

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.

~~127.002: Authority~~

~~105 CMR 127.000 is adopted under the authority of M.G.L. c. 111 §§3 and 5N through 5Q.~~

127.003: Citation

~~105 CMR 127.000 shall be known, and may be cited, as 105 CMR 127.000: *Licensing 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.

(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 ~~365 days except in a leap year in which case the period of time does not exceed 366 days~~ **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.

Certificate for a machine means a certificate of registration issued pursuant to 105 CMR 120.000.

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

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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.

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 symptomatic individuals.

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Diagnostic mammography services means mammography services that includes mammography of the breast of asymptomatic and/or symptomatic individuals using radiation emitting machines.

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.

Film-screen mammography means mammography in which the image is recorded on x-ray film that is used in conjunction with an intensifying screen or screens.

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.

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 2 of its original value.

Image receptor means any device, such as a fluorescent screen or radiographic film, 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.

Licensee means any person holding a license to operate a mammography facility. In the case of a licensee which is not a natural person, the term "licensee" shall also mean any shareholder owning 5% or more of any class of the outstanding stock; any limited partner owning five percent 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 which is a sole proprietorship; any mortgagee in possession; and any executor or administrator of any licensee which is an estate.

Machine means a radiation machine designed specifically for mammography.

Mammogram means the resulting radiographic image (film) 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 phantom means ~~a device designed to attenuate the x-ray beam in a way similar to a typical, compressed breast and to simulate breast tissue pathology. A mammography phantom~~

~~contains test objects that simulate microcalcifications, fibers, and tumor masses and is used both in the determination of typical radiation exposures and to evaluate imaging performance. X-ray images of the phantom are evaluated in terms of the number of the test objects of each type which are visualized under standard viewing conditions~~
a test object used to simulate 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.

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, a tube 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.

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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: film, screens, cassettes, grids, kilovolt peak (kVp), milliamperage (mA), exposure time, filtration, processor, and view boxes.

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 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.

Transfer of ownership shall include but not be limited to the following transfers:

- (1) A transfer of a majority interest in the ownership of a mammography facility;
- (2) In the case of a for profit corporation, transfer of a majority of any class of the stock thereof;

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- (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.

A transfer of ownership shall also be deemed to have occurred where foreclosure proceedings have been instituted by a mortgagee in possession.

Xeromammography means mammography in which the image is recorded on an electrostatically charged photoconductive plate held in a light-proof cassette.

127.006: Compliance with Requirements

(A) Unless otherwise provided, all mammography facilities licensed under 105 CMR 127.000 shall meet the requirements set forth in 105 CMR 127.000 *et seq.*

~~(B) Commentary. Commentaries may be used in 105 CMR 127.000 to provide guidance as to preferred practices. These commentaries do not constitute licensure requirements.~~

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.

~~127.009: General Requirements~~

~~Each facility licensed by the Department shall meet the following requirements:~~

127.010: Requirements of the Licensee

(A) Licensee Qualifications: A licensee is qualified to operate a mammography facility if

~~he/she~~ **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 *et seq.*, 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;
 - (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~~ ensuring that:

- (1) The facility maintains adequate staffing to meet the health and safety needs of the patients **including**, ~~at a minimum~~ 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(E).

~~(10) The facility possesses a valid certificate of registration for each mammographic x-ray machine.~~

~~(104)~~ Current Department licenses and certificates are prominently posted in the mammography facility: mammography facility license and certificate of inspection, Mammography Radiologic Technologist license(s), and mammographic x-ray machine certificate of registration.

~~(12) Promotional information to the public includes a statement that the mammography facility possesses a valid license and certificate of inspection issued by the Department.~~

(113) 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(E)(1) through (8).

(b) The quality assurance test devices referenced in 105 CMR 127.019(E)(9) through (14) 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/she~~ **he or she**:

(1) 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;**

(2) Actively practices medicine in Massachusetts at least ten hours per week;

~~(3) Has American Board of Radiology (A.B.R.) or American Osteopathy Board of Radiology (A.O.B.R.) certification, or has successfully completed and graduated from an accredited radiology residency within the past 24 months;~~

~~(4-3) Has read and interpreted an average of ten or more mammograms per work week in the prior six months~~ **960 mammograms in the prior 24 months;**

~~(4) and e~~Continues to perform mammograms at this frequency;

(5) Has successfully completed or taught a minimum of 40 hours post graduate instruction in mammography prior to beginning mammography activities; and,

(6) Completes or teaches a minimum of 15 hours of postgraduate work in mammography interpretation every 36 months while performing the duties of a Responsible Physician.

