~~DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES~~

~~RADIATION SAFETY SECTION~~

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

BUREAU OF HEALTH SYSTEMS - RADIATION SAFETY SECTION

IONIZING RADIATION RULES – PART 14. MAMMOGRAPHY

Filed with the Secretary of State on

These rules become effective immediately upon filing with the Secretary of State unless adopted under sections 33, 44, or 45a(6) of 1969 PA 306. Rules adopted under these sections become effective 7 days after filing with the Secretary of State.

(By authority conferred on the director of the department of licensing and regulatory affairs by section 13521, 1978 PA 368, MCL 333.13521 and Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, and 2011-4 being MCL 330.3101, 445.2001, 445.2011, and 445.2030)

R 325.5601,R 325.5602, R 325.5603, R 325.5605, R 325.5607, R 325.5608, R 325.5610, R 325.5611, R 325.5612, R 325.5613, R 325.5637, R 325.5655, and R 325.5656 of the Michigan Administrative Code are amended, and R 325.5601a, R 325.5626, R 325.5627, R 325.5628, R 325.5629, R 325.5630, R 325.5634, R 325.5635, R 325.5657, R 325.5658, R 325.5667, R 325.5668, R 325.5674, R 325.5675, R 325.5676, R 325.5677, R 325.5678, R 325.5679, R 325.5680, R 325.5681, R 325.5682, R 325.5683, R 325.5684, R 325.5685, R 325.5686, R 325.5687, R 325.5688, R 325.5689, R 325.5690, R 325.5691, R 325.5692, R 325.5693, R 325.5694, R 325.5695, R 325.5696, R 325.5697, and R 325.5698 are added to the Code, and R 325.5617, R 325.5618, R 325.5619, R 325.5621, R 325.5622, R325.5623, R325.5624, R 325.5625, R 325.5631, R 325.5632, R 325.5633, R 325.5638, R 325.5639, R 325.5640, R 325.5641, R 325.5642, R 325.5643, R 325.5644, R 325.5645, R 325.5646, R 325.5647, R 325.5648, R 325.5649, R325.5650, R 325.5651, R325.5652, R 325.5659, R 325.5660, R325.5661, R 325.5662, R 325.5663, R 325.5664, and R 325.5665 are rescinded as follows:

~~PART 14. MAMMOGRAPHY~~

GENERAL PROVISIONS

R 325.5601 Purpose and scope.

Rule 601. (1) This part establishes requirements governing the use of x-radiation for mammography and applies 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 R 325.5181 to R 325.5196 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~~ **all applicable** provisions of R 325.5001 to ~~R 325.5511~~ **R 325.5721**.

(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.

R 325.5601a Adoption by reference.

Rule 601a. Some of these rules refer to all or parts of the following nationally recognized standards, which are adopted by reference and identified by date:

(a) Standards of the United States department of health & human services, title 21 - food and drugs, part 900 - mammography. These standards are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss

(ii) The website of the United States department of health & human services, mammography quality standards act and program at http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm

(b) The regulations in 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major components" (April 9, 2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (June 10, 2005). These regulations are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss

(ii) The website of the United States department of health & human services, U.S. Food and Drug Administration at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

(c) Criteria of the American college of radiology, "Mammography Accreditation Program Requirements" (October 20, 2011), and "Stereotactic Breast Biopsy Accreditation Program Requirements" (September 23, 2011). These criteria are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss.

(ii) The website of the American college of radiology at http://www.acr.org.

R 325.5602 Definitions.

Rule 602. (1) As used in this part~~:~~ **the definitions in 21 C.F.R. 900.2, "Definitions" (2002), are adopted by reference with the exception of the definition of "mammography."**

(2) As used in this part the following definitions apply:

(a) "Act" means **1978 PA 368, as amended, MCL 333.1101 to 333.25211** ~~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.~~

(b) "Annual" means a period of ~~time that is not more than 365 days~~**12 consecutive months.**

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

~~(d) "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.~~

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

~~(f) "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.~~

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

~~(h) "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.~~

~~(i) "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.~~

~~(j) "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.~~

(c) "Interpreting physician" means a physician who interprets mammograms and who meets the requirements of R 325.5627 to R 325.5629.

~~(k)~~**(d)** "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 includes interventional mammography.**

(e) "Stereotactic breast biopsy" means the imaging of a breast performed in at least 2 planes to localize a target lesion during invasive interventions for biopsy procedures.

(f) "Stereotactic breast biopsy physician" means a physician licensed under article 15 of the act who conducts stereotactic breast biopsy.

~~(l) "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.~~

~~(m) "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.~~

~~(n) "Radiological physics" means the branch of medical physics that includes diagnostic physics, therapeutic physics, and medical nuclear physics.~~

~~(o) "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.~~

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

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

~~(2)~~**(3)** The terms defined in the act shall have the same meanings when used in these rules.

R 325.5603 Department inspections.

Rule 603. (1) The department shall inspect a mammography machine and system not later than 60 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.

(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~~ **applicable** provisions of R 325.5001 to R 325.~~5511~~**5721** 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 R 325.5001 to R ~~325.5511~~ **R 325.5721**.

