Part 14 – Mammography

Guidance for Mammography Rules

Table of Contents

General Provisions 2
R 325.5601 Purpose and scope. 2
R 325.5601a Adoption by reference. 2
R 325.5602 Definitions. 3
R 325.5603 Department inspections. 3
Mammography Authorization 4
R 325.5605 Standards for authorization. 4
R 325.5606 Temporary mammography authorization. 5
R 325.5607 Application. 5
R 325.5608 Application fee schedule; waiver. 6
R 325.5609 Application expiration. 6
R 325.5610 Supplemental machine information; effect of failure to submit information. 7
R 325.5611 Contracts for technical evaluation. 8
R 325.5612 Notice of change in application information; authorization not transferable. 8
R 325.5613 Authorization withdrawal; reinstatement. 9
Mammography - Personnel 10
R 325.5626 Scope of personnel requirements. 10
R 325.5627 Interpreting physician initial qualifications. 10
R 325.5628 Interpreting physician continuing experience and education. 11
R 325.5629 Interpreting physician reestablishment of qualifications. 12
R 325.5630 Radiologic technologists. 12
R 325.5634 Medical physicists. 12
R 325.5635 Retention of personnel records. 13
Mammography - X-Ray Equipment 13
R 325.5637 X-ray equipment; requirements. 13
R 325.5655 Enclosure requirements; use of mobile equipment. 14
R 325.5656 Conditions of operation. 14
Mammography - Medical Records and Mammography Report 14
R 325.5657 Medical records and mammography reports. 14
Mammography - Quality Assurance 15
R 325.5658 Quality assurance - general. 15
R 325.5667 Quality assurance – equipment. 16
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. 17
R 325.5669 Alternative requirements for personnel, x-ray equipment, medical records and mammography reports, and quality assurance. 17
Stereotactic Breast Biopsy – Personnel 17
R 325.5674 Radiologic technologists. 17
R 325.5675 Medical physicists. 18
Stereotactic Breast Biopsy – X-Ray Equipment 19
R 325.5676 Equipment requirements. 19
R 325.5677 Enclosures; use of mobile equipment. 19
R 325.5678 Conditions of operation. 19
Stereotactic Breast Biopsy – Medical Records and Stereotactic Breast Biopsy Reports 20
R 325.5679 Report contents. 20
R 325.5681 Communication of stereotactic breast biopsy results to health care providers. 20
R 325.5682 Record keeping. 20
R 325.5683 Stereotactic breast biopsy image identification. 21
Stereotactic Breast Biopsy – Quality Assurance 21
R 325.5684 Quality assurance – general. 21
R 325.5685 Responsible individuals. 21
R 325.5686 Quality assurance records. 22
R 325.5687 Radiologic technologist quality control tests. 22
R 325.5688 Annual medical physicist's quality control tests. 23
R 325.5689 Phantom image scores. 25
R 325.5690 Dosimetry. 25
R 325.5691 Quality assurance for mobile units. 25
R 325.5692 Use of quality assurance test results. 26
R 325.5693 Medical physicist surveys. 26
R 325.5694 Mammography equipment evaluations. 26
R 325.5695 Cleanliness in facilities using screen-film systems. 27
R 325.5696 Calibration of air kerma measuring instruments. 27
R 325.5697 Infection control. 27
R 325.5698 Medical outcomes audit. 28

