Rules of
Department of Health
Division 30—Division of Health Standards and Licensure
Chapter 11—Rules for Mammography

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Title 19—DEPARTMENT OF HEALTH
Divison 30—Division of Health Standards and Licensure
Chapter 11—Rules for Mammography

19 CSR 30-11.010 Mammography Authorization

PURPOSE: This rule establishes requirements for mammography authorization and payment of fees by mammography suppliers.

(1) All mammography suppliers shall meet the requirements of applicable rules of Chapter 10 of 19 CSR 20.

(2) Each applicant for mammography authorization shall submit a registration fee to the Department of Health prior to issuance of the mammography authorization. Fees are as follows: three (3)-year authorization, six hundred dollars ($600); temporary authorization for twelve (12) months, two hundred dollars ($200); and temporary authorization for six (6) months, one hundred dollars ($100).

(A) Each radiation machine shall be individually registered for mammography authorization.

(B) Application for authorization renewal shall be submitted not more than ninety (90) days and not less than thirty (30) days prior to the expiration date of the current authorization.

(C) Registration fees shall not be required for reinstatement of a mammography authorization which has been withdrawn by the Department of Health; reinstatement shall be effective only for the remainder of the original period of authorization.

(3) The Department of Health shall perform an initial inspection of each machine during the first year of authorization and annual inspections after that. A reinspection shall be performed after a mammography authorization has been withdrawn by the Department of Health. Fees for initial inspection, annual inspection and reinspection shall be one hundred dollars ($100) respectively, per radiation machine.

(A) Fees for initial inspection shall be submitted with the application for mammography authorization.

(B) Fees for annual inspection shall be submitted ten (10) working days prior to the anniversary date of the mammography authorization.

(C) Fees for reinspection shall be submitted upon application for reinstatement of mammography authorization.

(4) The Department of Health may accept mammography accreditation certificates issued by the American College of Radiology (ACR) as evidence of compliance with criteria for authorization. Suppliers who submit ACR accreditation certificates as evidence of compliance shall inform the Department of Health, in writing, of any change in their ACR accreditation status within thirty (30) days of that change. If the Department of Health evaluates mammography systems to determine compliance with criteria for authorization, evaluation shall be performed every three (3) years and shall include review and on-site evaluation of staff qualifications, equipment, quality control and quality assurance programs, phantom image quality, breast dose and processor quality control. In addition, the supplier shall submit two (2) sets of clinical films, one (1) of a fatty and one (1) of a dense breast, for image quality evaluation to the Department of Health or its designee. Each set shall consist of two (2) views of each breast totaling four (4) films for each type of breast. Failure to meet clinical image quality evaluation criteria shall result in the withholding or withdrawal of mammography authorization. The supplier may submit additional clinical films for reevaluation; however, all costs incurred for additional clinical image quality evaluation shall be the responsibility of the supplier. Fees for evaluation shall be five hundred dollars ($500) for the first radiation machine and one hundred dollars ($100) for each additional radiation machine.

(5) Failure of the supplier, upon inspection or evaluation, to meet the requirements of this chapter that significantly affect clinical image quality or interpretation shall result in immediate withdrawal of authorization. The Department of Health shall provide an opportunity for a hearing within five (5) working days after withdrawal of authorization. Whenever the Department of Health finds upon inspection or evaluation that there is a violation of other provisions of this chapter, the Department of Health shall notify the supplier of the nature of the violation and order that prior to a time fixed by the Department of Health, which shall not be later than thirty (30) days from the date of service of the notice, the supplier shall cease and abate causing, allowing or permitting the violation. Failure to meet this requirement shall result in withdrawal of authorization.

(6) Fees submitted to the Department of Health under this rule are nonrefundable. Failure to submit fees as required shall result in withdrawal of the mammography authorization.


19 CSR 30-11.020 Requirements for Suppliers of Mammography Services

PURPOSE: This rule establishes requirements for suppliers of mammography services, including responsibility for the quality of mammographic examinations.

(1) The supplier shall be responsible for the overall quality of mammography examinations conducted in each facility. The supplier shall have available the services of a physician consultant and a radiation physicist, either on staff or through arrangement.

(2) The supplier shall provide satisfactory assurances, as documented in its medical records, that the images or films of the first and subsequent mammography procedures and the related written reports of the physicians’ interpretations for each patient are either placed in the patient’s medical record kept by the supplier or sent to another person—including the patient—for placement in the patient’s medical record as directed by the patient or by the patient’s physician. If the records of the examination are retained by the supplier, they shall be retained for at least sixty (60) months following the date of service. If the supplier should cease to exist before the end of the sixty (60)-month period, the records shall be transferred to the patient or the patient’s primary care provider.

(3) With the consent of the patient, reasonable efforts shall be made by the supplier of the current examination to obtain any of the patient’s previous mammography records—including original images and films—copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammographies that...
might be available from others, for comparison with the current mammography records. Records of previous mammographies obtained and of current mammographies performed by the supplier shall be properly preserved and made available to other qualified mammography suppliers or others who submit a written request authorized by the patient.

