

PART V
QUALITY STANDARDS AND CERTIFICATION
REQUIREMENTS FOR FACILITIES PERFORMING MAMMOGRAPHY

RHB 5.1 Scope. This Part establishes quality standards and certification requirements for facilities performing mammography to ensure that all mammography facilities are adequately and consistently evaluated for compliance with the standards provided.

5.1.1 Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of Part IV. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within 15 days. Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

5.1.2 Exemptions.

5.1.2.1 Mammography units used only during invasive interventions for localization or biopsy procedures are exempt from the requirements of this Part, except that such systems shall satisfy the criteria specified in RHB 5.25, and all parts to which RHB 5.25 refers.

5.1.2.2 Each mobile mammography facility based outside of South Carolina that operates in South Carolina and which has not been certified by the Department is exempt from the requirements of RHB 5.3 and RHB 5.6, provided that:

5.1.2.2.1 The mobile mammography facility is certified to perform mammography by FDA or other FDA-approved certifying agency at all times while conducting operations in South Carolina; and

5.1.2.2.2 The mobile mammography facility meets the requirements of RHB 5.28.

5.1.2.2.3 The mobile mammography facility shall comply with all other requirements in Part V.

RHB 5.2 Requirements for Certification. A certificate issued by the Department is required for lawful operation of all mammography facilities subject to the provisions of this Part. After the effective date of these regulations, the Department will issue a certificate to each facility holding a currently valid certificate issued by FDA under the Mammography Quality Standards Act of 1992, Public Law 102-539, and 21 C.F.R. Part 900. The term of such certificate shall be for the same period of time as the remainder of the term of the certificate issued by FDA. Certificate holding facilities shall meet the requirements of RHB 5.6 and be accredited by an FDA-approved accreditation body.

RHB 5.3 Certificates.

5.3.1 In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body.

5.3.2 Following the Department's receipt of the accreditation body's decision to accredit a facility, the Department may issue a certificate to the facility, or renew an existing certificate, if

the Department determines that the facility has satisfied the requirements for certification or recertification.

5.3.3 Provisional Certificates.

5.3.3.1 A new facility is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process.

5.3.3.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements for provisional certification. A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90 day extension of the provisional certificate.

5.3.4 Extension of Provisional Certificate.

5.3.4.1 To apply for a 90 day extension to a provisional certificate, a facility shall submit to its accreditation body a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

5.3.4.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a 90 day extension of the provisional certificate to the facility upon determination that the facility has satisfied the requirements for the 90 day extension.

5.3.4.3 There can be no renewal of a provisional certificate beyond the 90 day extension.

5.3.5 Interim Notices. The Department may issue an interim notice of mammography certification by facsimile to a facility if a delay is anticipated in providing a certificate to the facility under one or more of the following circumstances:

5.3.5.1 The Department has been notified by an accreditation body that the facility meets the requirements for a provisional or provisional reinstatement certificate and delivery of the certificate may be delayed;

5.3.5.2 The Department has been notified by an accreditation body that the facility has completed accreditation or reaccreditation and delivery of the certificate to the facility may be delayed; or

5.3.5.3 The Department has been notified by an accreditation body that the facility has timely submitted an application for accreditation or reaccreditation but the completion of the accreditation process may extend beyond the expiration date of a facility's existing certificate through no fault of the facility.

5.3.5.4 An interim notice shall authorize the facility to perform mammography until the facility receives its certificate but in no case for more than 45 days. No more than one interim notice may be issued to a facility per application for certification.

RHB 5.4 Reinstatement Policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA or the Department, or that has had its certificate suspended or revoked by FDA or the Department, may apply for reinstatement. If reinstated, the facility will be eligible for a provisional certificate.

5.4.1 Unless prohibited from reinstatement under 5.4.4, a facility applying for reinstatement shall:

5.4.1.1 Contact an FDA-approved accreditation body to determine the requirements for reapplication or accreditation;

5.4.1.2 Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

5.4.1.2.1 Name and address of the facility under which it was previously provisionally certified or certified;

5.4.1.2.2 Name of previous owner/lessor;

5.4.1.2.3 FDA facility identification number assigned to the facility under its previous certification; and

5.4.1.2.4 Expiration date of the most recent FDA provisional certificate or certificate.

5.4.1.3 Justify application for reinstatement of accreditation by submitting to the accreditation body, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

5.4.2 The Department may issue a provisional certificate to the facility if:

5.4.2.1 Following the Department's receipt of the accreditation body's decision that a facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and

5.4.2.2 The Department determines that the facility has taken sufficient corrective action since the lapse of, denial or revocation of its previous certificate.

5.4.3 After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

5.4.4 If a facility's certificate was revoked on the basis of an act described in 5.24, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within two years of the date of revocation.

RHB 5.5 Appeals of adverse accreditation or reaccreditation decisions. The appeals procedures described in this Part are available only for adverse accreditation or reaccreditation decisions that preclude certification by the Department. Department decisions to suspend or revoke certificates that are already in effect shall be conducted in accordance with RHB 5.24.

5.5.1 Upon learning that a facility has failed to become accredited or reaccredited, the Department will notify the facility that the Department is unable to certify that facility without proof of accreditation.

5.5.2 A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body. A facility shall avail itself of the accreditation body's appeal process before requesting a review from the Department.

