## PART 13. MAMMOGRAPHY INSTALLATIONS

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PART 13. MAMMOGRAPHY INSTALLATIONS

Reorganize Rule order to match FDA order:

(A) Purpose, Scope, Authorization
(B) Personnel requirements (physicians, techs, physicists)
(C) Equipment
(D) Medical Records and Reports
(E) QA – General
(F) Quality Control Testing
(G) Etc.

GENERAL PROVISIONS

R325.5601. Purpose and scope.

Rule 601. (1) This part establishes requirements governing the use of x-radiation for mammography and apply to all persons who use x-radiation for mammography for the intentional exposure of humans. A person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department pursuant to the provisions of R325.5181 to R325.5196 and is specifically authorized to perform mammography pursuant to the provisions of the act.

(2) In addition to the requirements of this part, all persons are subject to the provisions of R325.5001 to R325.5511.

(3) A facility shall not misrepresent to its employees, to the public, or to the department its status with respect to accreditation of the mammography equipment by the American college of radiology, department authorization to perform mammography, or compliance with department rules.

R325.5602. Definitions A to B.

Rule 602. (1) As used in this part:

(a) "Accreditation body" means an entity that has been approved by FDA to accredit mammography facilities.

(b) "Act" means sections 13501 to 13536 of Act No. 368 of the Public Acts of 1978, as amended, being "333.13501 to 333.13536 of the Michigan Compiled Laws.

(c) "Action limits" means the minimum and maximum values of a quality assurance measurement that
can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

(d) "Action levels" (See "action limits").

e) "Adverse event" means an undesirable experience associated with mammography activities that include but are not limited to:

   (i) Poor image quality

   (ii) Failure to send mammography reports within thirty days to the referring physician or in a timely manner to the self-referred patient

   (iii) Use of personnel that do not meet the applicable requirements of these rules.

f) "Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.

g) "Annual" means a period of time that is not more than 365 days.

(h) "Asymptomatic" means without signs or symptoms of breast disease.

(i) "Automatic exposure control" means a device that automatically controls 1 or more technique factors to obtain a required quantity of radiation at a preselected location or locations.

(j) "Body" (See "accreditation body")

(k) "Breast implant" means a prosthetic device implanted in the breast.

**R325.XXX1. Definitions C to D.**

**Rule XXX1. (1)** As used in this part:

(a) "Calendar quarter" see "quarter".

(b) "Category I" means medical education activities that have been designated as category I by the accreditation council for continuing medical education (ACCME), the American osteopathic association (AOA), a state medical society, or an equivalent organization.

(c) "Certificate" means the certificate described in this part.
(d) "Certification" means the process of approval of a facility by the FDA or FDA approved certifying agency to provide mammography services.

(e) "Clinical image" means a mammogram.

(f) "Compression device" means a rigid apparatus that compresses the breast to immobilize the breast and provide uniform thickness during mammography.

(g) "Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

(h) "Contact hour" means an hour of training received through direct instruction.

(i) "Continuing education credit" (See "continuing education unit").

(j) "Continuing education unit" means one contact hour of training.

(k) "Control limits" (See "action limits").

(l) "Control levels" (See "action limits").

(m) "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.

(n) "Diagnostic mammography" means the mammographic examination of symptomatic individuals.

(o) "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.

(p) "Direct instruction" means

(i) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(ii) The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

(p) "Direct supervision" means that:

(i) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient’s records; or
During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

R325.XXX2. Definitions E to L.

Rule XXX2. (1) As used in this part:

(a) "Established operating level" means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

(b) "Facility" means, with reference to mammography, a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation.

(c) "FDA" means the Food and Drug Administration.

(d) "First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

(e) "Focal spot" means the primary source of x rays produced at the location where the anode of an x-ray tube intercepts the electron beam.

(f) "Grid" means a device which is used to control scattered radiation and which is composed of alternating strips of high-x ray-absorption material and low-x ray-absorption spacer material encased in a protective cover.

(g) "Image receptor support device" means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

(h) "Interim regulations" means the regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities (58 FR 67558-67565) and "Quality Standards and Certification Requirements for
Mammography Facilities” (58 FR 67565-67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

(i) "Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements set forth in this part.

(j) "Kerma" means the sum of the initial energies of all charged particles liberated by uncharged ionizing particles in a material of given mass.

(k) "Laterality" means the designation of either the right or left breast.

(l) "Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of this part. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

Rule XXX3. Definitions M to O.

(a) "Mammogram" means a radiographic image of the breast produced through mammography.

(b) "Mammographic Modality" means a technology for radiography of the breast. Examples are digital, and screen-film mammography.

(c) "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 does not include radiography of the breast performed during invasive interventions for localization or biopsy procedures.

(d) "Mammography equipment evaluation" means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in this part.

(e) "Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.
“Mammography phantom” means a device that is designed to attenuate the x-ray beam in a similar way as 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 patient 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 that are visualized under standard viewing conditions.

“Mammography supervisor” means the individual who is responsible for, and in control of, quality control, radiation safety, and the technical aspects of all x-ray examinations and procedures for a mammography machine and a mammography facility.

“Mammography unit(s)” 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.

“Mean optical density” means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

“Medical physicist” means a person trained in evaluating performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in this part.


“Multi-reading” means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

R325.XXX4. Definitions P to R.

Rule XXX4. (1) As used in this part:

(a) “Patient” means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.
(b) “Phantom” means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

(c) “Phantom image” means a radiographic image of a phantom.

(d) “Physical science” means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(e) “Positive mammogram” means a mammogram that has an overall assessment of findings that are either “suspicious” or “highly suggestive of malignancy.”

(f) “Provisional certificate” means the provisional certificate described in this part.

(g) “Qualified instructor” means an individual whose training and experience adequately prepared him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of this part would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer’s representatives.

(h) “Quality control technologist” means an individual meeting the requirements of this part who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

(i) “Quarter” means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

(j) “Radiologic technologist” means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and when performing mammography without direct supervision, also meets the requirements set forth in this part.

(a) “Radiological physics” means the branch of medical physics that includes diagnostic physics, therapeutic physics, and medical nuclear physics.

R325.XXX5. Definitions S to Z.

Rule XXX5. (1) As used in this part:

(a) “Screen-film mammography” means mammography in which the image is recorded on x-ray film that
is used in conjunction with an intensifying screen or screens.

(b) "Screening mammography" means the periodic mammographic examination of asymptomatic women to detect unsuspected breast cancer in its earliest stage.

(c) "Serious adverse event" means an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(d) "Serious complaint" means a report of a serious adverse event.

(e) "Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

(f) "Survey" means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

(g) "Time cycle" means the film development time.

(h) "Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two years and the results of the proficiency test conducted within 24 months of calibration show agreement within + 3 percent of the national standard in the mammography energy range.

(d) "Xeromammography" means mammography in which the image is recorded on an electrostatically charged photoconductive plate that is held in a lightproof cassette.

(2) The terms defined in the act shall have the same meanings when used in these rules.

R325.5603. Department inspections.

Rule 603. (1) The department shall inspect a mammography machine and system not later than 60-90 days after initial mammography authorization is issued. After that initial inspection, the department shall annually inspect the mammography machine and system and may inspect more frequently

Pending change in Part 135A of the public health code.
(2) After each satisfactory inspection by the department, the department shall issue a certificate of radiation machine inspection which identifies the facility and the machine inspected and which provides a record of the date that the machine was inspected. The facility shall conspicuously post the certificate on or near the inspected machine and in a location that is observable by patients.

(3) The department may issue a notice of violations certificate if violations found during an inspection are not corrected within the specified time limit or if the department has not received written verification of corrections within the specified time limit. The notice of violations certificate shall be conspicuously posted on or near the inspected machine and in a location observable by patients.

(4) A facility shall remove the certificate of radiation machine inspection if directed by the department due to subsequent failure to be in compliance with this part and the provisions of R325.5001 to R325.5511 (or appropriate numbering after update) as determined by follow-up inspections by the department.

(5) In conducting inspections, the department shall have access to all equipment, materials, records, personnel, and information that the department considers necessary to determine compliance with these rules. The department may copy, or require the facility to submit to the department, any of the materials, records, or information considered necessary to determine compliance with these rules.

(6) The department shall designate department employees to conduct regulatory inspections.

(7) The department may conduct tests and evaluations as the department deems appropriate to determine compliance with all of the provisions of this part and the provisions of R325.5001 to R325.5511 (or appropriate numbering after update).

MAMMOGRAPHY AUTHORIZATION

R325.5605. Standards for authorization.
Rule 605. The department shall issue a 3-year mammography authorization if the mammography facility is in compliance with all of the following standards:

(a) The radiation machine is in compliance with either of the following requirements:

(i) The machine meets the criteria for the American college of radiology mammography accreditation program dated October, 1991, and January, 1992 (most recent date?), and the facility submits an evaluation report issued by the American college of radiology as evidence that the mammography machine meets the criteria. A stereotactic breast biopsy or needle localization machine shall meet the criteria of the ACR stereotactic breast biopsy accreditation program dated 10/17/2004. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only. Copies of the criteria are available at no cost from the Division of Radiological Health, Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195, Lansing, Michigan 48909.

(ii) The machine is used in a facility that has successfully completed the department's evaluation of the machine for the items described in R325.6510.

(b) The radiation machine, the film, or other image receptor that is used with the machine and the facility where the machine is used are in compliance with the requirements of this part and R325.5001 to R325.5511 (or appropriate numbering after update).

(c) The radiation machine is specifically designed to perform mammography.

(d) The radiation machine is used exclusively to perform mammography.

(e) The radiation machine is used in a facility that, at least annually, has a qualified radiation medical physicist provide on-site consultation to the facility as described in these rules. Records and findings of on-site consultations shall be maintained for not less than 7 years.

(f) The radiation machine is used according to department rules on patient exposure and radiation dose levels, being R325.5661(5)(g) of this part.

(g) The radiation machine is operated only by an individual who can demonstrate to the department that he or she meets the standards described in this part or by an individual who is a physician or an osteopathic
Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664, Lansing, Michigan 48909.

R325.5606. Temporary mammography authorization.

Rule 606. (1) The department may issue a nonrenewable temporary mammography authorization. A temporary authorization may only be issued if additional time is needed to allow the submission of evidence that is satisfactory to the department to demonstrate compliance with the provisions of R325.5605.