(4) The supplier shall make a record for each patient of the mammography services it provides. This record shall include:
   (A) The date the mammography procedure was performed and the date of the interpretation;
   (B) The name of the patient;
   (C) The names of the supplier, the interpreting physician and the equipment operator;
   (D) A description of the procedures performed;
   (E) The name of the referring physician, if any, or other physician, if any, identified by the patient to receive the interpreting physician’s written report; and
   (F) The date the physician’s written report was sent to the appropriate physician or patient.

(5) The mammography supplier shall have an orientation program for operators of mammography equipment based on a procedures manual that is available to all staff. The manual shall incorporate relevant documents concerning the following:
   (A) Precautions to protect the operator of the equipment, the patient and individuals in the surrounding area from unnecessary exposure to radiation;
   (B) Determination of the area that will receive the primary beam-breast positioning;
   (C) Pertinent information on compression, exposure levels, resolution, contrast, noise, examination identification, artifacts and average glandular dose per view;
   (D) Proper use and maintenance of the equipment, including a discussion of the image receptors appropriate for use with mammography and the kilovoltage (kV)-target-filter combination to be used with each image receptor;
   (E) Proper maintenance of records; and
   (F) Possible technical problems and solutions.

(6) The supplier shall have a mechanism in place which provides for the notification/recall of patients if mammographic examination results are equivocal; notification shall be within two (2) working days after interpretation by the interpreting physician.

(7) The supplier shall maintain all documentation and records required by this rule for review by the Department of Health.


19 CSR 30-11.030 Requirements and Responsibilities for Physician Consultants

PURPOSE: This rule establishes requirements for physician consultants including qualifications and supervisory responsibilities.

(1) The physician consultant shall meet the requirements for the interpreting physician as specified in 19 CSR 20-11.040(1) and (2).

(2) The physician consultant shall document in writing annually that—
   (A) S/he has checked the procedural manuals and observed, at least monthly, the operator’s performance;
   (B) S/he has verified that equipment and personnel meet applicable rules of this chapter;
   (C) Safe operating procedures are used; and
   (D) All other requirements of this chapter are being met.


19 CSR 30-11.040 Requirements and Responsibilities for Interpreting Physicians

PURPOSE: This rule establishes requirements for interpreting physicians including qualifications, the mammography reporting process and responsibility to the patient.

(1) The results of all mammography procedures shall be interpreted by a qualified physician who is licensed to practice medicine in Missouri and—
   (A) Has completed two (2) months of documented, formal training in reading mammograms with instruction in medical radiation physics, radiation effects and radiation protection; or is certified by the American Board of Radiology (ABR) or the American Osteopathic Board of Radiology (AOBR); and
   (B) Has completed forty (40) hours of documented continuing medical education credits in mammography. Time spent in residency specifically devoted to mammography shall be accepted, if documented in writing.

(2) The interpreting physician shall obtain at least fifteen (15) hours of continuing education in mammography interpretation, technical aspects and subjects related to mammography every three (3) years.

(3) The interpreting physician shall—
   (A) Prepare and sign a written report on his/her interpretation of the results of the mammography procedure;
   (B) Provide a copy of the written report and the original images or films to the patient’s mammography supplier for inclusion in the patient’s medical record; and
   (C) Provide a written statement to the patient, either through a referring physician or the referring physician’s designate or, if a referring physician is not available, directly to the patient. The statement shall describe the test results, the next steps if the results are positive, the date of the procedure, the name of the facility providing the procedure, the physician—if any—to whom the patient wants a copy to be sent and shall indicate that the original images or films are being provided to the mammography supplier for inclusion in the patient’s medical record.


19 CSR 30-11.050 Requirements for Operators of Mammography Equipment

PURPOSE: This rule establishes requirements for operators of mammography equipment, including qualifications, certification and continuing education.

(1) Operators of mammography equipment shall be certified by the American Registry of Radiological Technologists (ARRT), the American Registry of Clinical Radiographic Technologists (ARCRT), Missouri or shall possess equivalent certification. Operators also shall meet the following requirements:

(A) Shall have completed a minimum of forty (40) hours of documented formal mammography instruction or on-the-job training as outlined in Appendix A, “Topics to be Covered in Mammography Instruction.” On-the-job training shall be documented to include the business address and qualifications of the instructor, a brief description of the training, the date and length of the training, and an evaluation of the student’s performance signed and dated by the instructor; and

(B) Shall obtain at least fifteen (15) hours of continuing education in technical aspects of mammography and related subjects every three (3) years.

(2) Individuals who hold a current ARRT Certificate of Advanced Qualification in Mammography or equivalent certification are exempt from the provisions of subsection (1)(A) of this rule.