5.5.3 In the event that a facility, after availing itself of the accreditation body's appeal process, receives an adverse accreditation or reaccreditation decision, the facility may within 30 days after such adverse decision submit a request for review of the adverse accreditation decision to the Department.

5.5.4 Within 30 days following receipt of such written request, the Deputy Commissioner for Health Services shall review the facility's appeal.

5.5.5 A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

RHB 5.6 Fees

5.6.1 The Department shall assess each certified mammography facility an annual certification fee of \$1000 in accordance with RHB 2.10. This certification fee includes one mammographic tube. The Department shall assess each certified mammography facility an additional fee of \$200 per mammographic tube for each additional tube.

5.6.2 For mammography facilities holding valid FDA mammography certificates on the effective date of this Part, the initial annual fee shall be billed as soon as practicable after the effective date of this regulation. The annual fee described in 5.6.1 applies to both fully and provisionally certified mammography facilities.

5.6.3 A new mammography facility issued an initial provisional certificate during the calendar year shall be issued a prorated fee for the remainder of the year, in accordance with RHB 2.10.

5.6.4 All fees shall be due and payable in accordance with RHB 2.10.

RHB 5.7 Personnel Requirements. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

5.7.1 Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

5.7.1.1 Initial qualifications. Unless the exemption in 5.7.1.3.1 applies, before beginning to interpret mammograms independently, the interpreting physician shall:

5.7.1.1.1 Be a licensed physician to practice medicine in this State;

5.7.1.1.2 Be certified in diagnostic radiology by either the American Board of Radiology, the American Osteopathic Board of Radiology, or Royal College of Physicians and Surgeons of Canada or have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of 5.7.1 of this Part.

5.7.1.1.3 Have a minimum of sixty 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 sixty of these hours shall be Category I and have at least fifteen hours of the Category I hours shall have been acquired within three years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

5.7.1.1.4 Unless the exemption in RHB 5.7.1.3.2 applies, have interpreted or multi-read at least 240 mammograms examinations within the 6 month period immediately prior to the date that the physician qualifies as an interpreting physician. The interpretation or multi-reading shall be under direct supervision of an qualified interpreting physician.

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

5.7.1.2.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.1.1 of this Part, were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the twenty-four months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

5.7.1.2.2 Following the third anniversary of the end of the calendar quarter in which the requirements of 5.7.1.1 of this Part were completed, the interpreting physician shall have taught or completed at least 15 Category I continuing medical education units in mammography during the thirty six months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This training shall include at least six Category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

5.7.1.2.3 Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least eight hours of training in the new mammographic modality.

5.7.1.2.4 Units earned through teaching a specific course can be counted only once towards the fifteen units required by RHB 5.7.1.2.2, even if the course is taught multiple times during the previous 36 months.

5.7.1.3 Exemptions

5.7.1.3.1 Those physicians who qualified as interpreting physicians under FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 5.7.1.1 of this Part. These physicians may continue to interpret mammograms provided they continue to meet the requirement of 5.7.1 and the continuing experience and education requirements of 5.7.1.2.

5.7.1.3.2 Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are exempt from 5.7.1.1.4.

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

5.7.1.4.1 Interpreting physicians who fail to meet the continuing experience requirements of 5.7.1.2.1 shall interpret or multi-read at least 240 mammographic examinations within six months or less under the direct supervision of an interpreting physician; or interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations from the prior twenty-four months, whichever is less. The interpretations required shall be done within the six months immediately prior to resuming independent interpretation.

5.7.1.4.2 Interpreting physicians who fail to meet the continuing education requirements of 5.7.1.2.2 shall obtain a sufficient number of additional Category I continuing medical education credits in mammography to bring their total up to the required fifteen credits in the previous thirty-six months before resuming independent interpretation.

5.7.2 Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education requirements:

5.7.2.1 General Requirements

5.7.2.1.1 Be registered in active status with the American Registry of Radiologic Technologists in the field of radiography; and

5.7.2.1.2 All provisions of RHB 4.2.3 apply to the operators of mammography equipment.

5.7.2.2 Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under FDA's interim regulations or completed at least forty contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

5.7.2.2.1 Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

5.7.2.2.2 The performance of a minimum of twenty- five examinations under the direct supervision of an individual qualified under 5.7.2; and

5.7.2.2.3 At least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams.

5.7.2.3 Continuing education requirements

5.7.2.3.1 Following the third anniversary date of the end of the calendar quarter in which the requirements of 5.7.2.1 and 5.7.2.2 were completed, the radiologic technologist who performs mammography shall have taught or completed at least fifteen continuing education units in mammography during the thirty-six months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any day in between the two. The facility will choose one of these dates to determine the 36 month period.

5.7.2.3.2 Units earned through teaching a specific course can be counted only once towards the fifteen hours of continuing education requirements required in 5.7.2.3.1, even if the course is taught multiple times during the previous 36 months.

5.7.2.3.3 At least six of the continuing education units required in 5.7.2.3.1 shall be related to each mammographic modality used by the technologist.

5.7.2.3.4 **Requalification.** Radiologic technologists who fail to meet the continuing education requirements of 5.7.2.3.1, shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous three years, at least six of which shall be related to each modality used by the technologist in mammography. The technologist shall not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

5.7.2.3.5 Before a radiologic technologist may begin independently performing mammography examinations using a mammographic modality other than one of those for which the technologist received training under 5.7.2.3.3, the technologist shall have at least eight hours of continuing education units in the new modality.