The Michigan Department of Licensing and Regulatory Affairs will not discriminate against any individual or group because of race, sex, religion, age, national origin, color, marital status, disability, or political beliefs. You may make your needs known to this agency if you need assistance with reading, writing, hearing, etc. under the *Americans wit Disabilities Act*.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 R 325.5181 to R 325.5196 and is specifically authorized to perform mammography pursuant to the act. **(2)** In addition to the requirements of this part, all persons are subject to all applicable provisions of R 325.5001 to 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.	AMENDED. Subrule (2) is changed. The full set of Ionizing Radiation Rules (IRR) now spans R 325.5001 to R 325.5721. The subrule reflects this change. Some minor style changes are also made.	There will be no substantive change for facilities.
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 2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (June 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" (May 2012), and "Stereotactic Breast Biopsy Accreditation Program Requirements" (May 2012). These criteria are available for no cost from either of the following sources:	NEW RULE. These rule amendments adopt parts of standards and regulations from outside entities. Current administrative rules style requires such a rule which names the adopted standards and their availability. The standards listed are: • The Federal Mammography Quality Standards Act (MQSA) • The Food and Drug Administration's (FDA) performance guidelines for new x-ray equipment, 21 C.F.R. 1020.30 and 21 C.F.R. 1020.31 • The American College of Radiology's (ACR) "Mammography Accreditation Program Requirements" and "Stereotactic Breast Biopsy Accreditation Program Requirements"	The effect of adopting the MQSA will eliminate the differences between federal regulations and Michigan rules.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
(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. **(b)** "Annual" means a period of 12 consecutive months. **(c)** "Interpreting physician" means a physician who interprets mammograms and who meets the requirements of R 325.5627 to R 325.5629. **(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. **(3)** The terms defined in the act shall have the same meanings when used in these rules.	AMENDED. All the definitions of the MQSA are adopted <u>except</u> the definition of "mammography." The format of the definition of "Act" is modified according to current style guidelines. The definition of "annual" is changed to 12 months as was done in Part 15 (Computed Tomography Installations). The definition of "mammography" is changed to state that interventional mammography is included. The following new definitions are added: "interpreting physician", "stereotactic breast biopsy", and "stereotactic breast biopsy physician."	Because the MQSA regulations are adopted, the "mammography supervisor" position is eliminated. "Annual" now means that a department inspection or medical physicist survey completed in a particular month of the first year needs to be repeated by the end of the same month the following year or earlier. This will prevent annual inspections and physicist surveys from occurring earlier each year. "Stereotactic Breast Biopsy" means imaging of the breast in at least 2 planes to localize a target lesion. Needle location procedures performed on a mammographic unit in only one direction are not subject to rules governing stereotactic breast biopsy (SBB).
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. The department may inspect more frequently than annually. **(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	AMENDED. Minor changes are made to subrules (1), (4), and (7) for style and to revise the administrative rule range of the IRR.	There will be no substantive change for facilities.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 comply with this part and applicable provisions of R 325.5001 to R 325.5721 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 325.5721.		
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 meets any of the following requirements: **(i)** The machine and the facility in which the machine is used meet the criteria for the American college of radiology mammography accreditation program dated May 2012, 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)** 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 May 2012, 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. A mammography machine that uses a specially designed add-on device for breast biopsy shall be authorized for both mammography and stereotactic breast biopsy.	AMENDED. Style changes are made throughout. R 325.5605(a)(ii) is new and adds authorization requirements for SBB. In R 325.5605(a)(i) the reference to the ACR accreditation program is updated to a more current version. In subdivision (b) the rule range is changed to the new full extent of the IRR. In subrule (e) “radiation physicist” is changed to “medical physicist” since we are adopting the terminology of the MQSA and ACR. In subrule (f) the reference for dose limits is changed from R 325.5661 (which is rescinded) to R 325.5667 for	The new specific authorization requirements for SBB will require the facility to either become ACR accredited or submit information to complete the department’s evaluation of the machine and facility as described in rule 610. The aim of the department evaluation is to be consistent with the ACR program.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
(iii) The machine is used in a facility that has successfully completed the department's evaluation of 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 comply with the requirements of this part and applicable provisions of R 325.5001 to R 325.5721. **(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 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 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.	mammographic and R 325.5690 for SBB machines.	