(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;

~~(4) E~~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) E~~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 ;
~~at least monthly during the first three months of employment and annually thereafter-;~~
- ~~(9) Ensuring that:~~
- ~~(a) A group orientation program is provided for the Responsible Physician, the Mammography Radiologic Technologist, the Interpreting Physician and the Medical Physicist based upon the Quality Assurance Procedures Manual, and individual completion of the program is documented.~~
- ~~(b) The Responsible Physician, the Mammography Radiologic Technologist, the Interpreting Physician and the Medical Physicist perform their duties in accordance with established policies specified in the Quality Assurance Procedures Manual.~~
- ~~(9+10)~~ 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(E)(1) through (4), (6), (7), and (14), the results of which are reviewed at least ~~quarterly~~ every six months by the Responsible Physician-;
- ~~(10+11)~~ 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 but in any case no longer than 30 days of completion of the tests-;
- ~~(11+12)~~ Ensuring that the Responsible Physician and Interpreting Physician meet mammography training and education standards outlined in 105 CMR 127.011 and 127.014.
- ~~(12+13)~~ Ensuring that an ongoing program to assess the quality of mammographic interpretation is implemented-; and
- ~~(13+14)~~ 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/she~~ he or she holds a current Massachusetts license in Radiography and Mammography issued under 105 CMR 125.000 *et seq.*

(B) Mammography Radiologic Technologist Duties. The Mammography Radiologic

Technologist shall be responsible for:

- (1) Prominently posting his/ **or** her license at the ~~machine-use location~~**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 8 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/she~~**he or she**:

(1) **Is currently registered with the Department as a Medical Physicist;** ~~(a) Is certified by one of the following:~~

- ~~1. the American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics;~~
- ~~2. The American Board of Medical Physics in Diagnostic Radiological Physics or Radiological Physics; or,~~
- ~~3. another certifying body in an equivalent specialty area acceptable to the Department; or,~~

(2)(b) 1. **Holds a Master's degree or higher in a physical science with no less than 20 semester hours in physics;** ~~of Science, Master of Arts, or a higher degree in an appropriate field from an accredited institution. Appropriate fields include physics, applied physics, radiological physics, biophysics, health physics engineering, and public health when the Bachelor's degree is in a physical science; and,~~

- ~~2. Has satisfactorily completed undergraduate or graduate training in biological sciences; and,~~
- ~~3. Has a least one year of training in medical physics in the area of diagnostic radiological physics; and,~~

(32) (a) ~~Has had at least two years of experience in conducting mammography equipment performance evaluations; and,~~ **Has 20 contact hours of specialized training in conducting mammography facility surveys;**

(4) **Has conducted surveys of at least one mammography facility and at least 10**

mammography units under the direct supervision of a qualified medical physicist; and

~~(b) Has obtained or taught at least 15 hours of documented continuing medical education, specifically in mammography physics in the last three year period.~~

(5) If the medical physicist was registered in Massachusetts 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 10 semester hours in physics;

(b) Has completed forty contact hours of documented specialized training in conducting surveys of mammography facilities; and,

(c) Has conducted surveys of at least 1 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)(5)(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(E); 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.

(E) New Mammography Modality Training. Medical Physicists must receive at least 8 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/she~~ **he or she**:

(1) **Is licensed to practice under M.G.L. c. 112, § 2;** ~~Holds a current Massachusetts license, issued by the Board of Registration in Medicine;~~

(2) **Is in compliance with applicable regulations issued by the Board of Registration in Medicine** ~~Meets the requirements established by the Board of Registration in Medicine and promulgated as 243 CMR 2.07(24);~~

(3) Has American Board of Radiology (A.B.R.), ~~or~~ American Osteopathy Board of Radiology (A.O.B.R.) certification, **or Royal College of Physicians and Surgeons of Canada certification; and**

(4) ~~Has~~ **Has** successfully completed and graduated from an accredited radiology residency within the past 24 months;

~~127.014: continued~~

~~(4) Has read and interpreted an average of ten or more mammograms per work week in the prior six months, and continues to perform mammograms at this frequency;~~

~~(5) Has successfully completed or taught a minimum of 40 hours post graduate instruction in mammography interpretation prior to beginning this activity; and,~~

~~(6) Completes or teaches a minimum of 15 hours of postgraduate work in mammography interpretation every 36 months while performing the duties of an Interpreting Physician.~~

~~105 CMR 127.014(3) through (6) remain in full force and effect until such time as regulations are promulgated by the Board of Registration in Medicine in accordance with M.G.L. c. 112 § 2 through 9B and M.G.L. c. 13 ' 10 and 243 CMR 2.00.~~

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

(1) ~~Ensuring~~ **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 original images or films 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 films; and,

(6) ~~Ensuring~~ **Ensuring** that he or she is readily available to the staff at the mammography facility.