5.7.2.3.6 Programs, courses or other activities intended to meet the requirement for initial, or requalification, mammography training or continuing education in mammography shall be approved by the Department.

5.7.2.3.7 Completion of initial or requalification mammography training and continuing education in mammography shall be verified to the Department.

5.7.2.4 Continuing experience requirements.

5.7.2.4.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.2.1 and 5.7.2.2 were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the twenty-four months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

5.7.2.4.2 **Requalification.** Radiologic technologists who fail to meet the continuing experience requirements of 5.7.2.4.1 shall perform a minimum of twenty five mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography.

5.7.3 Medical Physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program shall meet the following:

5.7.3.1 Initial Qualifications. The medical physicist must be approved by the Department as a Class IX vendor, prior to providing or offering to provide services, as required in 2.5.6.9. Unless the alternative initial qualifications in RHB 5.7.3.2 apply, the medical physicist must be certified in diagnostic radiological physics or radiological physics by either the American Board of Radiology (ABR), the American Board of Medical Physics (ABMP) or another FDA approved certifying board.

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

5.7.3.1.2 Have twenty contact hours of documented specialized training in conducting surveys of mammography facilities; and

5.7.3.1.3 Have the experience of conducting surveys of at least one mammography facility and a total of at least ten mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys shall be acquired under the direct supervision of a medical physicist who meets all the requirements of 5.7.3.1 and 5.7.3.3.

5.7.3.2 Alternative initial qualifications.

5.7.3.2.1 Have qualified as a medical physicist under FDA's interim-regulations and retained that qualification by maintenance of the active status of any licensure, approval or certification required;

5.7.3.2.2 Prior to April 28, 1999, obtained a bachelor's degree or higher in a physical science from an accredited institution with no less than ten semester hours or equivalent of college undergraduate or graduate level physics;

5.7.3.2.3 Prior to April 28, 1999, have forty contact hours of documented specialized training in conducting surveys of mammography facilities; and

5.7.3.2.4 Prior to April 28, 1999, have the experience of conducting surveys of at least one mammography facility and a total of at least twenty mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography survey requirement. The training and experience requirements shall be met after fulfilling the degree requirement.

5.7.3.3 Continuing education and experience.

5.7.3.3.1 Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of 5.7.3.1 and 5.7.3.2 were completed, the medical physicist shall have taught, or completed, at least fifteen continuing education units in mammography during the thirty six-months immediately preceding the date of the facility annual inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This

continuing education shall include hours of training appropriate to each mammography modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required fifteen continuing education units in a 36-month period, even if the course is taught multiple times during the thirty-six months.

5.7.3.3.2 Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.3.1 and 5.7.3.2 were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the twenty-four months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.

5.7.3.3.3 Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under 5.7.3.1 and 5.7.3.2, the physicist shall receive at least eight hours of training in surveying units of the new mammographic modality.

5.7.3.4 Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of 5.7.3.3 may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists shall reestablish their qualifications, as follows:

5.7.3.4.1 Medical physicists who fail to meet the continuing educational requirements of 5.7.3.3.1 shall obtain a sufficient number of continuing education units to bring their total units up to the required fifteen in the previous three years.

5.7.3.4.2 Medical physicists who fail to meet the continuing experience requirement of 5.7.3.3.2 shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualification of 5.7.3.1 and 5.7.3.3 to bring their total surveys up to the required two facilities and six units in the previous twenty-four months. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.

5.7.4 Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the Department. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and the Department has determined that the facility is in compliance with the MQSA/State personnel requirements of this Part.

RHB 5.8 Equipment Requirements. The equipment requirements of this Part are intended to ensure that mammography equipment is capable of producing quality mammograms over the full range of clinical conditions.

5.8.1 Prohibited equipment. Xeromammography equipment shall not be used for mammography procedures. Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography. This prohibition includes

systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in 21 CFR, Section 1020.31(f)(3).

5.8.2 General. Only special purpose equipment designed for mammography shall be specifically used for mammography and shall be certified pursuant to 21 CFR, Section 1010.2 as meeting the applicable requirements of 21 CFR, 1020.30, effective as of April 1, 1997.

5.8.3 Motion of tube-image receptor assembly.

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

5.8.3.2 The mechanism ensuring compliance with RHB 5.8.3.1 shall not fail in the event of power interruption.

5.8.4 Image receptor sizes.

5.8.4.1 Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

5.8.4.2 Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

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

5.8.5 Beam limitation and light fields.

5.8.5.1 All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.

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

5.8.6 Magnification

5.8.6.1 Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

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

5.8.7 Focal Spot Selection

5.8.7.1 When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

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

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

5.8.8 Compression. All mammography systems shall incorporate a compression device that shall be used for all routine projections and for all projections except when necessity requires imaging without compression.

5.8.8.1 Application of compression. Effective October 28, 2002, each system shall provide:

5.8.8.1.1 An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

5.8.8.1.2 Fine adjustment compression controls operable from both sides of the patient.

5.8.8.2 Compression paddle:

5.8.8.2.1 Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of subsections 5.8.8.2.4 and 5.8.8.2.5 of this Section.