(2) The department may withdraw a temporary authorization before its expiration if the radiation machine does not meet 1 or more of the criteria specified in R325.5605.

R325.5607. Application.

Rule 607. (1) Each person who has a machine that is authorized for use for mammography on the effective date of this part shall be required to complete a mammography authorization application form if requested by the department. This application form shall be returned to the department within 45 days of the department's request.

(2) An applicant who seeks mammography authorization shall apply to the department using an application form that is supplied by the department. If mammography is performed at more than 1 location or address, a separate application shall be used for each location or address. An applicant shall accurately provide all information that is requested on the form. The information submitted as part of the application shall be sufficient, as determined by the department, to address all of the standards for authorization. Applications that do not provide sufficient information shall be returned to the applicant for completion and resubmission. Applications shall include all of the following information:
(a) Information about the facility, including all of the following:

(i) Name, address, and telephone number.

(ii) Type of practice.

(iii) The name to be used or which is currently used on the certificate of registration.

(b) Personnel information, including the education, training, experience, and certification of the mammography supervisor, lead interpreting physician, any qualified radiation physicist who provides on-site consultation and evaluation of the mammography system, and any individual who actually performs mammography.

(c) Mammography machine technical information, including all of the following:

(i) Manufacturer.

(ii) Model.

(iii) Year of manufacture.

(iv) The imaging system in use.

(v) Target material.

(vi) Filter material.

(vii) Phototiming capability.

(viii) The nominal focal spot size.

(ix) The source-to-image distance.

(x) The half-value layer.

(xi) The type of compression device used.

(xii) The capability of magnification studies.

(xiii) The grid availability and type.

(xiv) The grid ratio.

(xv) Grid lines per inch or per centimeter.

(xvi) Film size and grid size capability.

(xvii) The make and model of film and screens.

(d) Image processor information, including all of the following:

(i) The manufacturer.
(ii) Model.

(iii) Whether the processor is dedicated to mammography image processing.

(iv) Chemistry type.

(v) Temperature.

(vi) Development time.

(e) Mammography techniques, including all of the following:

(i) Number of views per breast.

(ii) Typical views employed.

(iii) Machine settings for routine mammograms.

(iv) Grid use.

(f) A copy of the facility’s mammography quality assurance plan which includes a description of all of the following:

(i) Quality control tests performed.

(ii) The frequency of tests.

(iii) By whom the tests are performed.

(iv) The limits of acceptability of those tests.

(v) The protocol for making corrections when a test does not fall within the limits of acceptability.

(g) The type of patient medical history information collected by the facility, including whether a history is taken as part of the mammographic procedure and, if taken, the items that are included in the history.

(h) The type of patient physical examination information collected by the facility, including all of the following:

(i) Whether a physical examination is conducted and, if so, by whom.

(ii) The training the individual has specific to breast physical examination.

(iii) Whether the patient is instructed in breast self-examination during the physical examination or at any time by staff of the facility.

(i) Mammography interpretation reporting mechanisms, including all of the following:

(i) A description of whether the report includes both mammographic and clinical findings.

(ii) A description of the mechanism in place to follow-up on positive or equivocal results to assure
that a patient's physician has received the report and understands any recommendations.

(iii) An indication of whether patients who have equivocal results are contacted for a follow-up examination at a prescribed time.

(iv) A description of procedures for handling self-referred patients in terms of sending a report.

(v) A description of the follow-up mechanisms in place to determine factors such as the results of biopsies, the number of cancers with negative and positive mammograms, the number of localizations with positive results, and the proportion of cases for which additional views are done.

(j) Image retention policy.

(3) The department shall respond to an application within 30 days after the date of receipt of the application.

R325.5608. Application fee schedule; waiver.

Rule 608. (1) An application form for mammography authorization shall be accompanied by a nonrefundable payment, in full, by the applicant, for department evaluation of compliance with the provisions of R325.5605(a). The fee schedule is specified in the act.

(2) If an applicant for mammography authorization submits an evaluation report which is issued by the American college of radiology and which evidences compliance with the provisions of R325.5605(a), then the fee for department evaluation of compliance with the provisions of R325.5605(a) shall be waived.

R325.5609 Application expiration.

Rule 609. An application for mammography authorization submitted to the department shall expire 6 months from the date of the department's receipt of the completed application unless the time limit is extended by the department.
Rule 610.  (1)  Upon notice from the department that an application for mammography authorization
has been determined to be complete and to be in compliance with the requirements of these rules and at the
specific request of the department, the applicant shall, within 45 days of the department's request, provide all
of the following information for each machine for which mammography authorization is being sought:

(a) Confirmation that a mammography phantom that is approved by the department is on-site when
mammography is performed and is used in the facility's ongoing quality control program. The confirmation
shall include the make, model, and serial number of the phantom and the serial number of the wax insert
that contains imaging test objects.

(b) For each machine, processor quality control data and corrective actions, if any, taken as a result of
that data for a 30-day period beginning after the date the application was sent to the department.

(c) For each machine, an x-ray image of a mammography phantom which is approved by the department
and which is taken during the 30-day period for which processor quality control data is required pursuant to
the provisions of subdivision (b) of this subrule. The phantom image shall be taken using routine machine
settings being used by the facility for that mammography machine for a cranio-caudal view of a
4.5-centimeter compressed breast composed of 50% glandular and 50% adipose tissue. The phantom
image shall be accompanied by documentation of the date that the image was taken and the machine
settings that were used.

(d) For each machine, determinations of the half-value layer, radiation exposure at skin entrance, and
mean glandular dose that are made with the use of a department-approved thermoluminescent dosimetry
device that is placed on top of an approved mammography phantom during the same exposure of the
phantom that is used to produce an x-ray image to be submitted pursuant to the provisions of subdivision (c)
of this subrule or that are made by other methods as specified or approved by the department.

(e) For each machine, a set of clinical patient mammography images without pathology which is produced
by that machine for each of 2 representative patients, 1 with dense breasts and 1 with fatty breasts. Each
set of clinical images shall consist of not less than 2 standard views of each breast, totaling not less than 4
films for each type of breast. The images shall contain clear documentation of all of the following:
The date of the mammography examination shall be on or after the date that the application was sent to the department, and the x-ray images shall be accompanied by clear documentation of the mammography machine used, including the department-assigned machine registration number, and the name of the individual or individuals who operated the machine.

(2) The department may waive the requirements of subrule (1) of this rule if the mammography machine is accredited, or is in the process of becoming accredited, by the American college of radiology. To have the requirements of subrule (1) of this rule waived, an applicant shall provide, to the department, within 45 days of the department's request, copies of the applicant's current accreditation application, current accreditation-related correspondence to and from the American college of radiology, or current accreditation certificate that is issued by the American college of radiology.

(3) Failure of an applicant to submit the information required by the provisions of either subrule (1) or (2) of this rule within 45 days of the department's request may be considered a basis for withdrawal or denial of the mammography authorization, unless the time limit is extended by the department for cause.

R325.5611. Contracts for technical evaluation.

Rule 611. (1) In evaluating clinical image quality and acceptability for mammography authorization, upon receipt of the information required in R325.5610(1)(e), the department may enter into any necessary contracts with mammography experts, submit the images to those experts for technical evaluation, and rely upon their expert evaluation in arriving at a department conclusion regarding image quality and acceptability in terms of granting or not granting mammography authorization.
Technical parameters that are used in evaluating clinical image quality and acceptability pursuant to the provisions of subrule (1) of this rule shall include judgments of all of the following:

(a) Positioning.
(b) Compression.
(c) Radiation exposure and dose level.
(d) Sharpness.
(e) Contrast.
(f) Noise.
(g) Exam identification.
(h) Artifacts.
(i) Processing.

**R325.5612. Notice of change in application information; authorization not transferable.**

Rule 612. (1) A facility that is authorized to perform mammography shall notify the department, in writing, of any change in the information contained in the application or supporting material upon which authorization was granted or any change that affects the accuracy of information which is provided or obtained during the application and evaluation process for authorization. Changes that shall be reported include changes in any of the following:

(a) Facility ownership.
(b) Facility location.
(c) Mammography machine.
(d) Image processor.
(e) Brand or model of imaging materials in use.
(f) Personnel providing mammography supervision.
(g) Personnel providing interpretation of mammograms.
(h) Personnel providing qualified radiation physicist services.
(i) Personnel actually performing mammography.
(j) American college of radiology accreditation status.

(2) Upon receipt of a notice of change, the department shall advise the facility if reapplication for mammography authorization, resubmittal of phantom or clinical images, or other actions are deemed by the department to be necessary to establish that the facility, machine, system, and personnel remain in compliance with the requirements of these rules. Upon department request, a facility shall provide any requested information or materials within 45 days after the request is made.

(3) If changes in information are deemed to require reapplication for mammography authorization, the application shall be filed and processed in the same manner as set forth in R325.5607 and R325.5608.

(4) Mammography authorization that is issued by the department is not transferable between machines or between persons who own or lease a radiation machine.

R325.5613. Authorization withdrawal; reinstatement.

Rule 613. (1) Three-year mammography authorization is subject to continued compliance with this part and the provisions of R325.5001 to R325.5511 (or appropriate numbering after update). Authorization may be withdrawn based on evidence of noncompliance with this part and the provisions of R325.5001 to R325.5511 (or appropriate numbering after update) in accordance with the provisions of Act No. 306 of the Public Acts of 1969, as amended, being '24.201 et seq. (?) of the Michigan Compiled Laws.

(2) If the department withdraws the mammography authorization of a machine, the machine shall not be used for mammography. An application for reinstatement of a mammography authorization shall be filed and processed in the same manner as an application for mammography authorization pursuant to the provisions of R325.5607 and R325.5608.
(3) The department shall not issue a reinstated mammography authorization until the department receives the reinspection fee, inspects the machine, and determines that the facility meets the standards set forth in R325.5605.

MAMMOGRAPHY SUPERVISOR/LEAD INTERPRETING PHYSICIAN

Terminology change in order to be consistent with FDA MQSA final regulations. COMBINE THIS SECTION WITH RULE 660?

R325.5617. Designation; identification; agreement between supervisor/lead interpreting physician and facility; availability; continuing education.

Rule 617. (1) Each mammography facility shall designate a mammography supervisor/lead interpreting physician in order to be authorized to perform mammography.

(2) An applicant who seeks mammography authorization shall identify the mammography supervisor/lead interpreting physician on the application form for mammography authorization.