(C) Continued Experience and Education. The licensee 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; ~~free from dirt, rubbish, vermin, solid wastes, and objectionable odors;~~
- (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;
- (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 ~~renders~~**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 ~~insure~~ 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

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to all staff members, and,

~~(13) Provide a smoke free environment for patients.~~

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 **3mg as measured using an FDA-accepted mammography phantom accepted by the U.S. Food and Drug Administration.** ~~0.3 Roentgens Absorbed Dose (Rad) per exposure.~~

127.017: Equipment Standards

(A) Initial optimization of operating parameters shall be performed on all equipment used in producing mammograms, ~~including but not limited to: the x-ray units, film processors, screen, films, cassettes, view boxes and darkroom.~~ The process undertaken to perform the optimization and the results shall be documented.

(B) The image receptor systems and their individual components shall be specifically designed for mammography. Xeromammography is prohibited.

(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). ~~The generator must not operate above 35 kVp nor below 23 kVp.~~

~~(D) When used with film-screen image receptors, the useful beam shall have a half-value layer, measured with the compression paddle in the beam, of at least kVp/100 (mm aluminum equivalent) and no greater than kVp/100 +0.1(mm aluminum equivalent) for a molybdenum/molybdenum combination.~~

~~(E) The combination of focal spot size, source to image distance and magnification shall produce a radiograph with a resolution of at least 12 cycles per millimeter when measured with the test pattern placed 4.5 cm above the breast support platform. This standard applies to the routine mammographic film being utilized at the facility.~~

(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 the following: **automatic exposure control.**

- ~~(1) Cassettes of appropriate size so as to be able to obtain a complete breast image on a single film;~~
- ~~(2) Grids specifically designed for mammography for each size cassette; and,~~
- ~~(3) Automatic exposure control.~~

(F) X-ray systems shall indicate, or provide the means of determining, the milliamperere-seconds (mAs) resulting from each exposure made with automatic exposure control ~~for newly purchased units obtained after the enactment of 105 CMR 127.000~~ **for new units installed after 1994.**

~~(I) Transmission Limit for Image Receptor Supporting Devices Used for Mammography. For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgens for each activation of the tube. Exposure shall be measured with the system operated at the minimum Source to Image Distance (SID) for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.~~

127.017: continued

(JG) Special Attachments for Mammography:

- (1) 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.
- (2) Each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

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 on-going 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(E)**, 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 ~~noted~~ **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(E) may be performed by a Medical Physicist;
 - (b) Quality assurance tests outlined in 105 CMR 127.019(E)(1) through (4), (6), (7), and (14) may be performed by a licensed Mammography Radiologic Technologists; **and**
 - (c) Quality assurance tests outlined in 105 CMR 127.019(E)(1) and (7) may be performed by an individual familiar with the x-ray film processing.
- (6) Any individual specified in 105 CMR 127.019(E)(5) and (8) through (14) shall have

obtained special training and continuing education in diagnostic x-ray physics and quality assurance regarding mammography as approved by the Department.

(7) Any individual who performs the quality assurance tests required in 105 CMR 127.019(E) 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 highest quality mammograms:

- (a) Prior to initial use of the equipment; and,
- (b) At least yearly after the initial verification.