5.8.8.2.2 Except as provided in subsection 5.8.8.2.3 of this Part, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

5.8.8.2.3 Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

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

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

5.8.9 Technique factor selection and display.

5.8.9.1 Manual selection of milliAmpere seconds (mAs) or at least one of its component parts (milliAmpere (mA) and /or time) shall be available.

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

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

5.8.10 Automatic exposure control.

5.8.10.1 Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid, magnification, nonmagnification and various target- filter combinations.

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

5.8.10.2.1 The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.

5.8.10.2.2 The selected position of the detector shall be clearly indicated.

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

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

5.8.12 Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

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

5.8.14 Film Processor. The film processor shall be compatible with single emulsion film

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

5.8.16 Film masking devices. Facilities shall ensure that filmmasking devices that can limit the illumination area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians.

RHB 5.9 Medical Records and Mammography Reports

5.9.1 Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

5.9.1.1 The name of the patient and an additional patient identifier;

5.9.1.2 Date of examination;

5.9.1.3 The name of the interpreting physician who interpreted the mammogram;

5.9.1.4 Overall final assessment of findings, classified in one of the following categories:

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

5.9.1.4.2 "Benign." Also a negative assessment;

5.9.1.4.3 "Probably Benign." Finding(s) has a high probability of being benign;

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

5.9.1.4.5 "Highly suggestive of malignancy." Finding(s) has a high probability of being malignant,

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

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

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

5.9.2.1 Patients who do not name a health care provider to receive the mammography report shall be sent the report described in RHB 5.9.1 within 30 days, in addition to the written notification of results in lay terms.

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

5.9.3 Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

5.9.3.1 Provide a written report of the mammography examination, including the items listed in subsection 5.9.1 of this Section, to that health care provider as soon as possible, but no later than 30 days after the date of the mammography examinations; and

5.9.3.2 If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

5.9.4 Record keeping. Each facility that performs mammograms:

5.9.4.1 Shall, except as provided in RHB 5.9.3.2, maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility;

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

5.9.4.3 Any fee charged to the patient for providing the services in RHB 5.9.4 shall not exceed the documented costs associated with this service.

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

5.9.5.1 Name of patient and an additional patient identifier.

5.9.5.2 Date of examination.

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

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

5.9.5.5 Technologist identification.

5.9.5.6 Cassette/screen identification.

5.9.5.7 Mammography unit identification, if there is more than one unit in the facility.

RHB 5.10 Quality Assurance Requirements. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

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

5.10.1.1 Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of this Part. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

5.10.1.2 Interpreting physicians. All physicians interpreting mammograms for the facility shall:

5.10.1.2.1 Follow the facility procedures for corrective action when the images that they are asked to interpret are of poor quality; and

5.10.1.2.2 Participate in the facility's medical outcomes audit program.

5.10.1.3 Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in RHB 5.12 and RHB 5.13.

5.10.1.4 Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of RHB 5.11.

5.10.2 Quality assurance records.

5.10.2.1 The lead interpreting physician, quality control technologist and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control(including monitoring data, problems detected by analysis of that data, corrective actions and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated.

5.10.2.2 These quality control records shall be kept for each test specified in RHB 5.11 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.

5.10.2.3 A report of the medical physicist's test results with numerical values shall be submitted to the Department annually as required by RHB 5.12.

RHB 5.11 Equipment Quality Assurance Tests

5.11.1 Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid- density, and density difference, using the mammography film used clinically at the facility.

5.11.1.1 The base plus fog density shall be within plus or minus 0.03 of the established operating level.

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

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

5.11.1.4 The solution temperature control limits shall be plus or minus 1.0 degree F.

5.11.2 Weekly quality control tests. Facilities with screen-film systems shall perform a phantom image quality evaluation test, using an FDA-approved phantom, at least weekly.

5.11.2.1 The optical density of the film at the center of an image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

5.11.2.2 The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

5.11.2.3 The phantom image shall achieve at least the minimum score established by the accreditation body.

5.11.2.4 The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

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

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

5.11.3.2 Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

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

5.11.4.1 Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.20, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

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

5.11.4.3 Compression device performance. The compression device performance shall:

5.11.4.3.1 Be capable of maintaining a compression force of at least 111 newtons (25 pounds) for at least 15 seconds;

5.11.4.3.2 Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and two hundred nine newtons (forty-five pounds).

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

5.11.5.1 Automatic exposure control performance.

5.11.5.1.1 The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when the thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques(kVp and density control settings) for different breast thicknesses and compositions that shall be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.

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

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

5.11.5.2 Kilovoltage peak accuracy and reproducibility. The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at:

5.11.5.2.1 The lowest clinical kVp that can be measured by a kVp test device;

5.11.5.2.2 The most commonly used clinical kVp;

5.11.5.2.3 The highest available clinical kVp; and

5.11.5.2.4 At the most commonly used clinical setting of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. The kVp shall be checked annually or upon new x-ray tube installation.

5.11.5.3 Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated by measuring focal spot dimensions or by determining system resolution. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution. For focal spot dimensions, the measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the following tolerance limits:

Focal Spot Tolerance Limit

Nominal Focal Spot Size (mm)	Maximum Measured Dimensions	
	Width(mm)	Length(mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

5.11.5.3.1 System Resolution.

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

5.11.5.3.1.2 The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

5.11.5.3.1.3 When more than one target material is provided, the measurement shall be made using the appropriate focal spot for each target material.