R 325.5606 Temporary mammography authorization. **Rule 606. (1)** The department may issue a nonrenewable temporary mammography authorization. A temporary authorization may only be issued if additional time is needed to allow the submission of evidence that is satisfactory to the department to demonstrate compliance with the provisions of R 325.5605. **(2)** The department may withdraw a temporary authorization before its expiration if the radiation machine does not meet 1 or more of the criteria specified in R 325.5605.	No changes were made to this rule.	No change.
R 325.5607 Application. **Rule 607. (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 address, a separate application shall be used for each 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)** Mammography facility name, address, and telephone number. **(ii)** Type of practice. **(iii)** The facility registration number, if currently registered.	AMENDED. Subrule (1) is rescinded. Style changes are made throughout and many items to be included in the application form are deleted. Some items applicable to digital mammography have been added.	The authorization application should be easier to complete.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
(iv) A contact person's name and telephone number. **(b)** Personnel information, including the education, training, experience, and certification of the lead interpreting physician, any qualified medical physicist who provides on-site consultation, and any radiologic technologist who performs mammography. **(c)** Mammography machine technical information, including all of the following: **(i)** Machine registration number, if currently registered. **(ii)** Manufacturer. **(iii)** Model. **(iv)** Target material. **(v)** Filter material. **(d)** 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, as applicable, for machines using 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. **(e)** The date of the most recent medical physicist survey. **(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 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.	AMENDED. Minor style revision in subrule (2).	There will be no substantive change for facilities.
R 325.5609 Application expiration. **Rule 609.** An application for mammography authorization submitted to the department shall expire 6 months from the date of the department's receipt of the completed application unless the time limit is extended by the department.	No changes were made to this rule.	No change.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 is complete and complies with 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 is on-site when mammography is performed and is used in the facility's ongoing quality control program. **(b)** 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)** An x-ray image of a department-approved mammography phantom which is taken during the 30-day period for which processor quality control data is required under 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 4.2-centimeter compressed breast of average density. The phantom image shall be accompanied by documentation of the date that the image was taken and the machine settings that were used. **(d)** 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 dosimetry device exposed on the phantom during the same exposure of the phantom that is used to produce an x-ray image to be submitted under subdivision (c) of this subrule or that are made by other methods as specified or approved by the department. **(e)** A set of clinical images produced on or after the date that the application was sent to the department. Mammography images shall be without pathology for each of 2 representative patients, 1 with dense breasts and 1 with fatty breasts. 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 are examples of the facility's best work. **(ii)** The images are from actual patients. **(iii)** Both screen-film and digital images are labeled with the identification information required in R 325.5657 for mammography images or R 325.5683 for stereotactic breast biopsy images. **(iv)** The lead interpreting physician reviews and approves the clinical images. **(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	AMENDED. In R 325.5610(1)(c) 4.5 centimeters is changed to 4.2 centimeters. R 325.5610(1)(e)(i) to R 325.5610(1)(e)(iv) are replaced with requirements that are more consistent with the information required in the ACR accreditation application. Style changes are made throughout. This rule details the machine information that will be required in-lieu of evidence of ACR accreditation. This includes: • Confirmation that the facility has a phantom; and • Processor or printer QC data; and • A phantom image including relevant exposure data; and • Determination of the mean glandular dose obtained during the phantom image exposure; and • A set of clinical images.	The new subrule 605(a)(ii) requires SBB facilities to provide evidence of ACR accreditation or complete the department's evaluation in order to be authorized.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 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.	AMENDED. "Processing" is removed from the list of technical parameters used in evaluating clinical image quality and acceptability. Style change made in subrule (2).	There will be no substantive change for facilities.
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 modality. **(e)** American college of radiology accreditation status.	AMENDED. Items (d) through (i) in subrule (1) are rescinded as changes requiring reporting to the department to maintain authorization.	The list of items requiring a notice of change is reduced. This should reduce the frequency that facilities will need to update their authorization information.