(3) If the mammography supervisor/lead interpreting physician is not the employer of the mammography machine operators at the facility, a written agreement shall be executed between the mammography supervisor/lead interpreting physician and the facility. The written agreement shall include at least both of the following:

(a) A statement that the mammography supervisor/lead interpreting physician is responsible for assuring compliance with this part and the provisions of R325.5001 to R325.5511 (or appropriate numbering after update).

(b) A statement that the mammography supervisor/lead interpreting physician has been given the authority to make changes in the mammography program that are necessary to achieve compliance as specified in subdivision (a) of this subrule or a statement that the facility will make the changes requested by the mammography supervisor/lead interpreting physician to achieve compliance.
(4) A mammography supervisor, lead interpreting physician, shall be readily available telephonically or in person for consultation with any radiation machine operator who performs mammography.

(5) A mammography supervisor, lead interpreting physician, shall obtain not less than 15 hours of continuing education every 3 years in the technical aspects or clinical aspects, or both, of mammography and related subjects that is accredited by the American medical association or the American society of radiologic technologists or any other organizations acceptable to the department—meet all interpreting physician requirements of the public health code and the rules in this part.

Modified to simplify. This requirement is already listed for all interpreting physicians in Part 135a of the Public Health Code.

R325.5618. Responsibilities.
   Rule 618. A mammography supervisor, LEAD INTERPRETING PHYSICIAN, shall be responsible for each of the following:
      (a) Establishment and maintenance of a quality control program.
          This is the physicist’s responsibility under FDA MQSA regulations.
      (b) Annual review and updating of the procedures manual.
      (c) Evaluation of each mammography machine operator’s performance at least semiannually as described in R325.5619.
          Operator initial training, initial experience, continuing education, and continuing experience requirements along with daily oversight and review of images created by the operators is sufficient.
      (d) Assurance that each mammography machine operator other than a physician has successfully completed special mammography training as specified in R325.5621 and R325.5623 or possesses the American registry of radiologic technologists certificate of advanced qualifications in mammography as identified in R325.5622. Documents that verify training shall be maintained at the facility and copies shall be submitted to the department together with the facility application for mammography machine authorization.
      (e) Assurance that the mean glandular dose for 1 contact cranio-caudal view of a 4.5-centimeter compressed breast that is composed of 50% glandular and 50% adipose tissue is not more than the limits prescribed by R325.5661662(5)(g).
      (f) Assurance that mammography is performed only on dedicated equipment that is designed specifically for use for mammography and that has been authorized by the department for use for mammography.
      (g) Assuring that all patients who undergo mammography screening procedures designate a physician or other licensed health care provider responsible for primary care, to whom the written results of the mammography examination will be reported.
      (h) Assuring the review of records of mammography system quality assurance evaluations conducted by
a qualified radiation physicist and, when necessary, assuring the correction of deficiencies and violations.

(i) Compliance with quality assurance and radiation protection criteria prescribed by these rules.

This section is covered by the FDA regs inserted as rules 659 thru 661.


Rule 619. (1) A mammography supervisor shall evaluate the performance of each individual, other than a physician, who operates a mammography machine at least semiannually. The evaluation shall be based on both the mammography supervisor's direct observation of the operator during a standard mammography procedure being performed by the operator on at least 1 patient and on the mammography supervisor's review of clinical images.

(2) The performance evaluation shall evaluate all of the following:

(a) Proper and compassionate patient handling skills.
(b) Proper breast positioning for the cranio-caudal projection of the breast, including all of the following steps, unless other procedures are deemed appropriate and acceptable by the department:
   (i) Determining the proper image receptor size.
   (ii) Moving the photocell to the appropriate position.
   (iii) Standing on the medial side of the breast to be imaged.
   (iv) Elevating the inframammary fold to its maximum height, adjusting the height of the bucky accordingly.
   (v) Using 1 hand, gently scooping the breast onto the image receptor tray.
   (vi) Centering the breast over the photocell, with the nipple in profile, if possible.
   (vii) Anchoring the breast with 1 hand and not removing the hand until the compression process begins.
   (viii) With the other hand, draping the opposite breast over the corner of the bucky.
   (ix) Slightly rotating the patient's head away from the side being imaged.
   (x) Leaning the patient toward the machine with the head forward and around the tube.
   (xi) Placing an arm against the patient's back with a hand on the shoulder of the side being imaged, making sure the shoulder is relaxed.
   (xii) With a hand on the shoulder, sliding the skin up over the clavicle.
   (xiii) With the hand that is anchoring the breast pulling lateral tissue onto the image receptor tray, without losing medial tissue, while applying compression.
   (xiv) On the side being imaged, checking that the patient's arm is relaxed by her side with the shoulder externally rotated.

(c) Proper breast positioning for the medio-lateral oblique projection of the breast, including all of the following steps, unless other procedures are deemed appropriate and acceptable by the department:
   (i) Determining the proper image receptor size.
   (ii) Moving the photocell to the appropriate position.
   (iii) Determining the degree of obliquity parallel to the pectoral muscle.
   (iv) Rotating the C-arm so that the long edge of the bucky is parallel to the pectoral muscle.
   (v) Adjusting the height of the film tray so that the top is level with the axilla.
   (vi) Lifting the arm on the side to be imaged up and over the corner of the bucky.
   (vii) Placing the corner of the bucky in axilla, that is, anterior to the latissimus dorsi.
   (viii) Placing the patient's hand that is on the side being imaged on the C-arm, with the elbow flexed and the shoulder relaxed.
   (ix) Pulling the breast and muscle anteriorly and medially with the flat front surface of the hand.
   (x) Scooping the breast tissue up with the hand, grasping the lateral border of the breast with the fingers and the medial border of the breast with the thumb.
   (xi) Turning the patient toward the bucky making sure that the patient's feet are facing the machine.
   (xii) Centering the breast with the nipple in profile, if possible.
   (xiii) Holding the breast up and out by rotating the hand so that the base of the thumb supports the breast and so that the fingers are pointing away from the breast and continuing to hold the breast up and
Applying compression with the corner of the paddle below the clavicle.

Pulling down on the abdominal tissue to open the inframammary fold.

The use of appropriate compression.

Proper technique factor selection for the patient being x-rayed, including selecting the proper kVp-target-filter combination for the image receptor being used.

Proper maintenance of records, including examination identification information.

Familiarity with image processor quality assurance procedures and mammography machine quality assurance procedures that are applicable to the machine operator, including the use of a mammography phantom as a means of evaluating machine performance.

Knowledge of each of the following:

The American college of radiology accreditation status of the machine.

The most recent department inspection of the machine and regulatory inspection frequency.

The most recent consulting physicist evaluation of the mammography system and the frequency of those evaluations.

The radiation dose for an average patient.

The recent phantom image results for the machine being used.

The ability to produce acceptable clinical mammography images. Clinical images shall be evaluated on the basis of all of the following criteria:

Positioning.

Compression.

Optical density.

Sharpness.

Contrast.

Noise.

Exam identification.

Artifacts.

A machine operator performance evaluation shall be recorded on an evaluation form which includes all of the items described in subrule (2) of this rule and which contains all of the following information:

The names and signatures of the mammography supervisor and machine operator.

The date of the mammography examination for which the operator was evaluated.

Examination and x-ray image identification information.

The date the evaluation results were discussed with the operator.

The form shall also document that the operator has received a copy of the evaluation.

A mammography supervisor shall formally discuss the evaluation results with the operator within 10 days of observation. A copy of the evaluation form shall be given to the operator at the time the evaluation results are discussed.

If an individual fails to receive a satisfactory evaluation for any item specified in subrule (2) of this rule, the individual shall receive additional training pertaining to the deficient item and shall be reevaluated within 60 days of the original evaluation.

A facility shall maintain each evaluation form on permanent, available file for a period of not less than 7 years. Copies of the evaluation forms shall be forwarded to the department for review upon a written request by the department.

Upon termination of employment, an operator may request that a facility provide copies of the operator’s evaluation reports to the operator or to another designated individual. Upon written request, a facility shall provide evaluation reports to an employee or former employee for the 7-year period prior to the date of the request.

Operator performance testing is covered by the other operator training, education, and experience requirements.
Following are the quality standards for mammography, taken from the MQSA final regulations, Sec. 900.12 Quality standards. In cases where these standards and Michigan standards address the same area, any additional existing Michigan standards that are more stringent, but still needed, will be added and noted.

**MAMMOGRAPHY PERSONNEL**

R325.5621. Applicability.

**Rule 621.** Rules 622 through 624 apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities. Rule 622 does not apply to mammography performed using stereotactic breast biopsy or needle localization machines.

R325.5622. Interpreting physicians.

**Rule 622.** All physicians interpreting mammograms shall meet the following qualifications:

(a) **Initial qualifications.** Unless the exemption in paragraph (c) of this rule applies, before beginning to interpret mammograms independently, the interpreting physician shall:

(i) Be licensed to practice medicine in Michigan.

(ii) (1) Be certified in an appropriate specialty area by a body determined by the department to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or (2) have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of rule 622.

(iii) 3 years *(pending legislation change from 2 years)* after becoming eligible for board certification, all interpreting physicians must meet rule 622(a)(ii)(1).

(iv) Have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy.
pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution.

(v) Unless the exemption in Rule 622 (c)(ii) applies, have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

(b) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

(i) Following the second anniversary date of the end of the calendar quarter in which the requirements of Rule 622(a) were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility will choose one of these dates to determine the 24-month period.

(ii) Following the third anniversary date of the end of the calendar quarter in which the requirements of Rule 622(a) were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and

(iii) Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.
(iv) Units earned through teaching a specific course can be counted only once towards the 15 required by Rule 622(b)(ii), even if the course is taught multiple times during the previous 36 months.

(c) Exemptions.

(i) Those physicians who qualified as interpreting physicians prior to the effective date of these rules, are considered to have met the initial requirements of paragraph (a) of this rule. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(i) of this rule and the continuing experience and education requirements of paragraph (b) of this rule.

(ii) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(v) of this rule.

(d) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

(i) Interpreting physicians who fail to meet the continuing experience requirements of paragraph (b)(i) of this rule shall:

(A) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

(B) 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.

(C) The interpretations required under paragraph (d)(i)(A) or (d)(i)(B) of this rule shall be done within the 6 months immediately prior to resuming independent interpretation.