5.11.5.3.1.4 When more than one source-image receptor distance is provided, the test shall be performed at the SID most commonly used clinically

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

5.11.5.3.2 Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in this Part. The focal spot shall be checked annually or upon new x-ray tube installation.

5.11.5.4 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 for any specific combination of selected technique factors. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} > 5 (E_{max} - E_{min})$. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.5 Timer Reproducibility. The coefficient of variation of the timer shall not exceed 0.05. This requirement shall be deemed to have been met if, with a selected timer setting, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} > 5 (T_{max} - T_{min})$. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.6 Timer Accuracy. Deviation of the selected time setting from indicated time values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated time value. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.7 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

5.11.5.7.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

5.11.5.7.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere- seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

5.11.5.7.3 Measuring Compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. The two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than .45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the tube manufacturer. Linearity shall also be checked annually or upon new x-ray tube installation.

5.11.5.8 Beam quality and half-value layer (HVL). For mammography systems operating at x-ray tube potentials of less than 50 kVp, the HVL in millimeters of aluminum of the useful beam shall be equal to or greater than the product of the measured tube potential in kilovolts multiplied by 0.01. The half-value layer shall be measured with the compression device in the beam and shall be measured at the same tube potential used in Appendix A of this Part, Mammography Dose Measurement Protocol and Appendix B of this Part, Mammography Phantom Image Evaluation. The HVL shall be checked annually and after repairs to the system have been made that could affect the filtration or upon new x-ray tube installation.

5.11.5.9 Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

5.11.5.10 Dosimetry. The average glandular dose delivered during a single craniocaudal view of a phantom simulating a standard breast shall not exceed 3.0 milligray (Gy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast. The average glandular dose shall be checked annually or upon new tube installation.

5.11.5.11 X-ray field/light field/image receptor/compression paddle alignment.

5.11.5.11.1 All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement is for both large and small cassettes sizes.

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

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

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

5.11.5.13 System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

5.11.5.14 Radiation output.

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

5.11.5.14.2 The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

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

5.11.5.15.1 An override capability to allow maintenance of compression;

5.11.5.15.2 A continuous display of the override status; and

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

5.11.6 The quality assurance requirements of 4.2.18 and film processing requirements of 4.2.19.2 shall be met except where otherwise mentioned.

5.11.7 Quality control tests-other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer.

5.11.8 Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in RHB 5.11.1 through 5.11.7. In addition, at each examination location, before any examinations are conducted, the mobile

mammography system shall be tested using the mammography phantom image evaluation to establish the adequacy of the image quality produced by the unit.

5.11.9 Use of test results.

5.11.9.1 After completion of the tests specified in RHB 5.11.1 through 5.11.8, the facility shall compare the test results to the corresponding specified action limits; or, for non-screen film modalities, to the manufacturer's recommended action limits; or for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

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

5.11.9.2.1 Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests described in RHB 5.11.1, 5.11.2, 5.11.4.1, 5.11.4.2, 5.11.4.3, 5.11.5.10, 5.11.6, 5.11.7, or 5.11.8.

5.11.9.2.2 Within thirty days of the test date for all other tests described in RHB 5.11.

RHB 5.12 Surveys.

5.12.1 At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests and numerical values to ensure that the facility meets the quality assurance requirements of the annual tests described in RHB 5.11.5 and RHB 5.11.6 and the weekly phantom image quality test described in 5.11.2.

5.12.2 The results of all these tests conducted by the facility in accordance with RHB 5.11.1 through RHB 5.11.8, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

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

5.12.4 The survey report shall be sent to the facility within thirty days of the date of the survey.

5.12.5 The facility shall send a copy of the survey report to the Department within ten days of completion of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must be sent to the Department.

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

RHB 5.13 Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the applicable standards in

RHB 5.8 and RHB 5.11. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or an individual under the direct supervision of a medical physicist.

RHB 5.14 Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two 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 six percent (ninety-five percent confidence level) in the mammography energy range.

RHB 5.15 Additional Administrative Requirements. Each facility where mammography services are provided shall ensure the availability for each mammography patient:

5.15.1 Instructions on how to perform breast self-examination, and

5.15.2 Information that early detection of breast cancer is maximized through a combined approach, using monthly breast self-examination, a thorough physical examination performed by a physician, and mammography performed at recommended intervals; and

5.15.3 Information that mammography is the most accurate method for making an early detection of breast cancer, however, no diagnostic tool is 100% effective.

RHB 5.16 Facility Cleanliness

5.16.1 The facility shall establish and implement written procedures for maintaining darkroom, screen, and view box cleanliness.

5.16.2 The facility shall document that all cleaning procedures are performed at the frequencies specified in the written procedures.

RHB 5.17 Infection Control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

5.17.1 Comply with the manufacture recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

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

RHB 5.18 Mammography procedures, techniques, for mammography patients with breast implants.

5.18.1 Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

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

RHB 5.19 Consumer Complaint Mechanism. Each facility shall:

5.19.1 Establish a written and documented system for collecting and resolving consumer complaints.

5.19.2 Maintain a record of each serious complaint received by the facility for at least three years after the date the complaint was received;

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

5.19.4 Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

RHB 5.20 Clinical image quality. Clinical images produced by any certified facility shall continue to comply with the standards for clinical image quality established by that facility's accreditation body.