127.018: continued

(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) An identification of all elements that have an impact on image quality.~~
- ~~(23) Control Limits or parameters of acceptability for each element quality assurance test.~~
- ~~(34) Brief description of the quality assurance tests to be performed.~~
- ~~(45) Frequency of each quality assurance test.~~
- ~~(56) Forms to be used for each quality assurance test.~~
- ~~(67) A protocol for correcting each quality assurance finding that does not fall within the acceptable limits as specified in 105 CMR 127.017.~~
- ~~(78) A list of equipment to be used for performing quality assurance tests, which shall include at least the following:~~
 - ~~(a) Mammography phantom accepted or approved by ACR capable of demonstrating at least all of the following:~~
 - ~~1. Masses of 0.25 mm in thickness and greater;~~
 - ~~2. Calcium carbonate, aluminum or similar calcifications of 0.16 mm in diameter and greater; and,~~
 - ~~3. Nylon or similar material fibers of 0.75 mm in thickness and greater.~~
 - ~~(b) Wire mesh contact tool specifically designed for mammography quality assurance.~~
 - ~~(c) Thermometer (alcohol, digital, or electronic but NOT mercury thermometer) with $\pm 0.5^\circ\text{F}$ accuracy.~~
 - ~~(d) Sensitometer (blue or green, as appropriate) with reproducibility of ± 0.04 log exposure.~~
 - ~~(e) Densitometer with accuracy of ± 0.02 Optical Density (O.D.) and a range of 0.00 to 3.5 optical density.~~

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~~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;
 - (b) Verification that mammographic x-ray equipment is in safe operating order.
 - (c) Subsequent quality assurance test results;
 - (d) Processor sensitometric test results including: film speed index, film contrast index, film base + fog, and developer temperature, which shall be plotted on control charts;
 - (e) Film density, density difference, exposure time or mAs, and the number of visible objects seen on the mammography phantom image records, which shall be plotted on

control charts-;

(f) Notes regarding changes in operating conditions shall be recorded on the appropriate control charts-;

(g) Operating levels and control limits for all quality assurance tests shall be indicated on the appropriate control chart-;

(h) All records shall bear the date the procedure was done and the initials or name of the individual performing the test.

(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.

127.019: continued

(B) Quality Assurance Records for Film Processor.

- (1) Film processor control charts and control films shall be used to monitor and regulate proper processor function and shall be kept for at least one year.
- (2) Film processor maintenance logs shall include all of the following records, and these records shall be kept for at least one year:
 - (a) Preventive maintenance;
 - (b) Corrective maintenance;
 - (c) Cleaning and chemical replacement; and,
 - (d) Service including documentation of a check of:
 1. replenishment rates; **and**
 2. the specific gravity of the developer solution; ~~and,~~
 3. ~~makeup water hydrometer valve.~~
- (3) Each record entry shall be dated and signed or initialed by the individual who performed the quality assurance test and the time that the test was performed shall be recorded. A signature/initial card shall be kept in the file to aid in identification of the signatures and initials entered.

(C) Quality Assurance Records and Requirements for Test Equipment.

- (1) The quality assurance test equipment shall be in good operating order.
- ~~(2) The following devices used as quality assurance test equipment (dosimeter, kVp meter, and densitometer) shall be calibrated at least biannually. In between biannual calibrations, these meters shall be inter compared at least once with a similar unit that has been calibrated within the past six months.~~
- ~~(23)~~ Records of each repair and/or calibration of quality assurance test equipment shall include **at least the following: the date of repair and/or calibration.**
 - ~~(a) Date of repair and/or calibration;~~
 - ~~(b) Criteria used in repair and/or calibration; and,~~
 - ~~(c) Name of individual who performed repair and/or calibration and the name of company this individual represents.~~
- ~~(34)~~ Records of each repair and/or calibration of quality assurance test equipment shall be kept for at least three years.
- ~~(45)~~ **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, ~~on~~ human beings if such repair and/or replacement affects the following:
 - ~~(a) Image quality;~~
 - ~~(b) Automatic exposure control level or reproducibility;~~
 - ~~(c) Exposure timer accuracy;~~
 - ~~(d) Milliampere seconds (mAs) linearity;~~
 - ~~(e) Kilovolt peak (kVp) accuracy;~~
 - ~~(f) Skin entrance exposure and glandular tissue dose;~~
 - ~~(g) Focal spot size;~~
 - ~~(h) Half value layer;~~
 - ~~(i) Collimator alignment; or,~~

~~(j) Use and/or release of the compression cone.~~

(D) Quality Assurance Requirements for the Darkroom.