(ii) Interpreting physicians who fail to meet the continuing education requirements of paragraph (b)(ii) of this rule shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.
OPERATORS OF MAMMOGRAPHY EQUIPMENT

There is a question if old Rules 621 through 624 following are still needed or if we can remove them and use FDA wording.

R325.5621. Qualifications.

Rule 621. An individual, other than a physician, who operates a mammography machine shall meet all of the following qualifications:

(a) An individual who operates a mammography machine shall have successfully completed a radiography program that meets the standards for accrediting radiography programs adopted by the committee on allied health education and accreditation, or its successor, of the American medical association in cooperation with the joint review committee on education in radiologic technology, entitled "Essentials and Guidelines." (1990). These standards are adopted by reference in these rules. These standards are available from the Division of Radiological Health, Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195, Lansing, Michigan 48909, and from the American Medical Association, 515 North State Street, Chicago, Illinois 60610, at no charge at the time of adoption of this part. Accreditation of a radiography program by the committee on allied health education and accreditation of the American medical association in cooperation with the joint review committee on education in radiologic technology shall be prima facie evidence that the radiography program is in compliance with the standards adopted by reference in this subdivision.

(b) An individual who operates a mammography machine shall meet the standards for issuance of a registration certificate as a registered technologist from the American registry of radiologic technologists or meet the standards for issuance of a registration certificate as a radiography technologist from the American registry of clinical radiography technologists. These standards, entitled "Rules and Regulations," as revised in February, 1990, and "By-Laws," as revised in September, 1989, of the American registry of radiologic technologists and "Overview of the A.R.C.R.T. Organization," as revised in August, 1991, and "Application for Registration, Radiography Technologist," (1991), of the American registry of clinical radiography technologists, are adopted by reference in this rule. These standards are available from the Division of Radiological Health, Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195, Lansing, Michigan 48909, at no charge at the time of adoption of this part. The respective standards are also available from the American Registry of Radiologic Technologists, 1255 Northland Drive, Mendota Heights, Minnesota 55120, and from the American Registry of Clinical Radiography Technologists, 710 Higgins Road, Park Ridge, Illinois 60068, at no charge at the time of adoption of this part. A determination by the American registry of radiologic technologists or the American registry of clinical radiography technologists that an individual meets its respective standards for issuance of a registration certificate shall be prima facie evidence that the individual complies with the standards that are adopted by reference in this subdivision.

(c) Two years after the effective date of this part, shall have successfully completed a formal program of mammography instruction as prescribed by R325.5625.

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664, Lansing, Michigan 48909.]
R325.5622. Technologist exemptions.

Rule 622. (1) An individual who meets the standards of the American registry of radiologic technologists for its certificate of advanced qualification in mammography shall be exempt from the provisions of R325.5621(c). The standards, entitled "Handbook For Advanced Level Examinations," (November, 1991), are adopted by reference in this rule. These standards are available from the Division of Radiological Health, Michigan Department of Public Health, 3423 North Logan/Martin L. King Jr. Boulevard, P.O. Box 30195, Lansing, Michigan 48909, and from the American Registry of Radiologic Technologists, 1255 Northland Drive, Mendota Heights, Minnesota 55120, at no charge at the time of adoption of this part. A determination by the American registry of radiologic technologists that an individual meets the standards for issuance of a certificate of advanced qualification in mammography shall be prima facie evidence that an individual meets the standards adopted by reference in this subrule. However, the technologist shall be required to obtain continued education as prescribed by R325.5623 and meet performance requirements prescribed by R325.5619(2).

(2) Students in a radiography program that is in compliance with the requirements of R325.5621(a) shall be exempt from the provisions of R325.5621 while performing mammography within the context of the radiography program and under the direct supervision of a qualified mammography equipment operator. Registry eligible graduates of an accredited radiography program that is in compliance with the requirements of R325.5621(a) shall be exempt from the provisions of R325.5621(b) and (c) for 2 years after graduation.

[Note: As a result of Executive Orders 1996-1 and 1996-2, the authority, powers, duties, functions, and responsibilities of the radiation machine registration, licensing, and compliance program were transferred to the Michigan Department of Consumer & Industry Services. With respect to machine sources of ionizing radiation, any correspondence to the Michigan Department of Public Health should now be addressed to the Michigan Department of Consumer & Industry Services, BHS, Radiation Safety Section, P.O. Box 30664, Lansing, Michigan 48909.]

R325.5623. Continuing education.

Rule 623. An individual, other than a physician, who operates a mammography machine shall, every 3 years, obtain not less than 15 hours of continuing education in the technical aspects or clinical aspects, or both, of mammography and related subjects that is accredited by the American medical association or the American society of radiologic technologists or any other organizations acceptable to the department.

R325.5624. Operator prohibitions.

Rule 624. An individual, other than a physician, who operates a mammography machine shall not do any of the following:

(a) Perform mammography without the supervision of the mammography supervisor.

(b) Use a mammography machine without following standing orders and repeat film policies.

(c) Make a diagnosis based on any radiograph or image.

(d) Operate a mammography machine without having been trained to operate the mammography machine safely and effectively.

(e) Report any diagnosis to a patient, except as ordered by a licensed physician.

Moved to the technologist section.

R325.5625. Program of mammography instruction; topics.

Rule 625. A formal program of mammography instruction for operators of mammography equipment shall include all of the following topics:

(a) Anatomy and physiology of the female breast, including all of the following:

(i) Mammary glands.

(ii) External anatomy.

(iii) Subdivision for localization.

(iv) Retromammary space.
(v) Central portion.
(vi) Cooper's or suspensory ligament.
(vii) Vessels, nerves, and lymphatics.
(viii) Breast tissue.

(b) Classification of breast tissue, including all of the following types of tissue:
(i) Fibro-glandular.
(ii) Fibro-fatty.
(iii) Fatty.
(iv) Lactating.

(c) Epidemiology of breast cancer, breast cancer detection methods, and information sources.

(d) Influence of technical factors.

(e) Positioning of the breast, including all of the following:
(i) Cranio-caudal.
(ii) Medio-lateral oblique.
(iii) Axillary.
(iv) Magnification.
(v) Errors in positioning.

(vi) Special techniques for mammography for the postoperative breast and the augmented breast.

(vii) Special radiographic techniques for breast localization and specimen radiography.

(viii) Special techniques for additional mammography projections.

(f) Film or image evaluation and critique, including all of the following:
(i) Optimum mammographic images, including all of the following:
(A) Radiographic density.
(B) Radiographic contrast.
(C) Definition.
(D) Distortion.
(E) Positioning.
(ii) Detection of pathology.
(iii) Benign and malignant lesions.
(iv) Mass lesion borders as smooth, irregular, or with calcification.

(g) Radiation biology and radiation protection.

(h) Quality assurance.

R325.5623. Radiologic technologists.

Rule 623 All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(a) General requirements. Have general certification from the American Registry of Radiologic Technologists or one of the bodies determined by the department to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations.

(b) Mammography requirements. Have, prior to the effective date of these rules, qualified as a radiologic technologist under Part 14 of the previous rules, or completed at least 40 contact hours of
documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(i) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants.

(ii) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under Rule 623.

(iii) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams.

(c) Continuing education requirements.

(i) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a) and (b) of this rule were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(ii) Units earned through teaching a specific course can be counted only once towards the 15 required in paragraph (d)(i) of this rule, even if the course is taught multiple times during the previous 36 months.

(iii) At least six of the continuing education units required in paragraph (d)(i) of this rule shall be related to each mammographic modality used by the technologist.

(iv) Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (d)(i) of this rule shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.
(v) Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (b)(iii) of this rule, the technologist shall have at least 8 hours of continuing education units in the new modality.

(d) Continuing experience requirements.

(i) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a) and (b) of this rule were completed or of the effective date of these rules, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

(ii) Requalification. Radiologic technologists who fail to meet the continuing experience requirements of paragraph (e) of this rule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

Rule 624. An individual, other than a physician, who operates a mammography machine shall not do any of the following:

(a) Perform mammography without the supervision of the mammography supervisor.

(b) Use a mammography machine without following standing orders and repeat film policies.

(c) Make a diagnosis based on any radiograph or image.

(d) Operate a mammography machine without having been trained to operate the mammography machine safely and effectively.

(e) Report any diagnosis to a patient, except as ordered by a licensed physician.
Rule 631.  (1) A radiation physicist shall be certified in diagnostic or radiological physics by the American board of radiology or the American board of medical physics or shall meet equivalent requirements, as determined by the department, to be qualified to provide on-site consultation and evaluation of mammography systems to mammography facilities.

(2) “Equivalent requirements,” as used in subrule (1) of this rule, means that all of the following factors have been satisfied:

(a) The radiation physicist possesses either of the following:
   (i) A bachelor’s degree in physics or applied physics or in a physical science with the equivalent of a physics minor and, in addition, 11 years of work experience in diagnostic radiological physics.
   (ii) A masters or doctoral degree in medical physics or physics or in a physical science with the equivalent of a physics minor and, in addition, 3 years of work experience in diagnostic radiological physics.

(b) Work experience in diagnostic radiological physics shall have been performed under the supervision of a certified diagnostic or radiological physicist or a radiologist who is certified by the American board of radiology or the American osteopathic board of radiology.

(c) References have been provided listing the names of a physician certified in radiology and a physicist who is certified in diagnostic or radiological physics, 1 of whom has directed the individual’s training specified in subdivision (b) of this subrule.

(3) To be qualified to provide on-site consultation and evaluation of mammography systems to mammography facilities, a radiation physicist shall meet all of the following requirements on a continuing basis in addition to the requirements specified in subrule (1) or (2) of this rule:

(a) Submit evidence, acceptable to the department, of formal training or experience in medical physics and in the evaluation of mammography systems.

(b) Demonstrate competence in performing, recording, and interpreting the results of required quality control checks.

(c) Submit a sample of a mammography evaluation report, or the contents of a report, to the department for approval.

(d) Have appropriate testing equipment available to perform the medical physics quality control checks required by R325.5632(3).

(4) In evaluating the qualifications pursuant to this rule, the department shall establish an advisory committee of qualified mammography physicists to evaluate the submitted credentials. The department may rely on their expert evaluation in arriving at a department decision regarding the acceptability of the individual's qualifications.

R325.5632. Mammography system evaluation.