RHB 5.21 Mammography Medical Outcomes Audit. Each facility shall establish and maintain a mammography medical outcomes audit program to follow up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity and accuracy of the interpretation of mammograms.

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

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

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

RHB 5.22 Additional Mammography Review and Patient Notification.

5.22.1 If the Department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the Department, for review by the accreditation body. The Department will determine whether the facility is in compliance with this Part and if not, whether there is a need to notify affected patients, their physicians, or the public that the liability, clarity, and accuracy of interpretation of mammograms has been compromised.

5.22.2 If the Department determines that the quality of mammography performed by a facility, whether or not certified under RHB 5.3, was so inconsistent with the quality standards established in this Part as to present a significant risk to individual or public health, the Department may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures and such other relevant information as the Department may require.

RHB 5.23 Revocation of Accreditation. If a facility's accreditation is revoked by an accreditation body, the Department may conduct an investigation into the reasons for the revocation. Following such investigation, the Department may suspend or revoke the facility's certificate and take whatever other action or combination of actions to protect public health, including requiring the establishment and implementation of a corrective plan of action that shall permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is suspended or revoked because it has lost its accreditation may not practice mammography.

RHB 5.24 Suspension or Revocation of Certificates

5.24.1 Except as provided in 5.24.2, the Department may suspend or revoke a certificate if the Department finds that the owner, operator, or any employee of the facility:

5.24.1.1 Has been guilty of misrepresentation in obtaining the certificate;

5.24.1.2 Has failed to comply with the standards of RHB 5.2 through 5.22.

5.24.1.3 Has failed to comply with reasonable requests of the Department or the accreditation body for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of RHB 5.2 through RHB 5.22.

5.24.1.4 Has refused a reasonable request of a duly designated FDA inspector, Department inspector or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

5.24.1.5 Has violated or aided and abetted in the violation of any provision of this regulation;

5.24.1.6 Has failed to comply with prior sanctions imposed by the Department; or

5.24.1.7 Has failed to pay any required fees.

5.24.2 The Department may suspend the certificate of a facility if the Department makes a finding described in RHB 5.24.1 and also determines that:

5.24.2.1 The failure to comply with required standards present a serious risk to human health;

5.24.2.2 The refusal to permit inspection makes immediate suspension necessary; or

5.24.2.3 There is a reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

5.24.3 If the Department suspends a certificate in accordance with 5.24.2.

5.24.3.1 The facility may request a review from the Deputy Commissioner of Health Services no later than thirty days from the effective date of this suspension;

5.24.3.2 The suspension shall remain in effect until the Department determines that:

5.24.3.2.1 Allegations of violations or misconduct were not substantiated;

5.24.3.2.2 Violations of required standards have been corrected to the Department's satisfaction; or

5.24.3.2.3 The facility's certificate is revoked in accordance with 5.24.4;

5.24.4 The Department may revoke the facility's certificate if the Department determines that the facility:

5.24.4.1 Is unwilling or unable to correct violations that were the basis for suspension; or

5.24.4.2 Has engaged in fraudulent activity to obtain or continue certification.

RHB 5.25 Mammography Units Used for Localization or Stereotactic Breast Biopsy Procedures

5.25.1 Personnel. The following requirements apply to all personnel involved in localization or biopsy procedures performed with mammography units:

5.25.1.1 Interpreting Physicians. The interpreting physician shall:

5.25.1.1.1 Be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).

5.25.1.1.2 Be responsible for oversight of all quality control.

5.25.1.1.3 Be responsible for the supervision of the radiologic technologist and the medical physicist.

5.25.1.1.4 Be responsible for post-biopsy management of the patient.

5.25.1.1.5 Documentation of compliance with this Part shall be provided to the Department upon request.

5.25.1.2 Radiologic Technologists.

5.25.1.2.1 The radiologic technologist shall be currently registered in good standing with the American Registry of Radiologic Technologists.

5.25.1.2.2 The technologist shall have previously received documented training specifically in stereotactic breast biopsy procedures and techniques along with positioning for stereotactic units. This training shall consist of 15 hours of continuing education in mammography every three years and three hours of Category A continuing education in stereotactic breast biopsy every three years.

5.25.1.2.3 Documentation of registration and training shall be provided to the Department upon request.

5.25.1.3 Medical Physicists. The medical physicist shall:

5.25.1.3.1 Be approved by the Department as a Class IX vendor as required in 2.6.6.9 and be certified in diagnostic radiological physics or radiological physics by either the American Board of Radiology (ABR) or The American Board Medical Physics (ABMP);

5.25.1.3.2 Meet the requirements of RHB 5.7.3.1.1, 5.7.3.1.2, and 5.7.3.1.3.

5.25.1.3.3 Have fifteen hours of continuing education in mammography physics every three years.

5.25.1.3.4 Have performed at least two stereotactic breast biopsy surveys per year and;

5.25.1.3.5 Have three hours of continuing education in stereotactic breast biopsy physics every three years.

5.25.2 Equipment. Mammography units used for stereotactic breast biopsy or localization procedures shall meet the requirements of RHB 5.8, 5.11.5.2, 5.11.5.3, and 5.11.5.8 with the exception of RHB 5.11.5.10. Digital output mammography systems that do not use screen-film image receptors are exempt from the requirements of RHB 5.8 of these regulations as they relate to screen-film image receptors.