MAMMOGRAPHY AUTHORIZATION

R 325.5605 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~~ **complies** with ~~either~~ **any** of the following requirements:

(i) The machine **and the facility in which the machine is used** meet~~s~~ the criteria for the American college of radiology mammography accreditation program dated ~~October, 1991, and January, 1992~~**October, 2011**, and the facility submits an evaluation report issued by the American college of radiology as evidence that the ~~mammography machine meets the~~ criteria **are met**. 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) A machine used for stereotactic breast biopsy and the facility in which the machine is used meet the criteria of the American college of radiology stereotactic breast biopsy

accreditation program dated September, 2011, and the facility submits an evaluation report issued by the American college of radiology as evidence that the criteria are met. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only.

~~(ii)~~**(iii)** The machine is used in a facility that has successfully completed the department's evaluation of ~~the machine for~~ the items described in R 325.5610.

(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~~ **comply** with the requirements of this part and **applicable provisions of** R 325.5001 to R 325.~~5511~~**5721**.

(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, **before the machine is used on patients and** at least annually **thereafter**, 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 ~~R 325.5661~~ **R 325.5667** of this part **or R 325.5690 for stereotactic breast biopsy**.

(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 physician.~~

R 325.5607 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)~~**(1)** 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~~ **Mammography facility 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~~ **The facility registration number, if currently registered.**

(iv) A contact person's name and telephone number.

(b) Personnel information, including the education, training, experience, and certification of the ~~mammography supervisor~~ **lead interpreting physician**, any qualified ~~radiation~~ **medical** 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) Machine registration number, if currently registered.
~~(i)~~**(ii)** Manufacturer.
~~(ii)~~**(iii)** Model.
~~(iii) Year of manufacture.~~
~~(iv) The imaging system in use.~~
~~(v)~~**(iv)** Target material.
~~(vi)~~**(v)** 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~~ **Imaging system** information, including all of the following:
(i) The type of imaging system being used.
(ii) Review workstation monitor information, if the machine uses digital imaging.
(iii) Laser printer information, if the machine uses digital imaging.
(iv) Film and screen information, if the machine uses screen-film imaging.
(v) Film processor information, if the machine uses screen-film imaging.
~~(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.~~

(e) The date of the most recent medical physicist survey.

~~(3)~~**(2)** The department shall respond to an application within 30 days after the date of receipt of the application.

R 325.5608 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 R 325.5605(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~~ **demonstrates** compliance with the provisions of R 325.5605(a), then the fee for department evaluation of compliance with the provisions of R 325.5605(a) shall be waived.

R 325.5610 Supplemental machine information; effect of failure to submit information.

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~~ **complies** 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 **radiation** machine for which mammography authorization is being sought:

(a) Confirmation that a **department-approved** 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~~ **Processor or laser film printer** 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~~ **An** x-ray image of a **department-approved** 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~~**4.2**-centimeter compressed breast **of average density** ~~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~~ **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~~ **exposed on the** 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~~ **A** set of clinical ~~patient mammography~~ images **produced on or after the date that the application was sent to the department. Mammography images shall be** 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.~~ **Stereotactic breast biopsy images shall be from 1 calcification biopsy case that demonstrates accurate needle location and includes the case's corresponding mammograms. The submitted images shall meet all of the following:**

(i) The cases shall be examples of the facility's best work.

(ii) The images shall be from actual patients.

(iii) Digital images shall be on hardcopy.

(iv) Both screen-film and digital images shall be labeled with the identification information required in R 325.5657 for mammography images or R 325.5683 for stereotactic breast biopsy images.

(vii) The lead interpreting physician shall review and approve the hardcopy clinical images.

~~The images shall contain clear documentation of all of the following:~~

~~(i) The name of the facility.~~

~~(ii) The date of the mammography examination.~~

~~(iii) Mammography machine operator identification information.~~

~~(iv) Cassette-screen or xeroradiographic cassette-plate identification information.~~

~~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.

R 325.5611 Contracts for technical evaluation.

Rule 611. (1) In evaluating clinical image quality and acceptability for mammography authorization, upon receipt of the information required in R 325.5610(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.

(2) 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.~~

R 325.5612 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.~~ **Image modality.**

~~(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)~~**(e)** 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 R 325.5607 and R 325.5608.

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

R 325.5613 Authorization withdrawal; reinstatement.

Rule 613. (1) Three-year mammography authorization is subject to continued compliance with this part and the provisions of R 325.5001 to R 325.~~5511~~**5721**. Authorization may be withdrawn based on evidence of noncompliance with this part and the provisions of R 325.5001 to ~~R 325.5511~~ **R 325.5721** 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~~ **1969 PA 306, as amended, MCL 24.201 to 24.328**.

(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 R 325.5607 and R 325.5608.

(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 R 325.5605.