- (1) No smoking or eating ~~is~~**shall be** permitted in the darkroom.
- (2) The darkroom shall be kept free of dust.
- (3) Counter tops, floors, and processor feed trays shall be cleaned daily before any films are handled or processed.
- (4) Hands shall be clean and dry when touching films.
- (5) Darkroom safelights shall be equipped with an appropriate filter and bulb combination as established by the film manufacturer. This information shall be prominently posted in the dark room and included in the Quality Assurance Procedures Manual. Darkroom safelights shall be at the manufacturer's recommended distance from the counter or processor feed tray.
- (6) Screens shall be kept free of artifacts.
- (7) Screens shall be cleaned regularly.;

127.019: continued

(a) Screens shall be cleaned at intervals not to exceed one month with a screen cleaner recommended by the screen manufacturer. A copy of this requirement shall be kept in the Quality Assurance Procedures Manual.

~~Commentary The preferable practice is for screens to be cleaned weekly.~~

(b) Screens used with a mobile mammography operation shall be inspected at the end of each move and before any patients are radiographed.

(E) Quality Assurance Tests for Equipment.

(1) Film Processor.

(a) Quality assurance tests for film processor shall be performed daily unless otherwise specified, prior to the exam of the first patient.

(b) Test tools for quality assurance tests for the film processor shall include the following:

1. Densitometer
2. Sensitometer
3. Thermometer
4. Film (same film as used in mammography)

(c) Daily film processor quality assurance tests shall include:

1. Checking solution temperatures.
 - a. The developer and fixer temperatures shall be as recommended by the film manufacturer for the film-developer combination being used.
 - b. The recommendation document shall be prominently posted near the processor.
 - c. Mercury thermometers are prohibited for determining solution temperatures.
2. Determination and recording of the speed step. Maximum control limits shall not exceed ± 0.15 optical density (O.D.).
3. Calculation and recording of the contrast index or density difference. Maximum control limits shall not exceed ± 0.15 optical density (O.D.).
4. Measuring and plotting the Base + Fog. Maximum base plus fog density shall not exceed 0.25 optical density (O.D.).

(d) Chemistry replenishment rates shall be measured and recorded semi-annually.

(2) Mammography Phantom Image Quality.

(a) Quality assurance tests for image quality in fixed mammography facilities shall be performed weekly ~~at least monthly~~.

(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 patients at least weekly, ~~but not less than monthly~~.

(c) Each facility shall utilize a mammography phantom approved or accepted by ACR for performing quality assurance tests for image quality.

1. Image quality taken of the mammography phantom shall be compared to an image of the same mammography phantom taken at the time the machine was optimized. The results shall resolve at a minimum the four largest fibers, three largest speck groups and three largest masses.
2. The optical density of the film in the center of the mammography phantom image shall be between 1.10 and 1.50 for films exposed at the kVp used by the facility.

3. Mammography phantom films must be viewed using a magnifier on the viewbox and under the same viewing conditions as used for reading mammograms.
 4. Constancy from mammography phantom image is the crucial factor. With exposures made identical to previous mammography phantom images, the optical density in the center of the mammography phantom must not change by more than ± 0.20 and the density difference (contrast) shall not change by more than 0.05.
- (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(E)(2)(c).
- (3) Retake Analysis.
- (a) Quality assurance tests for retake analysis shall be performed at least quarterly, at intervals not to exceed three months.
- ~~Commentary. The preferable practice is to perform retake analysis quality assurance tests monthly.~~

127.019: continued

- (b) The test tools for performing quality assurance tests on retake analysis are rejected radiographs.
- (c) When performing quality assurance tests for retake analysis, the total number of films and the total number of rejected films used during the test period shall be evaluated for ascertaining the reason for rejection. The rejected films shall be identified in at least the following categories:
 - 1. Technique (too dark or light, over or under penetrated);
 - 2. Motion;
 - 3. Positioning error;
 - 4. Processing (development error); and,
 - 5. Film artifacts (dirty cassettes, dirty processor rollers, dust or lint in the darkroom, lint from patients' gowns, etc.).
- (4) Film/Screen Contact.
 - (a) Quality assurance tests for film/screen contact in fixed mammography facilities shall be performed at least semi-annually.
 - (b) Quality assurance tests for film screen contact in mobile mammography facilities shall be performed at intervals not to exceed one month.
 - (c) Each facility shall use a film-screen contact test tool specifically designed for performing quality assurance tests on mammography cassettes.
- (5) 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 the ACR 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~~0~~ 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. The calibration method used shall be documented and maintained at the facilities use location.
- ~~(6) Viewbox Masking and Uniformity of Illumination.~~
 - ~~(a) Quality assurance tests for adequate light masking of extraneous light from the viewboxes and uniform illumination of the viewboxes shall be performed at least semi-annually.~~
 - ~~(b) Each facility shall use a visual light meter for performing quality assurance tests.~~
- ~~(6)~~ Darkroom Integrity.
 - (a) Quality assurance tests for darkroom integrity shall be performed at least semi-annually.
 - (b) Each facility shall use pre-exposed film for performing quality assurance tests.
 - (c) When performing quality assurance tests for darkroom integrity, the density difference for a two minute test shall not exceed 0.10 (O.D.).
- ~~(7)~~ Exposure Timer or mAs Accuracy and Automatic Exposure Control.