Rule	***Description of Rule or Change***	***Effect of Rule or Change***
(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 325.5721. Authorization may be withdrawn based on evidence of noncompliance with this part and the provisions of R 325.5001 to R 325.5721 in accordance with the provisions of 1969 PA 306, 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 under 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 in R 325.5605.	AMENDED. Style changes and expansion of relevant rule range to include full IRR.	There will be no substantive change for facilities.
R 325.5617 Designation; identification; agreement between supervisor and facility; availability; continuing education. R 325.5618 Responsibilities. R 325.5619 Machine operator performance evaluation.	These rules are RECINDED. These rules described the role and responsibilities of the mammography supervisor.	These rules referred to the responsibilities of the “mammography supervisor”. The mammography supervisor position and the medical director for the delivery of mammography services are replaced with the “lead interpreting physician” whose responsibilities are described in the MQSA. The semi-annual operator evaluations are eliminated and the onsite visits by the medical director are eliminated.

Rule	***Description of Rule or Change***	***Effect of Rule or Change***
R 325.5621 Qualifications. R 325.5622 Technologist exemptions. R 325.5623 Continuing education. R 325.5624 Operator prohibitions. R 325.5625 Program of mammography instruction topics.	These rules are RECINDED These rules described the qualification requirements for mammography operators.	The MQSA qualifications requirements for radiologic technologists are adopted. Michigan will no longer maintain a list of approved courses to meet the initial qualifications requirement.
Mammography - Personnel		
R 325.5626 Scope of personnel requirements. **Rule 626.** The requirements of R 325.5627 to R 325.5634 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.	NEW RULE	No effect on facilities as they have had to meet this MQSA requirement.
R 325.5627 Interpreting physician initial qualifications. **Rule 627.** Before beginning to interpret mammograms independently, an interpreting physician shall meet all of the following requirements: **(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, including 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	NEW RULE. This rule which adopts MQSA regulations for interpreting physicians. An exception to the MQSA regulations is the requirement that a physician be board certified within 2 years of becoming eligible Note: This rules does not apply to stereotactic breast biopsy physicians.	This rule states the personnel qualification requirements for interpreting physicians. The requirements match the MQSA with the exception that physicians must be board certified within 2 years of becoming eligible. Board certification is stipulated in the statute.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 are 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 subdivision (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 subdivision.		
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).	NEW RULE. This rule which adopts the MQSA regulation for interpreting physician continuing experience and education. Note: This rule does not apply to stereotactic breast biopsy physicians.	This change to the continuing experience requirement resolves a discrepancy between the state of Michigan and MQSA. Formerly a physician was required to have interpreted at least 520 mammographic examinations each year. The MQSA requirement is that the physician have interpreted or multi-read at least 960 mammographic examinations in the prior 24 months. This prevents the facility from needing to maintain documentation for two separate standards.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
R 325.5629 Interpreting physician reestablishment of qualifications. **Rule 629.** 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 – Reestablishing qualifications" (2000).	NEW RULE. This rule which adopts the MQSA regulation for interpreting physician reestablishment of qualifications. Note: This rule does not apply to stereotactic breast biopsy physicians.	No effect on facilities as they have had to meet this MQSA requirement.
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).	NEW RULE. This rule which adopts MQSA regulations for radiologic technologists.	The MQSA qualification requirements for radiologic technologists are adopted with the exception that licensure from a different state will not be accepted in lieu of A.R.R.T. registration. Michigan will no longer maintain a list of approved courses to meet the initial qualifications requirement.
R 325.5631 Qualifications. R 325.5632 Mammography system evaluation. R 325.5633 Records of on site evaluations and consultations.	These rules are RESCINDED. These rules described the role and responsibilities of the radiation physicist.	The concept of "radiation physicist" is replaced with "medical physicist." A medical physicist will no longer have to obtain state approval before providing mammography consultation.
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).	NEW RULE. The MQSA qualification requirements for medical physicists are adopted by reference.	The department will no longer be issuing certificates of approval as a mammography physicist. Physicists who had valid state approval certificates prior to the promulgation of the new rules will be approved in lieu of board certification. After the effective date of the rules revision, new physicists will have to qualify under the MQSA.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 determines that the facility complies with the personnel requirements.	NEW RULE.	No effect on facilities as they have had to meet this MQSA requirement.
Mammography - X-Ray Equipment		
R 325.5637 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). **(2)** 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).	AMENDED. In subrule (1), the equipment requirements of R 325.5325 are replaced with the FDA equipment requirements of 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major components" and 21 C.F.R. 1020.31, "Radiographic equipment". In subrule (2), the mammography system must meet the MQSA requirements of 21 C.F.R. 900.12(b), "Equipment".	During department inspections, machine performance will be tested against the applicable federal performance standards.
R 325.5638 Machine output. R 325.5639 Accuracy of technique factors. R 325.5640 Permissible degree of coefficient of variation of radiation exposure for combination of selected technique factors. R 325.5641 Permissible difference in average ratios of exposure to indicated milliampere seconds product obtained at 2 consecutive settings. R 325.5642 Target and filter material R 325.5643 Nominal focal spot size. R 325.5644 Half-value layer. R 325.5645 Focal spot to image receptor distance. R 325.5646 Machine design; x-ray beam geometry. R 325.5647 Reciprocating grid capability; grid ratio; exception; grid lines. R 325.5648 Image receptor capability. R 325.5649 Beam limiting device. R 325.5650 Compression device. R 325.5651 Primary beam transmission through the image receptor support. R 325.5652 Automatic exposure control system.	These rules are RESCINDED. These rules described the minimum equipment standards for mammography machines.	There will be no substantive change for facilities. Most of these standards are included in the MQSA regulations or the federal performance standard.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
R 325.5655 Enclosure requirements; use of mobile equipment. **Rule 655. (1)** A fixed x-ray equipment enclosure shall 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 tube potential is less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum tube potential is greater 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 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 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.	AMENDED. Style changes are made to subrule (2). Subrules (3) to (5) governing shielding requirements for mobile mammographic machines are added.	There will be no substantive change for facilities. Subrules (3) to (5) are restatements of existing rules from Part 7 which have always applied. Subrule (3) restates R 325.5353(2), subrule (4) restates R 325.5352(2), and subrule (5) restates R 325.5353(3).
R 325.5656 Conditions of operation. **Rule 656.** The operation of each mammography x-ray machine shall comply with R 325.5333.	AMENDED. Subrule (2) is deleted. Style changes to the remainder.	There will be no substantive change for facilities. The requirement for mammogram film retention contained in the deleted subrule is replaced by new rule R 325.5657.
Mammography - Medical Records and Mammography Report		
R 325.5657 Medical records and mammography reports. **Rule 657.** A mammography facility shall comply with 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.	NEW RULE. Record retention requirements of the MQSA are adopted with some modification to comply with Michigan statute MCL 333.20175.	There will be no substantive change for facilities.