5.25.5 Quality Assurance.

5.25.5.1 Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity and accuracy of mammography localization or biopsy procedures performed at the facility.

5.25.5.2 Each facility shall have the services of a medical physicist available to survey mammography equipment and to oversee the equipment-related quality assurance practices of the facility.

5.25.5.3 The quality assurance program shall be in writing and shall have been developed by a medical physicist. The program shall include, but need not be limited to the following:

5.25.5.3.1 Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

5.25.5.3.2 Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

5.25.5.4 The medical physicist shall conduct a review of the quality assurance program each year. Such review shall include evaluation of the results of quality assurance testing and quality control tests as specified in the American College of Radiology's Stereotactic Breast Biopsy Accreditation Program Overview.

5.25.5.5 Each facility shall maintain written records of the radiation dose measurements and quality assurance testing performed, as required in this Part, for inspection by the Department for a period of at least one year, or until the next Department inspection, whichever is later. Such records shall include, but not be limited to, the following:

5.25.5.5.1 The date of the test and identification of the person performing the test;

5.25.5.5.2 Identification of the type of testing that was performed; and

5.25.5.5.3 Notification of whether the results of the testing were within the parameters established by the medical physicist.

5.25.5.6 The facility shall send a copy of the medical physicist's survey report to the Department within ten days of completions of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must to be sent to the Department.

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

RHB 5.26 Shielding. All mammography facilities shall meet the shielding requirements specified in RHB 4.4.

RHB 5.27 Operating procedures. All mammography facilities shall meet the requirements of RHB 4.2.4.

RHB 5.28 Notification Requirements for Mobile Mammography Facilities Certified by Another Certifying Agency. Mobile mammography facilities that operate in South Carolina and are certified under MQSA by the FDA, or another State authorized by FDA to certify mammography facilities under MQSA, shall:

5.28.1 Notify the Department by telephone, facsimile, or letter of each date and location of operation of the mobile mammography facility in South Carolina prior to conducting such operation.

5.28.2 At all times while operating in South Carolina, have the following documentation available for review and inspection by the Department:

5.28.2.1 A copy of the mammography facility certificate issued by the FDA or another State, showing that the facility is currently certified.

5.28.2.2 A summary of the most recent physics survey of the mammography machine(s) and documentation of any corrective actions recommended by the medical physicist who performed the physics survey.

5.28.2.3 Documentation that personnel meet the qualifications of RHB 5.7.

RHB 5.29 Failure of Mobile Mammography Facilities Certified by Another Certifying Entity to Meet Requirements. The Department shall notify the certifying entity of the facts and circumstances and may take other actions as may be appropriate under the Atomic Energy and Radiation Control Act and regulations thereunder if the Department has reason to believe that the owner, operator, or any employee of a mobile facility certified by another certifying entity:

5.29.1 Has been guilty of misrepresentation in obtaining the certificate;

5.29.2 Has failed to comply with the standards of this Part;

5.29.3 Has failed to comply with reasonable requests of the Department for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of this Part;

5.29.4 Has refused a reasonable request of a Department representative for permission to inspect the facility or the operations and pertinent records of the facility.

Appendix A Mammography Dose Measurement Protocol

The technique factors used for performing a mammography examination shall not permit the mean glandular absorbed dose to exceed the limits specified in RHB 5.11.5.10. Radiation measurements shall be performed with an integrating radiation measuring device that is appropriate to the high beam intensity and mammographic kilovoltage peak (kVp) used, and sufficiently sensitive to determine compliance with the criteria specified in RHB 5.14. The instrument shall have been calibrated as specified in RHB 5.14.

The mammography exam dose limits are based on an average compressed breast value of 4.2 centimeters having an average density (i.e., 50 percent adipose and 50 percent glandular).

Perform the following steps to determine the mean glandular dose to a nominal 4.2 centimeter compressed breast:

- a) Measure and record the x-ray system's useful beam half value layer (HVL). (See RHB 5.11.5.8.) Any compression device normally in the useful beam during mammography procedures shall be required to be placed between the x-ray tube target and measuring device when determining the HVL. The useful beam shall be collimated to a size encompassing the detector.

NOTE: Filters used for the HVL evaluation should be placed as close to the target as practical. The HVL for screen-film mammography should not exceed the minimum acceptable HVL by more than 0.1 millimeter of aluminum equivalent.

- b) Determine the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (see Appendix C of this Part) using the appropriate HVL, kVp and x-ray tube target-filter material.

NOTE: The kVp of screen-film mammography systems with molybdenum target-filter combinations should be accurately measured to determine the appropriate glandular dose to entrance exposure factor from Appendix C of this Part.

- c) If the equipment has the capability for variable source to image receptor distance, set the craniocaudal source to image receptor distance (SID) for the image receptor system used.
- d) Position in the useful beam any compression apparatus normally used.