- (a) Quality assurance tests for the exposure timer -- automatic exposure control (phototiming) -- at fixed mammography facilities shall be performed at least annually.
- (b) Quality assurance tests for the exposure timer -- automatic exposure control (phototiming) -- at mobile mammography facilities shall be performed at least semi-annually.
- (c) Each facility shall use the following test tools for performing quality assurance tests:
 - 1. Digital timer or mAs meter or Ion chamber; and;
 - 2. Breast phantom accepted or approved by ACR.
- (d) When performing the quality assurance tests for phototiming, the following requirements shall be met:

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1. The exposure timer/phototimer control must be checked for reproducibility.
2. The coefficient of variation of exposures shall not be greater than $\pm 5\%$ as measured on four consecutive exposures at a commonly used setting.
3. The system shall be capable of maintaining constant film optical density to within ± 0.30 of the average over the kVp range used for mammography phantom thicknesses of 2 cm to 6 cm and of limiting the maximum automatically controlled exposure to a fixed, reasonable mAs (600 to 1,000 mAs).
4. If the standard deviation of the control films does not exceed 0.05, the maximum and minimum optical densities from all cassettes shall be determined. The difference between the maximum and minimum measured optical densities shall not exceed 0.30.

(89) 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.
- (e) If the film optical density cannot be maintained to within ± 0.3 of the average over the range of clinically used kVp settings and mammography phantom thicknesses from 2 to 6 cm, a technique chart shall be developed that alters kVp and density control settings as a function of breast thicknesses and densities to produce optical densities within this narrower range under phototimed conditions.

(940) Milliampere-seconds (mAs) Linearity

- (a) Quality assurance tests for mAs linearity at fixed mammography facilities shall be performed at least annually.
- (b) Quality assurance tests for mAs linearity at mobile mammography facilities shall be performed at least semi-annually.
- (c) Each facility shall use the following tools for performing quality assurance tests:
 1. Ion chamber (manual timing), and/or
 2. Digital timer (automatic/photo timing).
- (d) When performing the quality assurance tests for mAs linearity, the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 10% times their sum.

(1044) 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 calibrated at the energy ranges used in

mammography for performing quality assurance tests.

(d) When performing quality assurance tests for glandular tissue dose, ~~the glandular dose shall be calculated by multiplying the measured skin entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination as shown in Appendix A.~~ the technique setting shall be those used for imaging a 4.5 cm compressed breast in the cranio-caudad 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 mg** ~~0.3 Roentgens Absorbed Dose (Rad) per exposure~~.

~~127.009:—continued~~

(1142) Focal Spot Size.

- (a) Quality assurance tests for focal spot size at fixed mammography facilities shall be performed at least annually.
- (b) Quality assurance tests for focal spot size at mobile mammography facilities shall be performed at least semi-annually.
- (c) Each facility shall use a star pattern test tool of one degree or less or slit camera to perform quality assurance tests.
- (d) When performing the quality assurance tests for focal spot size, the following requirements shall be met:
 - 1. The target and tilt angle of the mammography unit must be documented.
 - 2. The focal spot size for film/screen systems shall be as follows:
 - a. For contact mammography the nominal focal spot size should not exceed 0.3 mm and shall not exceed 0.6 mm.
 - b. For magnification mammography the nominal microfocal spot size shall not exceed 0.3 mm.
 - 3. The determination of focal spot size shall follow the standard outlined in the most recent edition of "Measurement of Dimensions and Properties of Focal Spots of Diagnostic X-Ray Tubes," the National Electrical Manufacturer Association's Publication NEMA XR-5².

(1243) 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.
- (c) Each facility shall use a set of five Aluminum alloy 1100 or pure Aluminum sheets with thickness of 0.1 mm and an appropriately calibrated ionization chamber.
- (d) 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.
- (e) When used with film-screen image receptors, the useful beam shall have a half-value layer, measured with the compression paddle in the beam, of at least kVp/100 (mm aluminum equivalent) and no greater than kVp/100 +0.1(mm aluminum equivalent) for a molybdenum/molybdenum combination. Other systems shall be evaluated on a case by case basis.