Rule	***Description of Rule or Change***	***Effect of Rule or Change***
2014 PA 517 This Act was filed with the Secretary of State on January 14, 2015 and is effective June 1, 2015.	Requires the lay summary to patients with dense breasts to include information about how dense breast tissue may affect the accuracy of the mammogram and that dense breast tissue may increase the risk of getting breast cancer.	The mammography facility will need to include the following information on the lay summary if the patient has heterogeneously dense or extremely dense breast tissue: "Your mammogram shows that your breast tissue is dense. Dense breast tissue is very common and is not abnormal. However, dense breast tissue can make it harder to find cancer through a mammogram. Also, dense breast tissue may increase your risk for breast cancer. This information about the result of your mammogram is given to you to raise your awareness. Use this information to discuss with your health care provider whether other supplemental tests in addition to your mammogram may be appropriate for you, based on your individual risk. A report of your results was sent to your ordering physician. If you are self-referred, a report of your results was sent to you in addition to this summary." The lay summary must be sent to the patient within 30 days of the mammographic examination.
Mammography - Quality Assurance		
R 325.5658 Quality assurance - general. **Rule 658.** A mammography facility shall comply with 21 C.F.R. 900.12(d), "Quality assurance general" (2000).	NEW RULE. The quality assurance requirements of the MQSA covering responsible individuals and quality assurance records are adopted (21 C.F.R. 900.12(d)).	Since all mammography facilities are currently required to comply with the MQSA, this adds nothing new.