Rule 632.  (1) At least annually, each mammography facility shall have a qualified radiation physicist provide an on-site consultation to the facility, including a complete evaluation of the entire mammography system to ensure compliance with the provisions of the act and the rules promulgated under the act. This evaluation of the mammography system shall be in addition to the annual regulatory inspection that is conducted by the department as prescribed by R325.5603.

(2) The mammography facility shall make and document appropriate corrections to any item found during the annual mammography system evaluation by a radiation physicist that does not meet the requirements of these rules.

(3) The items to be inspected and evaluated during on-site consultations shall include all of the following:

(a) Mammography machine performance to determine compliance with the provisions of R325.5637 to R325.5652.

(b) Measurement of skin exposure for a cranio-caudal view for a 4.5-centimeter compressed breast that is composed of 50% glandular and 50% adipose tissue. For equipment that has an automatic exposure control, the measurement shall be made with a mammography phantom which has a serial numbered wax...
insert and which is used in the American college of radiology accreditation program or a phantom that is
deemed to be equivalent by the department in the x-ray beam.

(c) Calculation of the average or mean glandular dose per cranio-caudal view of a 4.5-centimeter
compressed breast that is composed of 50% glandular and 50% adipose tissue. The mean glandular dose
shall not be more than any of the values specified in R325.5661.

(d) Evaluation of an image of a mammography phantom which has a serial numbered wax insert and
which is used in the American college of radiology accreditation program, or an alternate phantom that is
approved by the department, using exposure techniques for a cranio-caudal view of a 4.5-centimeter
compressed breast that is composed of 50% glandular and 50% adipose tissue. The image of the
mammography phantom shall be in compliance with the criteria prescribed by R325.5660.

(e) Measurement of the equivalent focal spot resolution, both parallel and perpendicular to the anode-
cathode axis with a focal spot test device.

(f) Evaluation of the performance of the automatic exposure control system with regard to all of the
following:

(i) Reproducibility.

(ii) Performance capability, including kilovoltage and thickness compensation.

(iii) Density control function.

(g) Evaluation of the darkroom for integrity and safelight conditions.

(h) Review of the film processing quality control records, including all of the following:

(i) Medium density.

(ii) Density difference.

(iii) Base plus fog.

(iv) Developer temperature.

(i) For screen-film mammography, evaluation of the uniformity of the radiographic speed of each
cassette-screen that is normally used for mammography. For each cassette-screen of a given class of
screen speed, the ratio of the optical density of a test image to the average optical density of the test images
shall fall within the range of 0.9 to 1.1.

R325.5633. Records of on-site evaluations and consultations.

Rule 633. Records of on-site evaluations and consultations shall be provided and maintained in
accordance with both of the following provisions:

(a) Records of evaluations and consultations performed pursuant to the provisions of
R325.5605(e) shall be provided to the mammography facility. The records shall be provided within 30 days
after completion of the evaluation and consultation. The records shall clearly indicate all of the following
information:

(i) The tests, evaluations, and consultations performed and the date these occurred.

(ii) The name of the person or persons who performed the tests, evaluations, and consultations.

(iii) The results of the tests, evaluations, and consultations.

(iv) The testing equipment used, including the date of the last calibration of radiation detection
equipment or cross-calibration to a calibrated instrument.

The records shall be in a format that is approved by the department. These records shall be maintained
by the mammography facility for not less than 7 years.

(b) Copies of records that are provided to mammography facilities shall also be maintained by the person
who performed the tests, evaluations, and consultations. These records shall be maintained for not less
than 7 years. Copies of the records shall be made available for examination by the department and, if
requested in writing by the department, copies shall be forwarded to the department within 30 days of the
written request.

Above physicist requirements are now covered by the modified MQSA final regulations as noted below.

R325.5624. Medical physicists.

Rule 624. All medical physicists conducting surveys of mammography facilities and providing oversight
of the facility quality assurance program under paragraph (e) of this section Rules 660(c), 662(9), and 662(10) shall meet the following:

(a) Initial qualifications.

(i) Certification. Have been approved by the department prior to [the effective date of the rules] or have certification in an appropriate specialty area by one of the bodies determined by the department to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey.

(ii) Education and experience. 

(A) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics.

(B) Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities.

(C) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After the effective date of these rules, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a) and (c) of this rule.

Alternative initial qualifications were not adopted from the MQSA regulations.

(b) Continuing qualifications.

(i) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a) or (b) of this rule were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility’s annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to
each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of
quality assurance programs. Units earned through teaching a specific course can be counted only once
towards the required 15 units in a 36-month period, even if the course is taught multiple times during the
36 months.

(ii) Continuing experience. Following the second anniversary date of the end of the calendar
quarter in which the requirements of paragraph (a) or (b) of this rule were completed or of the effective
date of these rules, whichever is later, the medical physicist shall have surveyed at least two
mammography facilities and a total of at least six mammography units during the 24 months immediately
preceding the date of the facility’s annual inspection or the last day of the calendar quarter preceding the
inspection or any date in-between the two. The facility shall choose one of these dates to determine the
24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit
within a period of 60 days can be counted towards this requirement.

(iii) Before a medical physicist may begin independently performing mammographic surveys of a
new mammographic modality, that is, a mammographic modality other than one for which the physicist
received training to qualify under paragraph (a) or (b) of this rule, the physicist must receive at least 8
hours of training in surveying units of the new mammographic modality.

(c) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing
qualifications of paragraph (c) of this rule may not perform the surveys without the supervision of a qualified
medical physicist. Before independently surveying another facility, medical physicists must reestablish their
qualifications, as follows:

(i) Medical physicists who fail to meet the continuing educational requirements of paragraph
(c)(i) of this rule shall obtain a sufficient number of continuing education units to bring their total units up to
the required 15 in the previous 3 years.

(ii) Medical physicists who fail to meet the continuing experience requirement of paragraph (c)(ii)
of this section shall complete a sufficient number of surveys under the direct supervision of a medical
physicist who meets the qualifications of paragraphs (a) and (c) of this section to bring their total surveys
up to the required two facilities and six units in the previous 24 months. No more than one survey of a
specific unit within a period of 60 days can be counted towards the total mammography unit survey
requirement.

(c) State Approval. To be qualified to provide on-site consultation and evaluation of
mammography systems to mammography facilities, a radiation physicist shall meet all of the following
requirements on a continuing basis in addition to the requirements specified in subrule (a) through (d)
of this rule:

(i) Submit evidence, acceptable to the department, of formal training or experience in medical
physics and in the evaluation of mammography systems. Meet the initial qualification requirements of rule
624.

(ii) Demonstrate competence in performing, recording, and interpreting the results of required quality
control checks.

(iii) Submit a sample of a mammography evaluation report, or the contents of a report, to the
department for approval.

(iv) Have appropriate testing equipment available to perform the medical physics quality control
checks required by Rule 662(9&10)

(d) Credential Advisory Committee. In evaluating the qualifications pursuant to this rule, the
department shall establish an advisory committee of qualified mammography physicists to evaluate the
submitted credentials. The department may rely on their expert evaluation in arriving at a department
decision regarding the acceptability of the individual's qualifications.

(d) and (e) are kept from the old rules.

R325.5625. Retention of personnel records.

Facilities shall maintain records to document the qualifications of all personnel who
worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These
records must be available for review by the inspectors. Records of personnel no longer employed by the
facility should not be discarded until the next annual inspection has been completed and the department
has determined that the facility is in compliance with the personnel requirements.
Most of the equipment requirements from the old rules are now covered under the MQSA equipment and annual equipment QC requirements to follow. Rules that are kept from this section are noted accordingly.

R325.5637. Compliance with provisions of R325.5325; machine design.

Rule 637. (1) The mammographic x-ray equipment shall
be in compliance with the requirements of R325.5325(1) and (17) to (23).

(2) The machine that is used for mammography shall be a radiation machine that is specifically designed
to perform mammography.


Rule 638. (1) Mammography machines shall generate a high-frequency, constant-potential, 3-phase, or
equivalent output.

(2) Mammography machines shall be capable of an output at 28 kilovolts of not less than 500
milliroentgens per second at breast entrance for a 4.5-centimeter compressed breast with the compression
plate in the beam for any mammographic technique that is used other than for magnification techniques.

R 325.5639. Accuracy of technique factors.

Rule 639. (1) The deviation of peak tube potential from indicated values shall not be more than 5% in the
useful mammographic range. The coefficient of variation for peak tube potential reproducibility shall not be
more than 5%, and a determination of compliance shall be based on not less than 4 consecutive
measurements.

(2) For machines with timer controls, the deviation of exposure time from indicated values shall not be
more than 5% for exposures that are more than 100 milliseconds and shall not deviate more than 10
milliseconds for shorter exposure times. The coefficient of variation for exposure timer reproducibility shall not
be more than 5% and a determination of compliance shall be based on not less than 4 consecutive
measurements.

R325.5640. Permissible degree of coefficient of variation of radiation exposure for combination of
selected technique factors.

Rule 640. For any specific combination of selected technique factors, the coefficient of variation of
radiation exposures shall be not greater than 5%. A determination of compliance shall be based on not less
than 4 consecutive measurements.

R325.5641. Permissible difference in average ratios of exposure to indicated milliampere-seconds
product obtained at 2 consecutive settings.

Rule 641. The average ratios of exposure to the indicated milliampere-seconds product, or mR/mAs,
obtained at any 2 consecutive mA or mAs settings shall not differ by more than 0.10 times their sum. That is:
\[ X_1 - X_2 \leq 0.10 \times (X_1 + X_2) \], where \( X_1 \) and \( X_2 \) are the average mR/mAs values that are obtained at each of 2
consecutive mA or mAs settings.

Rule 641 inserted into annual equipment QC requirements below.

R325.5642. Target and filter material.
Rule 642. (1) For screen-film mammography, the target material of the x-ray tube shall be molybdenum with molybdenum filtration and a beryllium window. Exceptions may be granted for other combinations if beam quality, imaging capabilities, and patient dose are consistent with the requirements of this part.

(2) For xeromammography, the target material of the x-ray tube shall be tungsten with aluminum filtration. Exceptions may be granted for other combinations if beam quality, imaging capabilities, and patient dose are consistent with the requirements of this part.

R325.5643. Nominal focal spot size.

Rule 643. (1) The nominal focal spot size of any available focal spot shall not be more than any of the following values:
(a) 0.6 at a source-image receptor distance of 80 centimeters or more.
(b) 0.5 at a source-image receptor distance of 65 to 79 centimeters.
(c) 0.4 at a source-image receptor distance of 50 to 64 centimeters.