(1344) Uniformity of Screen Speed.

- (a) Quality assurance tests for uniformity of screen speed of the cassette-screen combinations shall be performed at least semi-annually.
- (b) Each facility shall use the following procedure to ensure that all mammographic cassettes of a given size have similar response to x-ray exposure.
 - 1. Using film from the same box of film, expose each cassette using the **mammography** phantom at a typical kVp setting used for clinical studies with a manual mAs selection chosen to darken the film in the center of the **mammography** phantom to an optical density of 1.10 to 1.50 O.D.
 - 2. The same film processor shall be used for processing all of the films of this test.
 - 3. The measured mAs value for each exposure, the corresponding O.D. in the center

of the **mammography** phantom image and an identification of each cassette shall be recorded.

4. The average value of the mAs and the average value of the image optical density of each group of image receptors shall be recorded for each cassette-screen. The ratio of the optical density of each image at the center of the **mammography** phantom divided by the average optical density of each group of cassettes of a give size and screen speed shall fall within the range of 0.9 to 1.1. Any cassettes-screens which fall outside this range shall not be used for clinical studies.

(14) Non-Film Screen Imaging. Facilities using non-film screen imaging shall follow the manufacturer's recommendations for quality control.

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 ~~and the date of the interpretation;~~
- (2) The name, address, and date of birth of the patient;
- ~~(3) The name of the operator of the equipment and the name and business address of the Interpreting Physician;~~
- ~~(34) A description of the procedures performed;~~
- ~~(5) The date the Interpreting physician's written report was sent to the patient or the patient's physician and the name and business address of the referring physician (if any), or other physician (if any), identified by the patient to receive the Interpreting Physician's written report; and,~~
- ~~(46) The name and business address of the referring physician or other person to whom mammogram(s) (films) 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 original images or films 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 terms easily understood by a lay person **and be in a language that the patient understands. The facility shall read the required information to patients who are visually impaired or unable to read;**

(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 ~~and business address~~ of the physician (if any) to whom the patient wants a copy to be sent; and;
4. Indication that original films or 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 provide all information required by M.G.L. c. 111, §5Q.

(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) ~~Medications~~ **Hormones**;
- (5) Surgery;
- (6) Time and place of previous mammogram; and;
- (7) Child bearing history.

127.020: continued

(D) Record Management.

- (1) The facility shall develop and implement policies and procedures for record management.
- (2) All mammograms (films), 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 **5 years**~~120 calendar months~~ following the date of service **or, for hospitals and clinics, the records retention period specified 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 physician designated by the patient; and;
- (3) If the facility should cease to operate before the end of the ~~120-month~~**5-year** period, the records must be retained in a manner which provides security and which permits former patients or their physicians access to them for the remainder of the ~~120-month~~**5-year** period.
~~Commentary. The 120 calendar month retention period for mammography records applies to all mammography facilities including hospital and clinic based mammography facilities.~~

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 ~~she~~**the patient** should either arrange for ~~her~~ **the patient's** most recent prior mammogram (original film) 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 and without a referring physician;
 - (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, ~~directly or through her referring physician,~~ 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 or her referring physician;
 - (h) Be entitled to inspect and copy ~~her~~ **the patient's** medical record, upon request, during normal business hours at the facility;
 - (i) Be entitled, upon request, to receive on loan the original mammogram or a copy of

- the original mammogram, ~~for a reasonable copying fee~~; and;
- (j) Be provided with the name and address and telephone number of the Radiation Control Program (~~MDPH~~) 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" ~~in block letters at least one inch high~~ 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 ~~admittance~~ 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 ~~handout~~ material for each patient, ~~which includes:~~

- (1) ~~Risk factors for breast cancer;~~
- (2) ~~Signs and symptoms of breast cancer;~~

127.021: continued

- ~~(3) Instructions in breast self examination;~~
- ~~(4) Importance of mammography;~~
- ~~(5) Explanation of mammography examination; and,~~
- ~~(6) Recommended frequency of screening mammography examinations.~~

(C) The patients' rights statement and educational materials shall be written in clear plain language that a lay person can understand **and be in a language that the patient understands.** **The facility shall read the required information to patients who are visually impaired or unable to read.**

~~Commentary. If the mammography facility is serving a linguistically diverse clientele, the facility should use reasonable means to communicate the required information to patients who are not proficient in reading English. Under the Americans with Disabilities Act, the facility shall utilize alternate means to communicate to blind or visually impaired clients.~~

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** meets 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.