MAMMOGRAPHY SUPERVISOR

R 325.5617 ~~Designation; identification; agreement between supervisor and facility; availability; continuing education.~~ **Rescinded.**

~~Rule 617. (1) Each mammography facility shall designate a mammography supervisor in order to be authorized to perform mammography.~~

~~(2) An applicant who seeks mammography authorization shall identify the mammography supervisor on the application form for mammography authorization.~~

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

~~(a) A statement that the mammography supervisor is responsible for assuring compliance with this part and the provisions of R 325.5001 to R 325.5511.~~

~~(b) A statement that the mammography supervisor 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 to achieve compliance.~~

~~(4) A mammography supervisor shall be readily available telephonically or in person for consultation with any radiation machine operator who performs mammography.~~

~~(5) A mammography supervisor 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.~~

R 325.5618 ~~Responsibilities.~~ **Rescinded.**

~~Rule 618. A mammography supervisor shall be responsible for each of the following:~~

~~(a) Establishment and maintenance of a quality control program.~~

~~(b) Annual review and updating of the procedures manual.~~

~~(c) Evaluation of each mammography machine operator's performance at least semiannually as described in R 325.5619.~~

~~(d) Assurance that each mammography machine operator other than a physician has successfully completed special mammography training as specified in R 325.5621 and R 325.5623 or possesses the American registry of radiologic technologists certificate of advanced qualifications in mammography as identified in R 325.5622. 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 R 325.5661.~~

~~(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.~~

R 325.5619 ~~Machine operator performance evaluation.~~ **Rescinded.**

~~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 out throughout compression.

(xiv) Applying compression with the corner of the paddle below the clavicle.

(xv) Pulling down on the abdominal tissue to open the inframammary fold.

(d) The use of appropriate compression.

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

(f) Proper maintenance of records, including examination identification information.

(g) 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.~~

~~(h) Knowledge of each of the following:~~

~~(i) The American college of radiology accreditation status of the machine.~~

~~(ii) The most recent department inspection of the machine and regulatory inspection frequency.~~

~~(iii) The most recent consulting physicist evaluation of the mammography system and the frequency of those evaluations.~~

~~(iv) The radiation dose for an average patient.~~

~~(v) The recent phantom image results for the machine being used.~~

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

~~(i) Positioning.~~

~~(ii) Compression.~~

~~(iii) Optical density.~~

~~(iv) Sharpness.~~

~~(v) Contrast.~~

~~(vi) Noise.~~

~~(vii) Exam identification.~~

~~(viii) Artifacts.~~

~~(3) 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:~~

~~(a) The names and signatures of the mammography supervisor and machine operator.~~

~~(b) The date of the mammography examination for which the operator was evaluated.~~

~~(c) Examination and x-ray image identification information.~~

~~(d) 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.~~

~~(4) 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.~~

~~(5) 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.~~

~~(6) 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.~~

~~(7) 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.~~

R 325.5621 ~~Qualifications.~~ **Rescinded.**

~~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 R 325.5625.~~

R 325.5622 ~~Technologist exemptions.~~ **Rescinded.**

~~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 R 325.5621(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 R 325.5623 and meet performance requirements prescribed by R 325.5619(2).~~

~~(2) Students in a radiography program that is in compliance with the requirements of R 325.5621(a) shall be exempt from the provisions of R 325.5621 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 R 325.5621(a) shall be exempt from the provisions of R 325.5621(b) and (c) for 2 years after graduation.~~

R 325.5623 ~~Continuing education.~~ **Rescinded.**

~~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.~~

R 325.5624 ~~Operator prohibitions.~~ **Rescinded.**

~~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.~~

R 325.5625 ~~Program of mammography instruction; topics.~~ **Rescinded.**

~~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.~~

PERSONNEL

R 325.5626 Scope of personnel requirements.

Rule 626. The requirements of R 325.5627 to R 325.5634 shall apply to all personnel involved in any aspect of mammography, including but not limited to, the production, processing, and interpretation of mammograms and related quality assurance activities.

R 325.5627 Interpreting physician initial qualifications.

Rule 627. Before beginning to interpret mammograms independently, an interpreting physician shall:

(a) Be licensed as a physician or osteopathic physician under article 15 of the act to practice medicine.

(b) Meet either of the following requirements:

(i) Be certified in radiology or diagnostic radiology by the American board of radiology, the American osteopathic board of radiology, or the royal college of physicians and surgeons of Canada; have been eligible for certification in radiology or diagnostic radiology for not more than 2 years; or, be certified or determined to be qualified in radiology or diagnostic radiology by another professional organization 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.

(ii) If the physician has been eligible for certification in radiology or diagnostic radiology

for less than 2 years, he or she shall 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 of the training shall be under the direct supervision of a physician who meets the requirements of this rule.

(c) 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 1 and at least 15 of the category 1 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 shall be considered as equivalent to category 1 continuing education credits and shall be accepted if documented in writing by the appropriate representative of the training institution. A physician who meets the board certification requirements of subrule (b)(i) of this rule is deemed to have met this requirement.

(d) Have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualified as an interpreting physician. The interpretation or multi-reading shall be under the direct supervision of an interpreting physician. A physician who becomes appropriately board certified at the first allowable time, as defined by an eligible certifying body, shall 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. A physician who was qualified to interpret mammograms prior to the effective date of this rule is considered to have met the requirements of this subrule.

R 325.5628 Interpreting physician continuing experience and education.