(2) The focal spot dimensions, both parallel and perpendicular to the anode-cathode axis, shall be in compliance with vendor-provided specifications and national electrical manufacturers association specifications.

R325.5644. Half-value layer.

Rule 644. (1) The half-value layer for a screen-film system at a measured tube potential of 30 kilovolts shall not be less than 0.30 millimeter of aluminum and shall not be more than 0.42 millimeter of aluminum. It is recommended that the half-value layer be not more than 0.40 millimeter of aluminum at a measured tube potential of 30 kilovolts. The half-value layer shall be measured with the compression device in the x-ray beam.

(2) The half-value layer for xeromammography shall not be less than 1.0 millimeter of aluminum and shall not be more than 2.0 millimeters of aluminum at the clinically employed peak tube potential.

(3) Positive means shall be provided to insure that the minimum filtration that is needed to achieve the beam quality requirements set forth in this rule is in the useful beam during each exposure.

R325.5645. Focal spot to image receptor distance.

Rule 645. The focal spot to image receptor distance shall not be less than 50 centimeters.

R325.5646. Machine design; x-ray beam geometry.

Rule 646. A mammography machine shall be designed so that the plane of the useful beam that is adjacent to the chest wall is parallel to the chest wall and is perpendicular to the plane of the image receptor for all cassette sizes.

R325.5647. Reciprocating grid capability; grid ratio; exception; grid lines.

Rule 647. (1) Each mammography machine that is used for screen-film mammography shall be capable of using a reciprocating grid for each available film size. The grid ratio shall be less than or equal to 5:1. Exceptions may be granted for ratios higher than 5:1 if imaging capabilities and patient dose are consistent with these rules.

(2) Grid lines shall not be apparent on clinical or mammography phantom images.

Added to annual QC requirements below.
R325.5648. Image receptor capability.

Rule 648. Each location or address where screen-film mammography is performed shall have the capability of using both an 18 by 24-centimeter image receptor and a 24 by 30-centimeter image receptor.

R325.5649. Beam limiting device.

Rule 649. Each mammography machine shall have a means to limit the useful beam so 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 source-image receptor distance (SID) other than the edge of the image receptor that is designed to be adjacent to the chest wall. The x-ray field shall not extend beyond the edge of the image receptor that is designed to be adjacent to the chest wall by more than 2% of the SID. Each fixed aperture, beam-limiting device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed. For systems that are equipped with a light localizer, the light field shall be aligned with the x-ray field to within 2% of the SID.

R325.5650. Compression device.

Rule 650. Each mammography machine shall have a compression device. For screen-film mammography, the compression device shall be of the flat plate type. For xeromammography, a contoured compression paddle may be used and balloons shall not be used for compression.

R325.5651. Primary beam transmission through the image receptor support.

Rule 651. The transmission of the primary beam through any image receptor support provided with the system shall be limited so that the exposure 5 centimeters from any accessible surface of the supporting device beyond the plane of the image receptor is not more than 0.1 milliroentgen for each activation of the tube. Exposure shall be measured with the system operated at the minimum source-image receptor distance for which it is designed. Compliance shall be determined at the maximum peak tube potential clinically employed for the system and extrapolated to the maximum rated product of the tube current and exposure time for that peak tube potential.

Moved to equipment requirements below.

R325.5652. Automatic exposure control system.

Rule 652. (1) Each screen-film mammography machine shall be provided with an automatic exposure control system.

(2) The automatic exposure control system for screen-film mammography shall provide a coefficient of variation that is not more than 5% for exposure or image optical density. A determination of compliance shall be based on not less than 4 consecutive measurements with 4 centimeters of acrylic or BR-12 attenuator in the beam.

(3) One year after the effective date of this part, the automatic exposure control system for screen-film mammography shall maintain image optical density to within plus or minus 0.30 of the average as the kilovoltage is varied within the clinically employed range and as attenuator thickness is varied from 2 centimeters to 6 centimeters for each clinically employed kilovoltage. Two years after the effective date of this part, the automatic exposure control system shall maintain image optical density to within plus or minus 0.20 of the average as the kilovoltage is varied within the clinically employed range and as attenuator thickness is varied from 2 centimeters to 6 centimeters for each clinically employed kilovoltage. Compliance with this subrule is not required for specific attenuator thickness/kilovoltage combinations if, during the test with those attenuator thickness/kilovoltage combinations, the maximum automatically controlled exposure limit is reached, causing the test films to have an optical density lower than the standard. The attenuator that is used for determining compliance shall be either acrylic or BR-12 material.

(4) The automatic exposure control system for screen-film mammography shall limit the maximum
automatically controlled exposure to 750 milliampere-seconds.

Moved to draft rule 642(4).

(5) One year after the effective date of this part, each mammography machine shall indicate, or provide the means of determining, the milliampere-seconds resulting from each exposure made with the automatic exposure control.

R325.5655. Enclosure requirements.

Rule 655. (1) An x-ray equipment enclosure shall be in compliance with the requirements of R325.5331.

(2) For mammography, the operator’s barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum potential is limited electrically or mechanically to less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum potential is more than 35 kilovolts.

Enclosure requirements moved to Rule 648.

R325.5656. Operation requirements.

Rule 656. (1) The operation of each mammography x-ray machine shall be in compliance with the requirements of R325.5333.

(2) Mammograms shall be retained for not less than 7 years or shall be given to another person for placement in the patient’s medical record as directed by the patient or the primary care provider.

X-RAY EQUIPMENT

R325.5630. Compliance with provisions of R325.5325; machine design.

Rule 630. The mammographic x-ray equipment shall be in compliance with the requirements of R325.5325(1) and (17) to (23) (or appropriate numbering after update – general equipment requirements).

MQSA final regulations equipment standards and quality assurance standards are inserted below. Additions or changes based on current state regulations that are not addressed by MQSA are noted.

R325.5631. Prohibited equipment.

Rule 631. (1) Radiographic equipment designed for general purpose or special nonmammography
procedures shall not be used for mammography. This prohibition includes systems that have been
modified or equipped with special attachments for mammography. This requirement supersedes the
implied acceptance of such systems in \((\text{Sec. 1020.31(f)(3) of this chapter?})\).

(2) General. All radiographic equipment used for mammography shall be specifically designed for
mammography.

R325.5632. Primary beam transmission through the image receptor support.

Rule 632. The transmission of the primary beam through any image receptor support provided with the
system shall be limited so that the exposure 5 centimeters from any accessible surface of the supporting
device beyond the plane of the image receptor is not more than 0.1 milliroentgen for each activation of the
tube. Exposure shall be measured with the system operated at the minimum source-image receptor distance
for which it is designed. Compliance shall be determined at the maximum peak tube potential clinically
employed for the system and extrapolated to the maximum rated product of the tube current and exposure
time for that peak tube potential.

Moved from old rules.

R325.5633. Motion of tube-image receptor assembly.

Rule 633 (1) The assembly shall be capable of being fixed in any position where it is designed to
operate. Once fixed in any such position, it shall not undergo unintended motion.

(2) The mechanism ensuring compliance with paragraph \(b)(3)(i)\) Rule 635(1) of this section shall not
fail in the event of power interruption.

R325.5634. Image receptor sizes.

Rule 634 (1) Systems using screen-film image receptors shall provide, at a minimum, for operation with
image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.
2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

(4) Stereotactic breast biopsy and needle localization machines are exempt from this rule.

R325.5635. Light fields.

Rule 635. For any mammography system with a light beam that passes through the x-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

R325.5636. Magnification.

Rule 636. (1) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

(3) Stereotactic breast biopsy and needle localization machines are exempt from this rule.

R325.5637. Focal spot selection.
Rule 637.  (1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(3) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

R325.5638. Compression.

Rule 638.  (1) All mammography systems shall incorporate a compression device.

(2) Application of compression. Each system shall provide:

(a) An initial power-driven compression activated by hands-free controls operable from both sides of the patient.

(b) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for “spot compression”) may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) Rules 640(5&6) and (b)(8)(ii)(E) of this section.

(4) Except as provided in paragraph (b)(8)(ii)(C) of this section Rule 640(4), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.
(5) Equipment intended by the manufacturer’s design to not be flat and parallel to the breast support
table during compression shall meet the manufacturer’s design specifications and maintenance
requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the
image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the
image.

R325.5639. Technique factor selection and display.

Rule 639  (1) Manual selection of milliampere seconds (mAs) or at least one of its component parts
(milliampere (mA) and/or time) shall be available.

(2) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and
exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an
exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC)
are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(3) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs
used during the exposure. The mAs may be displayed as mA and time.

R325.5640. Automatic exposure control.
Rule 640. (1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

(a) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

(b) The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

(4) The automatic exposure control system for screen-film mammography shall limit the maximum automatically controlled exposure to 750 milliampere-seconds.

Old Rule 652(4) moved here.

R325.5641. X-ray film.

Rule 641. The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

R325.5642. Intensifying screens.

Rule 642. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.
R325.5643. Film processing solutions.

**Rule 643.** For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

R325.5644. Lighting.

**Rule 644.** The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

R325.5645. Film masking devices.

**Rule 645.** Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

R325.565546. Enclosure requirements.

**Rule 6546. (1)** An x-ray equipment enclosure shall be in compliance with the requirements of R325.5331. (or appropriate numbering after update)

**Rule 6546. (2)** For mammography, the operator’s barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum potential is limited electrically or mechanically to less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum potential is more than 35 kilovolts.

Enclosure requirements moved and re-numbered here from old rules.
R325.565647. Operation requirements.

Rule 6547 (1) The operation of each mammography x-ray machine shall be in compliance with the requirements of R325.5333 (or appropriate numbering after update).

The following section on records and reports has been added from the MQSA requirements.

MEDICAL RECORDS AND MAMMOGRAPHY REPORTS

R325.5652. Contents and terminology.

Rule 652. Each facility shall prepare a written report of the results of each mammography examination performed under its authorization. The mammography report shall include the following information:

(a) The name of the patient and an additional patient identifier.

(b) Date of examination.

(c) The name of the interpreting physician who interpreted the mammogram.