Rule	***Description of Rule or Change***	***Effect of Rule or Change***
R 325.5659 Quality control responsibilities of supervisor; establishment of quality assurance manual; provision of mammography phantom; submission of phantom images. R 325.5660 Phantom image quality. R 325.5661 Radiation dose limits. R 325.5662 Screen-film processor adjustment. R 325.5663 Mammography phantom imaging required; corrective action; phantom imaging for mobile units; repeat analysis; compression check. R 325.5664 Screen-film mammography quality control. R 325.5665 Xeromammography; plate management system.	These rules are RESCINDED**.** Quality control requirements are replaced by R 325.5658 and R 325.5667 which adopt parts of the MQSA.	The Michigan limit of 200 mrad for the mean glandular dose on film-screen systems is eliminated. The new dose limit for all imaging systems will be the MQSA limit of 300 mrad.
R 325.5667 Quality assurance – equipment. **Rule 667.** A mammography facility shall comply with 21 C.F.R. 900.12(e), "Quality assurance – equipment" (2000).	NEW RULE. This rule adopts 21 C.F.R. 900.12(e) of the MQSA. This rule includes: • Daily quality control tests • Weekly quality control tests • Quarterly quality control tests • Semiannual quality control tests • Annual quality control tests • Quality control tests for other modalities • Mobile units • Use of test results • Medical physicist surveys • Mammography equipment evaluations • Facility cleanliness • Calibration of air kerma measuring instruments • Infection control	Since all mammography facilities are currently required to comply with the MQSA, this adds nothing new.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 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).	NEW RULE. This rule adopts 21 C.F.R. 900.12 subdivisions (f) to (i): • Mammography medical outcomes audit • Mammographic procedures and techniques for mammography of patients with breast implants • Consumer complaint mechanism • Clinical image quality	Since all mammography facilities are currently required to comply with the MQSA, this adds nothing new.
R 325.5669 Alternative requirements for personnel, x-ray equipment, medical records and mammography reports, and quality assurance. **Rule 669.** The department may accept alternatives to a quality standard under 21 CFR 900.12 that have been approved by the U.S. Food and Drug Administration under 21 CFR 900.18, "Alternative requirements for § 900.12 quality standards" (2000).	NEW RULE. The rule states that the department may adopt alternative standards that are adopted by the U.S. Food and Drug Administration.	This is consistent with current MQSA practice and should not have a substantive effect for facilities.
Stereotactic Breast Biopsy – Personnel		
		Note: The Act does not provide authority to promulgate rules for stereotactic breast biopsy (SBB) physicians.
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 subdivision (a) of	NEW RULE. Qualification requirements for radiologic technologists performing SBB procedures are set.	New initial qualifications for SBB techs are: • Be qualified as an MQSA mammography tech (R 325.5630); and • Have 3 credits in SBB; and • Have performed 5 SBB procedures under supervision. The continuing experience and education requirements for SBB techs