Rule 628. An interpreting physician shall maintain his or her qualifications by meeting the continuing experience and education requirements of 21 C.F.R. 900.12(a)(1)(ii), "Personnel – Interpreting physicians – Continuing experience and education" (2000).

R 325.5629 Interpreting physician reestablishment of qualifications.

Rule 629. (1) An interpreting physician who failed to maintain the required continuing experience or continuing education requirements of R 325.5628 shall reestablish his or her qualifications before resuming the independent interpretation of mammograms, by meeting the reestablishing qualifications requirements of 21 C.F.R. 900.12(a)(1)(iv), "Personnel – Interpreting physicians – Restablishing qualifications" (2000).

R 325.5630 Radiologic technologists.

Rule 630. All mammographic examinations shall be performed by a radiologic technologist who meets the general requirements, mammography requirements, continuing education requirements and continuing experience requirements of 21 C.F.R. 900.12(a)(2), "Radiologic technologists" (2000), with the exception of 21 C.F.R. 900.12(a)(2)(i)(A).

RADIATION PHYSICIST

R 325.5631 ~~Qualifications.~~ **Rescinded.**

~~Rule 631. (1) A radiation physicist shall be certified in diagnostic or radiological physics by the American board of radiology or by 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 R 325.5632(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.~~

R 325.5632 ~~Mammography system evaluation.~~ **Rescinded.**

~~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 R 325.5603.~~

(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 R 325.5637 to R 325.5652.

(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 R 325.5661.

(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 R 325.5660.

(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.

R 325.5633 Records of on-site evaluations and consultations. **Rescinded**

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 R 325.5605(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.~~

R 325.5634 Medical physicists.

Rule 634. A medical physicist who conducts surveys of mammography facilities and provides oversight of a facility's quality assurance program shall meet the initial qualifications, continuing qualifications and reestablishing qualification requirements of 21 C.F.R. 900.12(a)(3), "Medical physicists" (2000).

R 325.5635 Retention of personnel records.

Rule 635. A mammography facility shall maintain records to document the qualifications of all personnel who work at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records shall be made available for review during department inspections. Records of personnel no longer employed by the mammography facility shall be kept on file until the next inspection following the employee's termination has been completed, and the department has determined that the facility complies with the personnel requirements.

X-RAY EQUIPMENT

R 325.5637 ~~Compliance with provisions of R 325.5325; machine design~~ **X-ray equipment requirements.**

Rule 637. (1) The mammographic x-ray equipment shall be **maintained** in compliance with the **applicable regulations in 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major components" (2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (2005).** ~~requirements of R 325.5325(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.~~ **The mammography machine, x-ray film, intensifying screens, film processing solutions, film illumination, and film masking devices shall meet the requirements of 21 C.F.R. 900.12(b), "Equipment" (2000).**

R 325.5638 ~~Machine output.~~ **Rescinded.**

~~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.~~ **Rescinded.**

~~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.~~

R 325.5640 ~~Permissible degree of coefficient of variation of radiation exposure for combination of selected technique factors.~~ **Rescinded.**

~~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.~~

R 325.5641 ~~Permissible difference in average ratios of exposure to indicated milliampere seconds product obtained at 2 consecutive settings.~~ **Rescinded.**

~~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: $X_1 - X_2$ 0.10 $(X_1 + X_2)$; where X_1 and X_2 are the average mR/mAs values that are obtained at each of 2 consecutive mA or mAs settings.~~

R 325.5642 ~~Target and filter material.~~ **Rescinded.**

~~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.~~

R 325.5643 ~~Nominal focal spot size.~~ **Rescinded.**

~~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.~~

R 325.5644 ~~Half-value layer.~~ **Rescinded.**

~~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.~~

R 325.5645 ~~Focal spot to image receptor distance.~~ **Rescinded.**

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

R 325.5646 ~~Machine design; x-ray beam geometry.~~ **Rescinded.**

~~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.~~

R 325.5647 ~~Reciprocating grid capability; grid ratio; exception; grid lines.~~ **Rescinded.**

~~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.~~

R 325.5648 ~~Image receptor capability.~~ **Rescinded.**

~~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.~~

R 325.5649 ~~Beam limiting device.~~ **Rescinded.**

~~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.~~

R 325.5650 ~~Compression device.~~ **Rescinded.**

~~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.~~

R 325.5651 ~~Primary beam transmission through the image receptor support.~~ **Rescinded.**

~~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.~~

R 325.5652 ~~Automatic exposure control system.~~ **Rescinded.**

~~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.~~

~~(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.~~

R 325.5655 Enclosure requirements**; use of mobile equipment**.

Rule 655. (1) ~~An~~ **A fixed** x-ray equipment enclosure shall ~~be in compliance~~ **comply** with the requirements of R 325.5331.

(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.

(3) An individual operating a mobile or portable mammography machine shall wear a protective apron of a minimum 0.5 millimeter lead equivalence unless portable shielding is provided as specified in subrule (2) of this rule.

(4) Mobile or portable mammography equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of rule R 325.5331.

(5) Mobile or portable mammography equipment shall not be used for routine mammography in hospitals or private offices of practitioners of the healing arts. This equipment shall be used only when it is medically inadvisable to move a patient to a fixed mammographic installation.