~~(e)~~**(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.

(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 ~~Department shall require that 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;

127.023: continued

- (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 and film processor 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 ~~received, read, and~~ 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 ~~to cover the necessary license fee. The fee for a license and annual renewal thereof shall be determined by the Executive Office of Administration and Finance.~~ **is specified in 801 CMR 4.00.**

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.**
- (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 ~~endeavor to act on~~ **process** applications for original licensure ~~within 60 days of~~ **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 ~~endeavor to act upon~~ **process** renewal licenses ~~within 60 days~~ **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 ~~within the 60 day period~~ **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.

~~(C) The Department may issue guidelines for processing applications for facility licenses which grant deemed status equivalency to certain components of the American College of Radiology (ACR) accreditation survey process.~~

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 ~~may~~**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) 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 ~~S~~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 ~~cause such certification to be displayed~~**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 then 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.

127.033: continued

(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, ~~State Laboratory, 305 South Street, Jamaica Plain, MA 02130, Tel. (617) 727-6214.~~

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

- (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 ~~deleted~~ **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, §50, 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.

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- (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.

127.036: continued

- (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.
- (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, §50 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.

127.037: continued

(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 re-inspect 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.
- (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 non-compliant with applicable laws and regulations regarding licensure, the Department may initiate enforcement procedures as set forth below.

(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 1.01 *et seq.*

(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 1.01 *et seq.* 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 review 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).

127.037: continued

(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 the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et seq.*

(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 1.01 *et seq.*

(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.

(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) Public Health Council 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 the Public Health Council 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:

(a) The willfulness of violation;

(b) The actual and potential danger to the public health or the environment;

(c) The actual or potential cost of such danger to the public health or the environment;

(d) The actual or potential damage or injury to the public health or environment;

(e) The actual and potential cost of such damage or injury;

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- (f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 127.000;
- (g) 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;

127.037: continued

- (h) 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;
 - (i) Whether imposition of a civil penalty is likely to deter future non-compliance;
 - (j) The financial condition of the person being assessed the civil penalty; and,
 - (k) 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 \$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.
- (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) Nonexclusivity 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.

127.039: Appendix A

— Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
 4.5 cm Breast Thickness — 50% Adipose/50% Glandular Breast Tissue*
 ————— Mo/Mo Target Filter X-Ray Tube Voltage (kVp)

HVL	23	24	25	26	27	28	29	30	31	32	33	34	35
0.23	109												
0.24	113	116											
0.25	117	120	122										
0.26	121	124	126	128									
0.27	126	128	130	132	134								
0.28	130	132	134	136	138	139							
0.29	135	137	139	141	142	143	144						
0.30	139	141	143	145	146	147	148	149					
0.31	144	146	147	149	150	151	152	153	154				
0.32	148	150	151	153	154	155	156	158	159	160	160		
0.33	153	154	155	157	158	159	160	162	163	164	164		
0.34	157	159	160	161	162	163	164	166	167	168	168	169	
0.35		163	164	166	167	168	169	170	171	172	172	172	173
0.36			168	170	171	172	173	174	175	176	176	176	176
0.37				174	175	176	177	178	178	179	180	180	181
0.38					179	180	181	182	182	183	184	184	186
0.39						184	185	186	186	187	188	188	189
0.40							189	190	191	192	192	192	193
0.41								194	195	196	196	196	197
0.42										200	200	200	201
0.43											204	204	204

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo target/filter system at 30 kVp with a measured HVL of 0.36 mm aluminum yields an average glandular dose of $(0.50 \text{ R}) \times (174 \text{ mrad/R}) = 87 \text{ mrad}$ or 0.87 mGy.

¹—NCRP Report No. 85 may be obtained from:

NCRP Publications
 7910 Woodmont Ave., Suite 1016
 Bethesda, MD 20814

²—The most recent edition of "Measurement of Dimensions and Properties of Focal Spots of Diagnostic X-Ray Tubes", Publication NEMA XR-5 may be obtained from:

National Electrical Manufacturer's Association
 2101 L Street, North West
 Washington, D.C. 20037

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

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