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 2. The facility shall choose 1 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.		are: • Perform 24 SBB procedures in the previous 24 months; and • Obtain at least 2 credits pertinent to SBB each biennium.
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 have complied with all of the following: **(i)** Met 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 before 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 subdivision (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 1 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 subdivision (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 2. The facility shall choose 1 of these dates to determine the 36-month period.	NEW RULE. Qualification requirements for medical physicists surveying SBB facilities are set.	New initial qualifications for SBB medical physicists are: • Be qualified as an MQSA medical physicist (R 325.5634); and • Have performed 1 survey under supervision or 3 surveys independently prior to the rule's effective date. The continuing experience and education requirements for SBB medical physicists are: • Perform 2 SBB surveys in the previous 24 months; and • Obtain at least 3 CMEs in SBB in 36 months.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
Stereotactic Breast Biopsy – 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 1 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.	NEW RULE. Subrule (1) states that SBB equipment shall comply with the existing part 7 requirements (R 325.5325(1) and R 325.5325(17) to (23).	The requirements of this rule are not new. There should be no substantive change for facilities.
R 325.5677 Enclosures; use of mobile equipment. **Rule 677. (1)** A fixed x-ray equipment enclosure shall comply with 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 tube potential is less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum tube potential is greater 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 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.	NEW RULE. The rule sets shielding requirements for SBB x-ray equipment. The rule contains analogous language to R 325.5655 for mammographic equipment.	There will not be substantive changes for facilities.
R 325.5678 Conditions of operation. **Rule 678.** The operation of a mammography x-ray machine shall comply with R 325.5333.	NEW RULE. This rule sets conditions of operation standards for SBB equipment. Equipment shall be operated consistent with existing rule R 325.5333.	There will not be substantive changes for facilities.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
Stereotactic Breast Biopsy – Medical Records and Stereotactic Breast Biopsy Reports		
R 325.5679 Report contents. **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.	NEW RULE. This rule sets standards for contents of a SBB report of the procedure.	The facility must prepare a written report of the SBB.
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 not later than 30 days after the date that the stereotactic breast biopsy procedure was performed.	NEW RULE. This rule requires a written report of the SBB results be provided to the patient's health care provider.	The facility must provide a report of the SBB results to the patient's health care provider within 30 days of the procedure.
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: **(i)** A medical institution. **(ii)** A patient's physician. **(iii)** 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.	NEW RULE. This rule addresses retention of SBB images and reports.	SBB images and reports must be retained for at least 7 years or not less than 10 years if no additional SBB procedures are performed at the facility. If requested by the patient, the images and copies of records must be transferred to another medical institution, the patient's physician, or directly to the patient.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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)** Cassette identification, if applicable. **(e)** Stereotactic breast biopsy unit identification if there is more than 1 unit in the facility.	NEW RULE. This rule requires identification of the SBB image.	SBB images must be labeled with the elements described in the rule.
Stereotactic Breast Biopsy – 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.	NEW RULE. This rule requires SBB facilities to establish and maintain a quality assurance program.	A SBB facility will need to establish a quality assurance program to ensure the safety, reliability, clarity, and accuracy of SBB services.
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 do both of the following: **(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	NEW RULE. This rule requires SBB facilities to assign personnel responsibilities for the quality assurance program.	The responsibilities for the quality assurance program are: • The lead interpreting physician is responsible for assuring the quality assurance program , the QA tech and medical physicist meet the requirements of the rules. • SBB physicians are responsible for following the facility's procedures for corrective action when images are of poor quality and to participate in the medical outcomes audit program. • The medical physicist is responsible for performing annual surveys, SBB equipment

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 delegated to other qualified personnel by the quality control technologist. When other personnel are utilized for these tasks, the quality control technologist shall ensure that they were completed in compliance with R 325.5687.		evaluations, and providing the facility with reports of the surveys. • The quality control technologist is responsible for assuring the technologist's QC tests are properly performed.
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 2 additional times at the required frequency, whichever is longer.	NEW RULE. This rule requires the updating and maintenance of quality assurance records.	The facility is required to maintain and update the following items: • SBB techniques and procedures • QC, including monitoring data and corrective actions • Safety • Employee qualifications
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. If the overall repeat or reject rate exceeds 20% based on an image volume of not less than 150 patients, the reason for the change shall be determined. A repeat	NEW RULE. This rule sets the minimum quality control tests for a SBB facility.	Required technologist tests include: • Localization accuracy test before clinical use • Weekly phantom evaluation • Monthly hardcopy output test (if applicable) • Semiannual compression test • Semiannual repeat analysis Additional required tests for screen-film systems include: • Daily processor test • Quarterly fixer retention analysis • Semiannual screen-film contact

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 not 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 not 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.		test • Semiannual darkroom fog test.
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 3 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.	NEW RULE. This rule sets the minimum quality control tests to be performed by the medical physicist.	The facility is required to have an annual medical physics survey. The required tests are: • Collimation assessment; • Focal spot performance and spatial resolution;

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
(ii) For digital image receptors, the x-ray field may extend beyond the edge of the image receptor on all 4 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. **(iii)** For digital systems that are not equipped with region of interest signal measurements, the machine will meet the receptor uniformity requirements specified by the manufacturer. **(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		• kVp accuracy and reproducibility; • Beam quality assessment; • AEC or manual exposure assessment; • Image receptor speed uniformity; • Breast entrance exposure and average glandular dose; • Image quality evaluation; • Artifact evaluation; • Localization accuracy.