R 325.5656 ~~Operation requirements~~ **Conditions of operation.**

Rule 656. ~~(1)~~ The operation of each mammography x-ray machine shall ~~be in compliance~~ **comply** with the requirements of R 325.5333.

~~(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.~~

MEDICAL RECORDS AND MAMMOGRAPHY REPORTS

R 325.5657 Medical records and mammography reports.

Rule 657. A mammography facility shall comply with the requirements of 21 C.F.R. 900.12(c), "Medical records and mammography reports" (2000), except that the reference to retention of records in 21 C.F.R. 900.12(c)(4)(i) is changed from "not less than 5 years" to "not less than 7 years" in accordance with MCL 333.20175.

QUALITY ASSURANCE

R 325.5658 Quality assurance - general.

Rule 658. A mammography facility shall comply with the requirements of 21 C.F.R. 900.12(d), "Quality assurance – general" (2000).

QUALITY CONTROL

R 325.5659 ~~Quality control responsibilities of supervisor; establishment of quality assurance~~

~~manual; provision of mammography phantom; submission of phantom images.~~ **Rescinded.**

~~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.~~

R 325.5660 ~~Phantom image quality.~~ **Rescinded.**

~~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.~~

R 325.5661 ~~Radiation dose limits.~~ **Rescinded.**

~~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.~~

R 325.5662 ~~Screen-film processor adjustment.~~ **Rescinded.**

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

R 325.5663 ~~Mammography phantom imaging required; corrective action; phantom imaging for mobile units; repeat analysis; compression check.~~ **Rescinded.**

~~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 R 325.5660, 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 R 325.5660. 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 R 325.5660 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.~~

R 325.5664 ~~Screen-film mammography quality control.~~ **Rescinded.**

~~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.~~

~~(j) Mammography clinical images shall be interpreted in subdued ambient lighting conditions on a view box that is masked to reduce glare. View box surfaces shall be cleaned weekly.~~

R 325.5665 ~~Xeromammography; plate management system.~~ **Rescinded.**

~~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.~~

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

R 325.5667 Quality assurance – equipment.

Rule 667. A mammography facility shall comply with the requirements of 21 C.F.R. 900.12(e), "Quality assurance – equipment" (2000).

R 325.5668 Quality assurance - mammography medical outcomes audit; mammographic procedure and techniques for mammography of patients with breast implants; consumer complaint mechanism; and clinical image quality.

Rule 668. A mammography facility shall comply with the requirements in 21 C.F.R. 900.12(f), "Quality assurance – mammography medical outcomes audit" (2000); 21 C.F.R. 900.12(g), "Mammographic procedure and techniques for mammography of patients with breast implants" (2000); 21 C.F.R. 900.12(h), "Consumer complaint mechanism" (2000) and 21 C.F.R. 900.12(i), "Clinical image quality" (2000).

STEREOTACTIC BREAST BIOPSY

PERSONNEL

R 325.5674 Radiologic technologists.

Rule 674. All stereotactic breast biopsy procedures shall be performed by a radiologic technologist who meets all of the following requirements:

(a) Initial qualifications. Before beginning to perform stereotactic breast biopsy procedures independently, a technologist shall do all of the following:

(i) Meet the requirements of R 325.5630.

(ii) Have 3 hours of category A continuing education units in stereotactic breast biopsy.

(iii) Have performed 5 stereotactic breast biopsy procedures under supervision of a

stereotactic breast biopsy physician or a qualified stereotactic breast biopsy technologist.

(b) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the initial qualifications of subrule (a) of this rule were completed, the stereotactic breast biopsy technologist shall have performed at least 24 stereotactic breast biopsy procedures 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.

(c) Continuing education. A technologist shall comply with the American registry of radiologic technologist's requirements for continuing education for the imaging modality in which he or she performs services. The continuing education shall include credits pertinent to stereotactic breast biopsy.

R 325.5675 Medical physicists.

Rule 675. A stereotactic breast biopsy medical physicist shall meet all of the following requirements:

(a) Initial qualifications. Before independently performing surveys of stereotactic breast biopsy facilities a medical physicist shall:

(i) Meet the requirements of R 325.5634.

(ii) Have performed 1 hands-on stereotactic breast biopsy physics survey under a qualified stereotactic breast biopsy medical physicist or 3 independent stereotactic breast biopsy surveys prior to the effective date of this rule.

(b) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the initial qualifications of subrule (a) of this rule were completed, the stereotactic breast biopsy medical physicist shall have performed at least 2 stereotactic breast biopsy physics surveys 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 2. The facility shall choose one of these dates to determine the 24-month period.

(c) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the initial qualifications of subrule (a) of this rule were completed, the stereotactic breast biopsy medical physicist shall have completed at least 3 continuing medical education credits in stereotactic breast biopsy 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.

X-RAY EQUIPMENT

R 325.5676 Equipment requirements.

Rule 676. (1) The stereotactic breast biopsy mammographic x-ray equipment shall comply with the requirements of R 325.5325(1) and (17) to (23).

(2) A machine that is used for stereotactic breast biopsy shall be one of the following:

(i) A radiation machine that is specifically designed to perform stereotactic breast biopsy.