NOTE: Some mammography systems have the capability of providing automatic adjustment of technique factors through feedback from the position of the compression device. On such systems, the compression device should be lowered to a position 4.2 centimeters above the breast support assembly (BSA). The device should then be removed, inverted and replaced to allow placement of the phantom and measuring device on the BSA below the compression device. If the compression device cannot be replaced in an inverted position, the device should be placed in the beam using auxiliary support.

- e) Placement of the Radiation Measuring Device

- 1) For systems equipped with automatic exposure control (AEC):

- A) Place a properly loaded film cassette in the cassette holder.

NOTE: The loaded cassette is placed in the cassette holder to simulate, as much as is possible, the conditions under which actual patient exposures are made. Following radiation measurements, the film should be discarded and the cassette reloaded with unexposed film.

- B) Place a mammography phantom (see the definition for "Phantom" in RHB 9.168) on the breast support assembly (BSA). Align the phantom so that the edge of the phantom is aligned with the chest wall side of the BSA and the phantom is over the automatic exposure control device(s).
- C) Place a radiation measuring device in the useful beam so the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and immediately adjacent to either side of the mammography phantom.
- 2) For systems not equipped with AEC, place a radiation measuring device in the useful beam so that the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned so that it is centered 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and at the center line of the BSA. No part of the devices detector area shall be outside of the useful beam.
- f) Collimate the x-ray field to the size normally used and assure that the area covered by the useful beam includes the detector area of the radiation measuring device and the mammography phantom if the equipment is equipped with automatic exposure.
- g) Set the appropriate technique factors or automatic exposure controls normally used for a nominal 4.2 centimeter compressed breast.
- h) Measure and record the exposure in air with the radiation measuring device.
- i) Calculate the mean glandular dose for a 4.2 centimeter compressed breast by multiplying the measured exposure in millicoulombs per kilogram or in roentgens by the glandular dose to entrance exposure factor, which was determined using the procedure described in subsection (b) of this Appendix.

EXAMPLE: A mammography system is provided with a molybdenum target-filter combination, and the HVL and kVp are determined to be 0.3 and 30, respectively. Therefore, for a 4.2 centimeter compressed breast, the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (Appendix C of this Part) would be 159 mrad. The measured roentgen output determined in subsection (h) of this Appendix is determined to be 1.8 R. Therefore, the mean glandular dose would be 1.8 R multiplied by 159 mrad/R- This results in a mean glandular dose measurement of 286 mrad. As such, the system would be in compliance with RHB 5.11.5.10.

Appendix A

Information To Be Submitted By Persons Proposing To Conduct Healing Arts Screening. Persons requesting that the Department approve a healing arts screening program shall submit the following information for review and approval:

1. Name and address of the applicant, and where applicable, the names and addresses of agents within the State.
2. Diseases or conditions for which the X-ray examinations are to be used.
3. Description in detail of the X-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the X-ray examinations.
6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the X-ray examinations procedures to be used.
9. The qualifications of each individual who will be operating the X-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the X-ray system(s).
11. The name and address of the individual who will interpret the radiograph(s).
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

Appendix B Mammography Phantom Image Evaluation

Mammography Phantom image evaluation shall be performed using the procedure below. The evaluation shall be performed weekly as a part of the quality assurance program. The evaluation shall be performed with the mammography phantom specified in RHB 9.168.

- a) Equipment necessary for mammography phantom image evaluation includes a densitometer, the mammography phantom and mammographic cassette and film.
- b) Load film in the mammographic cassette according to the manufacturer's instructions.
- c) Place the properly loaded cassette in the cassette holder.
- d) Place the mammography phantom on the breast support assembly (BSA) so that the edge of the phantom is aligned with the chest wall side of the BSA. Align the phantom so that the masses in the phantom are nearest the chest wall edge of the BSA and the fibers in the phantom are away from the chest wall edge of the BSA. If the mammography machine has the capability of automatic exposure control, place the phantom so that the phantom covers the phototimer sensor.
- e) Position the compression device so that it is in contact with the phantom.
- f) Select the technique factors used most frequently in the clinical setting for a 4.2 centimeter compressed breast and make an exposure of the phantom.
- g) Process the film in the processor used for clinical mammography films.
- h) Examine the processed image for areas of nonuniformity of optical density and for the presence of artifacts due to dirt, dust, grid lines or processing.

NOTE: If any of the problems noted above are evident on the processed image, the mammography machine film processor and film cassette(s) should be evaluated and the problem corrected. The phantom image evaluation should be repeated after the problem is corrected.

- i) Measure and record the optical density of the film near the center of the phantom image. The optical density of the film at the center of the image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.
- j) Examine the phantom image and count and record the number of masses visualized. Repeat this procedure for the speck groups and the fibrils and record the number of objects visualized. There are a total of 16 imaging objects (5 masses, 5 speck groups and 6 fibrils) in the phantom. Evaluation criteria for objects visualized in the phantom image are in RHB 5.11.2.3. and RHB 5.11.2.4. As a minimum, the objects that must be visualized in the phantom image are:
 - 1) The masses that are 0.75 millimeter or larger (a total of 3 masses);
 - 2) The speck groups that are 0.32 millimeter or larger (a total of 3 speck groups);
 - 3) The fibrils that are 0.75 millimeter or larger (a total of 4 fibrils).

NOTE: The phantom image should be compared with previous films, including the original phantom image, to determine if subtle changes are occurring from week to week.