<table>
<tr><th>Rule</th><th>Description of Rule or Change</th><th>Effect of Rule or Change</th></tr>
<tr><td>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.</td><td></td><td></td></tr>
<tr><td>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
<table>
<tr><th></th><th colspan="3">Standard Mammography Phantom</th><th colspan="3">Mini Stereotactic Phantom</th></tr>
<tr><th>Image System</th><th>Fibers</th><th>Speck Groups</th><th>Masses</th><th>Fibers</th><th>Speck Groups</th><th>Masses</th></tr>
<tr><td>Screen-film</td><td>4.0</td><td>3.0</td><td>3.0</td><td>2.0</td><td>2.0</td><td>2.0</td></tr>
<tr><td>Digital</td><td>5.0</td><td>4.0</td><td>3.5</td><td>3.0</td><td>3.0</td><td>2.5</td></tr>
</table></td><td>NEW RULE.
This rule establishes standards for SBB phantom images.</td><td>Minimum standards for phantom images are set according to the ACR accreditation standards.</td></tr>
<tr><td>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.</td><td>NEW RULE.
This rule sets the maximum dose for a phantom image.</td><td>Maximum average glandular dose, when determined with technique factors and conditions used clinically, are limited to 3.0 milligray (300 millirads).</td></tr>
<tr><td>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.</td><td>NEW RULE.
Quality assurance requirements for mobile units are set.</td><td>The rule requires facilities to perform an image quality evaluation at each new location prior to clinical use.</td></tr>
</table>

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 within the following time frames: **(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 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 R 325.5687 to R 325.5691.	NEW RULE.	This rule will require facilities to take corrective action when tests fall outside of control limits. For failures of tests involving localization accuracy, phantom image evaluation, compression tests, and film processing, the facility must take corrective action before performing additional procedures. For failures of other required tests, the facility must take corrective action within 30 days.
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.	NEW RULE. This rule states the minimum standards for the annual medical physics surveys for SBB facilities.	The annual medical physicist survey must include: • Performing the annual medical physicist's QC tests • Review of the technologists QC tests • A survey report signed and dated by the medical physicist must be provided to the facility within 30 days
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	NEW RULE. This rule states the minimum standards for equipment evaluations following major repairs for SBB facilities.	The medical physicist must conduct an equipment evaluation whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new

Rule	***Description of Rule or Change***	***Effect of Rule or Change***
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.		location, or major components of a SBB unit or processor are changed or repaired.
R 325.5695 Cleanliness in facilities using screen-film systems. **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.	NEW RULE. This rule sets minimum standards for darkroom and view box cleanliness for SBB facilities using screen-film.	Facilities must establish and implement protocols for darkroom, screen, and view box cleanliness. The facility must document that the 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.	NEW RULE. This rule sets the calibration standards for the medical physicists test equipment used in surveys of SBB facilities.	This requirement is the same as what is required of mammography air kerma measuring instruments.
R 325.5697 Infection control. **Rule 697.** A stereotactic breast biopsy facility shall establish and comply with procedures to be followed for cleaning and disinfecting stereotactic breast biopsy equipment after contact with blood or other potentially infectious materials. The procedures shall include methods for documenting facility compliance with the infection control procedures.	NEW RULE. This rule requires SBB facilities to establish procedures for infection control.	The facility must establish and comply with procedures to be followed for cleaning and disinfecting SBB equipment after contact with blood or other potentially infectious materials.

Rule	*Description of Rule or Change*	*Effect of Rule or Change*
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 not 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 1 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.	NEW RULE. This rule sets minimum standards for medical outcomes audits for SBB facilities.	The facility must establish and maintain a SBB medical outcomes audit program that collects and reviews the following: • Total number of procedures • Total number of cancers found • Total number of benign lesions • Total number of SBB needing repeat biopsy • Total number of complications The audit must be conducted at least once every 12 months. The facility must designate a SBB physician to review the medical outcomes audit data annually. The physician must: • Record the dates of the audit period • Analyze and document the results of the audit • Notify other SBB physicians of the results and the facility's aggregate results. • Ensure any follow-up actions are documented.