(ii) A mammography machine with a specially designed add-on device for breast biopsy.

(iii) A mammography machine that exclusively uses lateral arm devices if the needle can

be seen in 2 ways in relation to the target lesion.

R 325.5677 Enclosures; use of mobile equipment.

Rule 677. (1) A fixed x-ray equipment enclosure shall comply with the requirements of R 325.5331.

(2) For stereotactic breast biopsy, 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.

(3) An individual operating mobile or portable stereotactic breast biopsy equipment shall wear a protective apron of a minimum 0.5 millimeter lead equivalence unless portable shielding is provided as specified in subrule (2) of this rule.

(4) Mobile or portable stereotactic breast biopsy equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of R 325.5331.

(5) Mobile or portable stereotactic breast biopsy equipment shall not be used for routine mammography in hospitals or private offices of physicians or osteopathic physicians. This equipment shall be used only when it is medically inadvisable to move a patient to a fixed mammographic installation.

R 325.5678 Conditions of Operation.

Rule 678. The operation of a mammography x-ray machine shall comply with the requirements of R 325.5333.

MEDICAL RECORDS AND STEREOTACTIC BREAST BIOPSY REPORTS

R 325.5679 Report contents and terminology.

Rule 679. A stereotactic breast biopsy facility shall prepare a written report of the results of each stereotactic breast biopsy procedure. The stereotactic breast biopsy report shall include all of the following information:

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

(b) The date of the procedure.

(c) The name of the stereotactic breast biopsy physician who conducted the procedure.

(d) The procedure performed.

(e) Designation of the left or right breast.

(f) Description and location of the lesion.

(g) Approach used to target and biopsy the lesion.

(h) Type and amount of local anesthesia, if used.

(i) Skin incision, if made.

(j) Gauge of needle and type of biopsy device, such as spring-loaded or vacuum-assisted.

(k) Number of specimen cores or samples, if applicable.

(l) Specimen radiographs, if performed, and their results.

(m) Tissue marker placement, if performed.

(n) Complications and treatment, if performed.

(o) Post-procedure mammography, if obtained, documenting tissue marker placement

and location of the marker with respect to the biopsied lesion.

R 325.5680 Communication of stereotactic breast biopsy results to the patients.

Rule 680. (1) A stereotactic breast biopsy facility shall send each patient a summary of the stereotactic breast biopsy report written in lay terms within 30 days of the stereotactic breast biopsy procedure.

(2) A patient who does not name a health care provider to receive the stereotactic breast biopsy report shall be sent the report described in R 325.5679 within 30 days, in addition to the written summary required by subrule (1) of this rule.

(3) A stereotactic breast biopsy facility that accepts patients who do not have a health care provider shall maintain a system for referring these patients to a health care provider when clinically indicated.

R 325.5681 Communication of stereotactic breast biopsy results to health care providers.

Rule 681. When a patient has a referring health care provider or a patient has named a health care provider, the stereotactic breast biopsy facility shall provide a written report of the stereotactic breast biopsy procedure, including the items listed in R 325.5679, to that health care provider no later than 30 days after the date that the stereotactic breast biopsy procedure had been performed.

R 325.5682 Record keeping.

Rule 682. (1) A facility that performs stereotactic breast biopsy procedures shall comply with both of the following:

(a) Maintain stereotactic breast biopsy images and reports in a permanent medical record of the patient for a period of not less than 7 years, or not less than 10 years if no additional stereotactic breast biopsy procedures of the patient are performed at the facility.

(b) Upon request by, or on behalf of, a patient, permanently or temporarily transfer the original stereotactic breast biopsy images and copies of the patient's reports to any of the following: a medical institution, a patient's physician, or the patient directly.

(2) Any fee a facility charges a patient for providing the services specified in subrule (1)(b) of this rule shall not exceed the documented costs associated with this service.

R 325.5683 Stereotactic breast biopsy image identification.

Rule 683. A stereotactic breast biopsy 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 unique patient identifier.

(b) Date of the procedure.

(c) Designation of left or right breast.

(d) View and laterality. This information shall be placed on the image in a position near the axilla.

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

(f) Technologist identification.

(g) Cassette identification, if applicable.

(h) Stereotactic breast biopsy unit identification, if there is more than one unit in the

facility.

QUALITY ASSURANCE

R 325.5684 Quality assurance – general.

Rule 684. A stereotactic breast biopsy facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of stereotactic breast biopsy services performed at the facility.

R 325.5685 Responsible individuals.

Rule 685. Responsibility for the quality assurance program and for each of its elements shall be assigned to the following individuals who are qualified for their assignments:

(a) Lead stereotactic breast biopsy physician. The facility shall identify a lead stereotactic breast biopsy physician who shall be responsible for ensuring that the quality assurance program meets all requirements of R 325.5684 to R 325.5698. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead stereotactic breast biopsy physician has determined that the individual is qualified to perform the assignment.

(b) Stereotactic breast biopsy physicians. All stereotactic breast biopsy physicians conducting stereotactic breast biopsy procedures for the facility shall:

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

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

(c) Medical physicist. The facility shall have the services of a medical physicist available to survey stereotactic breast biopsy equipment and oversee the equipment-related quality assurance practices of the facility. The medical physicist shall be responsible for performing the surveys and stereotactic breast biopsy equipment evaluations and providing the facility with the reports described in R 325.5693 and R 325.5694.