(d) Overall final assessment of findings, classified in one of the following categories:

(i) **"Negative:"** Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

(ii) **"Benign:"** Also a negative assessment;

(iii) **"Probably Benign:"** Finding(s) has a high probability of being benign;

(iv) **"Suspicious:"** Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(v) **"Highly suggestive of malignancy:"** Finding(s) has a high probability of being malignant;

(e) In cases where no final assessment category can be assigned due to incomplete work-up, **"Incomplete: Need additional imaging evaluation"** shall be assigned as an assessment and reasons
why no assessment can be made shall be stated by the interpreting physician; and

(f) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

R325.5653. Communication of mammography results to the patients.

Rule 653. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are “Suspicious” or “Highly suggestive of malignancy,” the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(a) Patients who do not name a health care provider to receive the mammography report shall be sent the report described in Rule 652 within 30 days, in addition to the written notification of results in lay terms.

(b) Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

R325.5654. Communication of mammography results to health care providers.

Rule 654. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(a) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section Rule 652, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and

(b) If the assessment is “Suspicious” or “Highly suggestive of malignancy,” make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.
R325.5655. Recordkeeping.

Rule 655. Each facility that performs mammograms:

(a) Shall (except as provided in paragraph (c)(4)(ii) of this section Rule 655(b)) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility; and

(b) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

(c) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section Rule 655(b) shall not exceed the documented costs associated with this service.

R325.5656. Mammographic image identification.

Rule 656. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(a) Name of patient and an additional patient identifier.

(b) Date of examination.

(c) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body shall be used to identify view and laterality.

(d) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(e) Technologist identification.

(f) Cassette/screen identification.

(g) Mammography unit identification, if there is more than one unit in the facility.

R325.5657. Stereotactic breast biopsy and needle localization exemptions.
Rule 657. Stereotactic breast biopsy and needle localization procedures are exempt from Rules 652 through 655.

The following quality control section is deleted and replaced by FDA MQSA quality assurance requirements with the exception of the dose limit as noted below.

QUALITY CONTROL

R325.5659. Quality control responsibilities of supervisor; establishment of quality assurance manual; provision of mammography phantom; submission of phantom images.

Rule 659. (1) A mammography supervisor shall be responsible for maintaining a quality control program and for insuring the standardization of quality control methodology. This responsibility may be delegated to a quality control technologist, although the mammography supervisor shall be ultimately responsible.

(2) A mammography facility shall establish a written quality assurance manual, which shall include all of the following:

(a) The quality control tests to be performed.
(b) The frequency of each quality control test.
(c) The forms to be used to record the results of the quality control tests.
(d) The limits of acceptability of each quality control test.
(e) A protocol for making corrections when a quality control test does not fall within the limits of acceptability.

The quality assurance manual shall be available at the facility for examination by the department.

(3) The owner or person who is in control of mammography x-ray equipment shall provide a mammography phantom at each location or address where mammography is performed. The phantom shall be a mammography phantom which has a serial numbered wax insert and which is used in the American college of radiology accreditation program or any other phantom that is deemed appropriate and acceptable by the department.

(4) Upon written request by the department, a mammography facility shall, for each of its mammography x-ray machines, submit to the department an x-ray image of a mammography phantom which has a serial numbered wax insert and which is used in the American college of radiology accreditation program or other department-approved phantom taken at routine machine settings used for a 4.5-centimeter compressed breast that is composed of 50% glandular and 50% adipose tissue. For each phantom image that is submitted to the department, the facility shall specify all of the following information:

(a) The serial number of the phantom.
(b) The registration number of the x-ray machine.
(c) The machine settings used, such as kilovoltage, milliamperage, time, and density setting.
(d) The type of x-ray film and intensifying screens used.

R325.5660. Phantom image quality.

Rule 660. The quality of an image of a mammography phantom which has a serial numbered wax insert
and which is used in the American college of radiology accreditation program, or other department-approved phantom, taken at clinically employed machine settings for a 4.5-centimeter compressed breast that is composed of 50% glandular and 50% adipose tissue, shall be in compliance with all of the following criteria as determined by the department:

(a) Each fibril down to and including the 0.75-millimeter fibril shall be visualized.

(b) Each mass down to and including the 0.75-millimeter thick mass shall be visualized.

(c) All specks in each group down to and including the 0.32-millimeter speck group shall be visualized.

R325.5661. Radiation dose limits.

Rule 661. The mean glandular dose for a cranio-caudal view of a 4.5-centimeter compressed breast that is composed of 50% glandular and 50% adipose tissue shall not be more than any of the following values:

(a) Screen-film without grid: 100 millirads per view.

(b) Screen-film with grid: 200 millirads per view.

(c) Xeromammography: 400 millirads per view.

R325.5662. Screen-film processor adjustment.

Rule 662. A processor for screen-film mammography shall be adjusted to optimize image quality.

R325.5663. Mammography phantom imaging required; corrective action; phantom imaging for mobile units; repeat analysis; compression check.

Rule 663. (1) A mammography phantom which has a serial numbered wax insert and which is used in the American college of radiology accreditation program, or other department-approved phantom, shall be imaged at least monthly at machine settings that are normally used for an average patient with 4.5-centimeter compressed breasts that are composed of 50% glandular and 50% adipose tissue. The facility shall maintain an available file of such images for inspection by the department and for comparison with earlier images to note changes in image quality. If the phantom image does not meet the criteria prescribed by R325.5660, corrective action shall be taken. After corrective action and before the machine is used on a patient, an additional phantom image shall be obtained to demonstrate compliance with R325.5660. Each operator of mammography equipment shall also be familiar with phantom imaging procedures and the use of the phantom as a method of evaluating machine performance.

(2) After each relocation of a mobile unit or transportable van, and before the machine is used on a patient, a mammography phantom image, at machine settings that are normally used for an average patient with 4.5-centimeter compressed breasts that are composed of 50% glandular and 50% adipose tissue, shall be made for comparison with earlier images to assure the proper functioning of the mammography system. The resultant milliampere-seconds shall be recorded and compared with the mean milliampere-seconds determined from the most recent exposure reproducibility test of the automatic exposure control system. The facility shall maintain an available file of the images for inspection by the department and for comparison with earlier data to note changes in mammography system performance. Mammograms and phantom images shall be processed within 24 hours of being obtained. If the phantom images do not meet the criteria prescribed by R325.5660 or if the resultant milliampere-seconds is not within plus or minus 15% of the mean milliampere-seconds determined from the most recent exposure reproducibility test of the automatic exposure control system, corrective action shall be taken.

(3) A repeat analysis shall be performed at least quarterly, or, for low volume practices, after 250 patients, by comparing the number of rejected or repeated films to the total number of films that were used during the test period.

(4) Compression in the manual and powered modes shall be checked at least semiannually. The maximum compression force shall be not less than 25 pounds nor more than 40 pounds in the power drive mode.

R325.5664. Screen-film mammography quality control.
Rule 664. All of the following quality control procedures for screen-film mammography shall be performed at the indicated intervals and when components are initially placed into service, when problems are suspected, or after service or preventive maintenance:

(a) The darkroom that is used for mammography shall be cleaned each operational day before processing or handling any films.

(b) A facility shall have a sensitometer, densitometer, non-mercury thermometer, and control charts or computerized control charts readily available to perform and record the required processor quality control tests. The control film shall be of the same type that is used in mammography.

(c) A facility shall conduct processor quality control tests at the beginning of each operational day before processing any patient films. The tests shall include measuring and plotting all of the following data points:

(i) Medium density, which is the optical density of a particular step on the sensitometric step wedge, which is determined during the establishment of processor quality control operating levels, and which has an average density closest to 1.20.

(ii) Density difference, which is the difference in optical density between 2 consistently chosen sensitometric steps. These steps, which are determined during the establishment of processor quality control operating levels, shall be the step that has a density closest to 2.20 and the step that has a density closest to, but not less than, 0.45.

(iii) Base plus fog, which is the optical density from the unexposed area of the sensitometric film.

(iv) Developer temperature.

(d) Processor quality control operating levels for medium density, density difference, and base plus fog shall be determined over not less than 5 consecutive days after the processor is cleaned. Developer temperature shall be set at the temperature that is specified in the film manufacturer’s written literature.

(e) The medium density and density difference shall be within plus or minus 0.10 of their respective operating levels, and the base plus fog shall be within plus or minus 0.03 of its operating level. If the medium density or density difference falls outside of the plus or minus 0.10 control limits, but is within plus or minus 0.15, the test shall be repeated immediately. If the same result is obtained, it shall be acceptable to process clinical films, but the processor shall be monitored closely. If the medium density or density difference exceeds the control limits of plus or minus 0.15, the source of the problem shall be determined and corrected before clinical mammograms are processed in that processor. If the base plus fog exceeds the control limit of plus or minus 0.03, immediate corrective action shall be taken before clinical mammograms are processed.

(f) The processor crossover rollers shall be cleaned each operational day.

(g) Mammography intensifying screens shall be cleaned at least weekly using the manufacturer’s recommended materials and procedures. The outside of film cassettes shall be checked or cleaned at least monthly.

(h) Mammography darkroom fog shall be checked semiannually, when safelight filters or bulbs are changed, or when fog is suspected. Film that is exposed to visible light with a sensitometer and then exposed for 2 minutes in the darkroom shall not produce more than a 0.05 density increase in the mid-density of 1.30 to 1.40 optical density portion of the sensitometric strip.

(i) Mammography screen-film contact shall be checked semiannually.

R325.5665. Xeromammography; plate management system.

Rule 665. (1) Each facility that utilizes xeromammography shall maintain a plate management system to track suspected plate artifacts. If an artifact is observed on an image, the facility shall record the serial number of the suspect plate, the type of artifact, and the date of observance of the artifact. The suspect plate shall be cycled through the system for reevaluation or removed from service. If on reevaluation the artifact is determined to be reproducible and to be significant enough to affect diagnostic quality, that plate shall be removed from service.

(2) Dark dusting of each newly installed plate shall be performed before the plate is put into service to evaluate the plate for artifacts. Dark dusting means processing a charged plate without exposing the plate. If artifacts that would affect diagnostic quality are noted, the plate that has the noted artifacts shall not be put into service.
service.

(3) If artifacts are observed that are not plate-related, the source of the problem shall be determined and corrected.

FDA MQSA quality assurance requirements:

QUALITY ASSURANCE

R325.5659. Quality assurance--general.

Rule 659. (1) Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

(2) A mammography facility shall establish a written quality assurance manual, which shall include all of the following:

(a) The quality control tests to be performed.

(b) The frequency of each quality control test.

