suspension or cease and desist order, a threat to public health, safety or the environment.

(d) In the event that the Department determines that the violation of state law or of 105 CMR 127.000 which posed a threat is corrected prior to the decision of the Hearing Officer, the Department may lift the suspension by giving written notice to the mammography facility.

(2) Denial, Modification, Limitation, Revocation, or Refusal to Renew a License Based on Failure to File Reports or Pay Fees or Maintain Insurance. No hearing shall be afforded where denial, modification, limitation, revocation, suspension or refusal to renew is based solely upon failure of the licensee to file timely reports, schedules or applications or to pay lawfully proscribed fees, or to maintain insurance coverage as required by any law or regulation. M.G.L. c. 30A, § 13(3).

(3) Denial, Modification, Limitation, Revocation or Refusal to Renew a License; Orders to Cease an Activity; Civil Penalties.

(a) All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

(b) Except for circumstances specified in 105 CMR 127.037(D)(2), if the Department determines that a license should be denied, modified, limited, revoked, or refused renewal, and/or that a mammography facility should cease an activity, and/or that a civil penalty should be imposed, and if the Department notifies the applicant or licensee of its intended action, upon receipt of a Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

(c) The Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that the license should be denied, modified, limited, revoked or refused renewal; that an activity should be ceased; and/or that a civil penalty be imposed based on relevant facts as they existed at or prior to the time the Department initiated the hearing procedure.

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- (d) If the Hearing Officer finds any single ground for denial, modification, limitation, revocation, suspension, or refusal to renew a license; for a cessation of an activity; and/or for imposition of a civil penalty, then the Hearing Officer shall render a recommended decision affirming the issuance of the Department's Order.
- (4) Final Agency Decision and Judicial Review.
- (a) The recommended decision of a Hearing Officer in any adjudicatory proceeding conducted under 105 CMR 127.000 shall be reviewed by the Commissioner. The Commissioner's decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.
- (b) Any applicant or licensee that fails to exercise its right to an adjudicatory proceeding under 105 CMR 127.000 waives both its right to administrative review by the Commissioner and its right to judicial review pursuant to M.G.L. c. 30A, § 14.
- (E) Civil Penalties.
- (1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a mammography facility has not complied with an order issued pursuant to M.G.L. c. 111, § 5O or with any provision of M.G.L. c. 111, §§ 5N through 5Q or with any applicable rule, regulation, license or registration adopted or issued thereunder, the Department, in *lieu* of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license, may assess civil penalties in an amount not exceeding \$100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.
- (2) Factors in Determining Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:
- The willfulness of violation;
  - The actual and potential danger to the public health or the environment;
  - The actual or potential cost of such danger to the public health or the environment;
  - The actual or potential damage or injury to the public health or environment;
  - The actual and potential cost of such damage or injury;
  - The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 127.000;
  - Whether the person being assessed the civil penalty did everything reasonable to prevent failure to comply from occurring, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
  - Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5Q or any other rule or regulation adopted hereunder;
  - Whether imposition of a civil penalty is likely to deter future noncompliance;
  - The financial condition of the person being assessed the civil penalty; and
  - The public interest.
- (3) Civil Penalty for Operation without a License. Operation of a mammography facility without a license constitutes a violation of law punishable by a civil penalty of up to \$100,000. Each day during which a mammography facility operates without a license shall constitute a separate offense.
- (4) Payment of the Civil Penalty. If after hearing, or waiver thereof, the Department imposes a civil penalty then the civil penalty shall be due and payable to the Commonwealth of Massachusetts on the 30th day after final agency action.
- (5) Non-exclusivity of Civil Penalties. By imposing a civil penalty, the Department does not waive its right to invoke other enforcement procedures, such as modification, limitation, suspension, revocation or refusal to renew a license, registration or certificate of inspection.
- (F) Criminal Enforcement. The Department may elect to enforce any section of 105 CMR 127.000 or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or 5O or any rule, regulation, license, registration, or order adopted or issued under M.G.L. c. 111, § 5N or 5O shall be fined not less than \$100,000 nor more than \$200,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than \$1,000 nor more than \$20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

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(G) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5Q and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(H) Non-exclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 127.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

127.038: Severability

The provisions of 105 CMR 127.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

REGULATORY AUTHORITY

105 CMR 127.000: M.G.L. c. 111, §§ 3 and 5N through 5Q.

(PAGES 539 THROUGH 544 ARE RESERVED FOR FUTURE USE)