(d) Quality control technologist. Responsibility for tasks within the quality assurance program not assigned to the lead stereotactic breast biopsy physician or the medical physicist shall be assigned to a quality control technologist. The tasks are to be performed by the quality control technologist, but may be performed by other qualified personnel. When other personnel are utilized for these tasks, the quality control technologist shall ensure that they were completed in compliance with R 325.5687.

R 325.5686 Quality assurance records.

Rule 686. (1) The lead stereotactic breast biopsy physician, quality control technologist, and medical physicist shall ensure that records concerning the following items are properly maintained and updated:

(a) Stereotactic breast biopsy techniques and procedures.

(b) Quality control, including monitoring data and corrective actions taken.

(c) Safety.

(d) Employee qualifications to meet assigned quality assurance tasks.

(2) The quality assurance records specified in subrule (1) of this rule shall be kept for each test specified in R 325.5684 to R 325.5698 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.

R 325.5687 Radiologic technologist quality control tests.

Rule 687. A stereotactic breast biopsy facility shall have a radiologic technologist perform the following quality control tests at the intervals specified in this rule:

(a) A localization accuracy test shall be performed daily before the equipment is used on patients. Each of the indicated needle tip coordinates shall be within 1 millimeter of the actual preset needle tip location.

(b) A phantom image evaluation shall be performed at least weekly. The phantom image shall achieve at least the minimum score established in R 325.5689.

(c) A hard copy output quality test shall be performed at least monthly, if hard copies are produced from digital data.

(d) A compression test shall be performed at least semiannually. The maximum compression force for the power drive mode shall be between 25 pounds and 45 pounds.

(e) A repeat analysis shall be performed at least semiannually. The overall repeat or reject rate shall be less than 20% based on an image volume of not less than 150 patients. A repeat analysis shall be assessed semiannually even if fewer than 150 patients are examined during that period.

(f) If stereotactic breast biopsy is performed using a screen-film system, the following tests shall be required:

(i) A processor quality control test shall be performed at least daily. Film processors used to develop stereotactic breast biopsy films shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed at the beginning of each operational day before processing any clinical images. The test shall use the mammography film used clinically at the facility and shall include an assessment of base plus fog density, mid-density, and density difference as follows:

(A) The base plus fog density shall be within 0.03 of the established operating level.

(B) The mid-density shall be within plus or minus 0.15 of the established operating level.

(C) The density difference shall be within plus or minus 0.15 of the established operating level.

(ii) An analysis of fixer retention in film assessed at least quarterly. The residual fixer shall be no more than 5 micrograms per square centimeter.

(iii) A screen-film contact test shall be performed at least semiannually. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for stereotactic breast biopsy shall be tested.

(iv) A test of darkroom fog shall be performed at least semiannually. 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 optical density, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up.

R 325.5688 Annual medical physicist's quality control tests.

Rule 688. A stereotactic breast biopsy facility shall have the medical physicist perform the following quality control tests at least annually after equipment installation:

(a) Collimation assessment that meets either of the following:

(i) For screen-film systems, the x-ray field shall be contained within the image receptor on all three sides except the chest wall edge. The x-ray field shall not extend beyond the chest wall edge of the image receptor by more than 2% of the source-to-image receptor distance.

(ii) For digital image receptors, the x-ray field may extend beyond the edge of the image receptor on all four sides, but no edge of the x-ray field shall extend beyond the image receptor by more than 5 millimeters on any side. Distances shall be measured in, or referred to, the plane of the digital image receptor.

(b) Focal spot performance and system limiting spatial resolution. Assess consistency of system-limiting resolution over time and in comparison to acceptance testing results using a line pair test pattern.

(c) Kilovoltage peak (kVp) accuracy and reproducibility. The kVp shall be accurate to within plus or minus 5% of the indicated or selected kVp. The coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02 at the most commonly used clinical settings of kVp.

(d) Beam quality assessment. The half-value layer (HVL) shall be equal to or greater than the value kVp/100 in units of millimeter of aluminum.

(e) Automatic exposure control system or manual exposure performance assessment that meets either of the following:

(i) For screen-film systems, the image optical density shall be within plus or minus 0.15 of the mean optical density when thicknesses of a homogeneous material is varied over a range of 4 to 8 centimeters using the clinical techniques for each thickness. If the optical densities do not meet this criterion, the medical physicist shall develop a technique chart which meets this criterion.

(ii) For digital systems, the signal value at the center of the digital field of view shall remain within 20% of the signal obtained for the 4 centimeter phantom when thicknesses of a homogeneous material is varied over a range of 4 to 8 centimeters using the clinical techniques for each thickness. If the signal values do not meet this criterion, the medical physicist shall develop technique chart which meets this criterion.

(f) Image receptor speed uniformity that meets either of the following:

(i) For screen-film systems, the difference between the maximum and minimum optical densities of all the cassettes in the facility shall not exceed 0.30.