(c) The forms to be used to record the results of the quality control tests.

(d) The limits of acceptability of each quality control test.

(e) A protocol for making corrections when a quality control test does not fall within the limits of acceptability.

The quality assurance manual shall be available at the facility for examination by the department.

Old Rule 659(2) inserted here.

R325.5660. Responsible individuals.

Rule 660. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(a) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have
the general responsibility of ensuring that the quality assurance program meets all requirements of
paragraphs (d) through (f) of this section Rules 659 through 663. No other individual shall be assigned
or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has
determined that the individual's qualifications for, and performance of, the assignment are adequate.

(b) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

(i) Follow the facility procedures for corrective action when the images they are asked to
interpret are of poor quality, and

(ii) Participate in the facility's medical outcomes audit program.

(c) Medical physicist. Each facility shall have the services of a medical physicist available to survey
mammography equipment and oversee the equipment-related quality assurance practices of the facility.
At a minimum, the medical physicist(s) shall be responsible for performing the surveys and
mammography equipment evaluations and providing the facility with the reports described in paragraphs
(e)(9) and (e)(10) of this section Rules 662(9&10).

(d) Quality control technologist. Responsibility for all individual tasks within the quality assurance
program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a
quality control technologist(s). The tasks are to be performed by the quality control technologist or by
other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the
quality control technologist shall ensure that the tasks are completed in such a way as to meet the
requirements of paragraph (e) of this section Rule 662.

R325.5661. Quality assurance records.

Rule 661. The lead interpreting physician, quality control technologist, and medical physicist shall
ensure that records concerning mammography technique and procedures, quality control (including
monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of
the corrective actions), safety, protection and employee qualifications to meet assigned quality assurance
tasks are properly maintained and updated. These quality control records shall be kept for each test
specified in paragraphs (e) and (f) of this section Rules 662 and 663 until the next annual inspection has
been completed and the department has determined that the facility is in compliance with the quality
assurance requirements or until the test has been performed two additional times at the required
frequency, whichever is longer.

R325.5662. Quality assurance—equipment.

Rule 662. (1) Daily quality control tests.
   (a) Film processors used to develop mammograms shall be adjusted and maintained to meet the
technical development specifications for the mammography film in use. As part of this, the crossover
rollers shall be cleaned on each day that clinical films are processed. A processor performance test
shall be performed on each day that clinical films are processed before any clinical films are processed
that day. The test shall include an assessment of base plus fog density, mid-density, density difference,
and developer temperature using the mammography film used clinically at the facility.
   (i).  The base plus fog density shall be within ± 0.03 of the established operating level.
   (ii). The mid-density shall be within ± 0.15 of the established operating level.
   (iii). The density difference shall be within ± 0.15 of the established operating level.

(b) Machines used for localization procedures shall perform a needle localization accuracy test each
day of use.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality
evaluation test, using a department-accepted phantom, at least weekly.
   (a) The optical density of the film at the center of an image of a standard department-accepted
phantom shall be at least 1.20 when exposed under a typical clinical condition.
   (b) The optical density of the film at the center of the phantom image shall not change by more than ±
0.20 from the established operating level.
   (c) The phantom image shall achieve at least the minimum score established by the accreditation
body.
(d) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than ± 0.05 from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(a) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(b) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed. For stereotactic breast biopsy and needle localization machines, the repeat analysis test shall be performed at least semiannually.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(a) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(b) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

(c) Compression device performance.

(i) A compression force of at least 111 newtons (25 pounds) shall be provided.

(ii) Effective October 28, 2002, The maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality...
control tests at least annually:

(a) Automatic exposure control performance.

(i) After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within \( \pm 0.15 \) of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

(ii) The optical density of the film in the center of the phantom image shall not be less than 1.20.

(b) Kilovoltage peak (kVp) accuracy and reproducibility.

(i) The kVp shall be accurate within \( \pm 5 \) percent of the indicated or selected kVp at:

(A) The lowest clinical kVp that can be measured by a kVp test device;

(B) The most commonly used clinical kVp;

(C) The highest available clinical kVp, and

(ii) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

(c) Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

(i) System Resolution.

(A) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeter (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(B) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.
(C) When more than one target material is provided, the measurement in paragraph 1966(e)(iii)(A) of this section Rule 662(5)(c)(i) shall be made using the appropriate focal spot for each target material.

(D) When more than one SID is provided, the test shall be performed at SID most commonly used clinically.

(E) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(II) Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1.

<table>
<thead>
<tr>
<th>Focal Spot Tolerance Limit</th>
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<tbody>
<tr>
<td>Nominal Focal Spot Size (mm)</td>
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<td></td>
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<tr>
<td>0.10</td>
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<td>0.15</td>
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<td>0.20</td>
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<td>0.30</td>
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<td>0.40</td>
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<tr>
<td>0.60</td>
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</tbody>
</table>
**(d)** Beam quality and half-value layer (HVL). The HVL shall meet the specifications shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation. The HVL shall be measured with the compression device in the x-ray beam.

<table>
<thead>
<tr>
<th>Designed Operating Range (kV)</th>
<th>Measured Operating Voltage (kV)</th>
<th>Minimum HVL (millimeters of aluminum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 50</td>
<td>20</td>
<td>0.20</td>
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<tr>
<td></td>
<td>25</td>
<td>0.25</td>
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<tr>
<td></td>
<td>30</td>
<td>0.30</td>
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</tbody>
</table>

**(e)** Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

**(f)** Dosimetry. The average glandular dose delivered during a single cranio-caudal view of a department-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

Some new technologies require doses above the current 0.2 rad limit for optimal imaging. We do not wish to limit optimal imaging, and yet do not want to allow excessive exposure that could be reduced by optimizing film processing and/or quality assurance. It appears that the ACR/FDA limit of 0.3 rad may be set higher than necessary, but we wish to be consistent with established national standards. Therefore a 0.25 rad standard of care advisory limit should be used in conjunction with this rule to encourage minimizing dose while maintaining optimal film quality.

**(g)** X-ray/light field/image receptor/compression paddle alignment.
(I) X-ray field alignment. All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.

(ii) Light-field alignment. If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

(iii) Compression paddle alignment. The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

(h) Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

(i) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically. Grid lines shall not be apparent on clinical or mammography phantom images.

Last sentence added from old rules.

(j) Radiation output. The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, The system.
under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate. The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

(k) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

(i) An override capability to allow maintenance of compression;

(ii) A continuous display of the override status; and

(iii) A manual emergency compression release that can be activated in the event of power or automatic release failure.

(6) Quality control tests--other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section Rule 662(5)(g).

(7) Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section Rules 662(1) through 662(7). In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

(8) Use of test results.

(a) After completion of the tests specified in rules 662(1-7) of this section, the facility shall compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the
manufacturer’s recommended action limits; or, for post-move, preexamination testing of mobile units, to
the limits established in the test method used by the facility.

(b) If the test results fall outside of the action limits, the source of the problem shall be identified and
corrective actions shall be taken:

(i) Before any further examinations are performed or any films are processed using a
component of the mammography system that failed any of the tests described in paragraphs (e)(1),
(e)(2), (e)(4)(i), (e)(4)(ii), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section; Rules 662(1), (2), (4),
(5)(d), (6), and (7).

(ii) Within 30 days of the test date for all other tests described in paragraph (e) of this section
Rule 662.

(9) Surveys.

(a) At least once a year, each facility shall undergo a survey by a medical physicist or by an individual
under the direct supervision of a medical physicist. At a minimum, this survey shall include the
performance of tests to ensure that the facility meets the quality assurance requirements of the annual
tests described in paragraphs (e)(5) and (e)(6) of this section Rules 662 (5 and 6) and the weekly
phantom image quality test described in paragraph (e)(2) of this section Rule 662(2).

(b) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through
(e)(7) of this section Rules 662 (1-7), as well as written documentation of any corrective actions taken
and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

(c) The medical physicist shall prepare a survey report that includes a summary of this review and
recommendations for necessary improvements.

(D) The survey report shall be sent to the facility within 30 days of the date of the survey.

(E) The survey report shall be dated and signed by the medical physicist performing or supervising
the survey. If the survey was performed entirely or in part by another individual under the direct
supervision of the medical physicist, that individual and the part of the survey that individual performed
shall also be identified in the survey report.

(F) The survey report shall include the testing equipment used, including the date of the last
(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section Rules 630 through 647 and Rule 662. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

(11) Facility cleanliness.

(a) The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.

(b) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(12) Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of ± 6 percent (95 percent confidence level) in the mammography energy range.

(13) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:
(a) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and

(b) Comply with the manufacturer’s recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(c) If adequate manufacturer’s recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

R325.5663. Quality assurance-mammography medical outcomes audit.

Rule 663. (1) Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician’s findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(2) General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician’s mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

(3) Frequency of audit analysis. The facility’s first audit analysis shall be initiated no later than 12 months after the date the facility becomes authorized, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(4) Audit interpreting physician. Each facility shall designate at least one interpreting physician to
review the medical outcomes audit data at least once every 12 months. This individual shall record the
dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This
individual shall also be responsible for documenting the results and for notifying other interpreting
physicians of their results and the facility aggregate results. If followup actions are taken, the audit
interpreting physician shall also be responsible for documenting the nature of the followup.

R325.5664. Mammographic procedure and techniques for mammography of patients with
breast implants.

Rule 664. (1) Each facility shall have a procedure to inquire whether or not the patient has breast
implants prior to the actual mammographic exam.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast
implants undergoing mammography shall have mammographic views to maximize the visualization of
breast tissue.

R325.5665. Consumer complaint mechanism.

Rule 665. Each facility shall:

(a) Establish a written and documented system for collecting and resolving consumer complaints;

(b) Maintain a record of each serious complaint received by the facility for at least 3 years from the
date the complaint was received;

(c) Provide the consumer with adequate directions for filing serious complaints with the facility’s
 accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;

(d) Report unresolved serious complaints to the accreditation body in a manner and timeframe
 specified by the accreditation body.

R325.5666. Clinical image quality.
Rule 666. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility’s accreditation body.

R325.5667. Additional mammography review and patient notification.

RULE 667. (1) If the department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the department, for review by the accreditation body or other entity designated by the department. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the department determines that the quality of mammography performed by a facility, whether or not authorized, was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, the department may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the department may require. Such notification shall occur within a timeframe and in a manner specified by the department.