(ii) For digital systems, the signal-to-noise ratios (SNR) measured in each corner of the image shall be within plus or minus 15% of the SNR measured at the center of the field of view.

(g) Breast entrance exposure, average glandular dose, and exposure reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05. The average glandular dose delivered during a single exposure of a department-approved phantom simulating a standard breast shall not exceed 3.0 milligray (300 millirad) per exposure.

(h) Image quality evaluation. An image of a department-approved phantom shall achieve at least the minimum score established in R 325.5689.

(i) Artifact evaluation. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the full area of the exposed image receptor on the breast support assembly.

(j) Localization accuracy test. Using a phantom made of gelatin or similar material, the biopsy needle shall capture the intended object in the phantom.

R 325.5689 Phantom image scores.

Rule 689. A stereotactic breast biopsy phantom image score for the tests required in rules R 325.5687(b) and R 325.5688(h) shall be not less than the values specified in table 689:

TABLE 689

Image System	Standard Mammography Phantom			Mini Stereotactic Phantom		
	Fibers	Speck Groups	Masses	Fibers	Speck Groups	Masses
Screen-film	4.0	3.0	3.0	2.0	2.0	2.0
Digital	5.0	4.0	3.5	3.0	3.0	2.5

R 325.5690 Dosimetry.

Rule 690. The average glandular dose delivered during a single exposure of a department-approved phantom simulating a standard breast shall not exceed 3.0 milligray (300 millirad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

R 325.5691 Quality assurance for mobile units.

Rule 691. A stereotactic breast biopsy facility shall verify that mammography units used to produce interventional mammograms at more than 1 location meet the requirements in R 325.5687 to R 325.5690. At each examination location and before any examinations are conducted, the facility shall verify satisfactory performance of these units by using a test method that establishes the adequacy of the image quality produced by the unit.

R 325.5692 Use of quality assurance test results.

Rule 692. (1) After completion of tests specified in R 325.5687 to R 325.5691, the facility shall compare the test results to the corresponding specified action limits or the limits established by the facility to verify the image quality of mobile units following a move.

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

(a) 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 rules R 325.5687(a),(b),(d),(f)(i), (f)(iii), (f)(iv); R 325.5688(g) and (h); or R 325.5691.

(b) Within 30 days of the test date for all other tests described in rules R 325.5687 to R 325.5691.

R 325.5693 Medical physicist surveys.

Rule 693. (1) A stereotactic breast biopsy facility shall annually undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. The survey shall include, at a minimum, the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in R 325.5688 and the weekly phantom image quality test as provided in R 325.5687(b).

(2) The results of all tests conducted by the facility in accordance with R 325.5687 to R 325.5691 and written documentation of any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

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

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

(5) The survey report shall be dated and signed by the medical physicist who performed or supervised the survey. If the survey was performed entirely or in part by an individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall be identified in the survey report.

R 325.5694 Mammography equipment evaluations.

Rule 694. (1) Additional evaluations of stereotactic breast biopsy 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 stereotactic breast biopsy 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 R 325.5676 to R 325.5678 and R 325.5687 to R 325.5691, as applicable. Problems revealed by the evaluation shall be corrected before the new or changed equipment is put into service for procedures or film processing.

(2) The equipment evaluations specified in subrule (1) of this rule shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

R 325.5695 Facility cleanliness.

Rule 695. (1) A stereotactic breast biopsy facility shall establish and implement protocols for maintaining darkroom, screen, and view box cleanliness.

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

R 325.5696 Calibration of air kerma measuring instruments.

Rule 696. Instruments used by a medical physicist in his or her annual survey to measure the air kerma or air kerma rate from a stereotactic breast biopsy unit shall be calibrated 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 plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

R 325.5697 Infection control.

Rule 697. A stereotactic breast biopsy facility shall establish and comply with a system that specifies procedures to be followed by the facility for cleaning and disinfecting stereotactic breast biopsy equipment after contact with blood or other potentially infectious materials. The 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;

(b) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the stereotactic breast biopsy equipment used in the facility;

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

R 325.5698 Medical outcomes audit.

Rule 698. A stereotactic breast biopsy facility shall establish and maintain a stereotactic breast biopsy medical outcomes audit program that complies with the following:

(a) General requirements. A stereotactic breast biopsy facility shall establish a system to collect and review all of the following data:

(i) Total number of procedures.

(ii) Total number of cancers found.

(iii) Total number of benign lesions.

(iv) Total number of stereotactic breast biopsy needing repeat biopsy.

(v) Total number of complications.

(b) Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes registered with the department, or 12 months after the effective date of this rule, whichever date is later. The audit analysis shall be completed within an additional 12 months to permit completion of procedures and data collection. Subsequent audit analyses shall be conducted at least once every 12 months.

(c) Audit stereotactic breast biopsy physician. A stereotactic breast biopsy facility shall designate at least one stereotactic breast biopsy physician to review the medical outcomes audit data at least once every 12 months. This physician shall record the dates of the audit period; analyze results based on the audit; document the results; and notify other stereotactic breast biopsy physicians of the results and the facility’s aggregate results. The audit stereotactic breast biopsy physician shall ensure that any follow up actions are documented.