19 CSR 30-11.070 Mammography Equipment Requirements

PURPOSE: This rule establishes requirements for mammography equipment, including radiation machines and other components of mammography systems.

Editor’s Note: The secretary of state has determined that the publication of this rule in its entirety would be unduly cumbersome or expensive. The entire text of the material referenced has been filed with the secretary of state. This material may be found at the Office of the Secretary of State or at the headquarters of the agency and is available to any interested person at a cost established by state law.

(1) The equipment used for mammography shall be specifically designed for mammography and shall meet the following requirements:

(A) Equipment shall meet the Food and Drug Administration (FDA) performance standards for diagnostic X-ray systems and their major components in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31 upon installation and while in use;

(B) The image receptor systems and all their individual components shall be designed specifically for mammography and shall function properly;

(C) The equipment shall be limited to providing kilovoltage (kV)-target-filter combinations appropriate to image receptors meeting the requirements of subsection (1)(B);

(D) The half value layer (HVL) in millimeters of aluminum of the useful beam for systems operating at X-ray tube potentials of less than thirty-five kilovoltage potential (35 kVp) shall be equal to or greater than the product of the tube potential in kilovolts multiplied by one-hundredth (0.01) and shall not exceed this calculated product by more than plus one-tenth millimeter (+0.1 mm) of aluminum;

(E) Devices parallel to the imaging plane shall be available to adequately immobilize and compress the breast;

(F) Film-screen units shall have the capability for using anti-scatter grids;

(G) Film-screen units shall have the capability of automatic exposure control;

(H) The equipment shall have a control panel that includes a device, usually a millimeter, or a means for an audible signal to give positive indication of the production of X rays whenever the X-ray tube is energized. The control panel shall include appropriate indicators—labeled control settings or meters that show the physical factors, such as kVp, milliamperes (mA), milliampere-seconds (mAs), exposure time or whether timing is automatic—when used for exposure;

(I) The developer temperature of the photographic processor shall be maintained as specified by the film manufacturer for the particular film-developer-processor-development time combination; and

(J) The focal spot size and source-to-image receptor distances shall be limited to those appropriate for mammography.


19 CSR 30-11.080 Quality Assurance

PURPOSE: This rule establishes requirements for calibration of mammography equipment and monitoring of the mammography system.

(1) All variable parameters of the equipment shall be calibrated as follows:

(A) When the equipment is first installed;
(B) After any major changes or replacement of parts;
(C) At least annually while in use; and
(D) When quality assurance tests indicate that calibration is needed.

(2) The following parameters of the system shall be monitored as follows:
(A) Processor performance shall be monitored on a daily basis to include solution temperatures, sensitometric-densitometric evaluation through the use of control charts which shall include speed step or mid-density step with a control limit of plus or minus fifteen-hundredths optical density (±0.15 OD), contrast index or density difference with a control limit of plus or minus fifteen-hundredths optical density (±0.15 OD) and base plus fog with a control limit of plus three-hundredths optical density (±0.03 OD) of the operating level;
(B) Processor chemical replenishment rates shall be monitored at least quarterly;
(C) Half-value layer shall be determined at least annually with the compression device located in the primary beam, halfway between the image receptor assembly and the X-ray tube;
(D) Millampere-seconds (mAs) linearity shall be determined at least annually based on the average ratios of exposure to the indicated millampere-seconds product (mR/mAs) obtained at any two (2) consecutive tube current settings, which shall not differ by more than than-hundredths (0.10) times their sum as measured with a minimum of four (4) consecutive exposures or a maximum of ten (10) consecutive exposures at commonly used settings;
(E) Manual and automatic exposure control (AEC) reproducibility shall be determined at least annually based on the coefficient of variation of exposures, which shall not be greater than plus or minus five percent (±5%) as measured with a minimum of four (4) consecutive exposures or a maximum of ten (10) consecutive exposures at a commonly used setting;
(F) Kilovoltage potential (kVp) accuracy shall be determined at least annually. The actual kVp shall be maintained within plus or minus five percent (±5%) of the indicated kVp;
(G) kVp reproducibility shall be determined at least annually based on the coefficient of variation of kVp values, which shall not be greater than plus or minus five percent (±5%) as measured with a minimum of four (4) consecutive exposures or a maximum of ten (10) consecutive exposures at commonly used kVp settings;
(H) AEC thickness response shall be determined at least annually based on film density, which shall be maintained within plus or minus three-tenths optical density (±0.3 OD) of the average OD over the kVp range used for phantom thicknesses of two, four and six centimeters (2, 4 and 6 cm). If the OD cannot be maintained to within plus or minus three-tenths (%0.3) of the average of each clinically used setting, a technique chart shall be developed that alters kVp and density control settings as a function of breast thicknesses and densities to produce optical densities within this range under phototimized conditions;
(I) Compression device response shall be monitored at least annually;
(J) Adequacy of film storage shall be monitored at least annually, both before use and after exposure, if processing does not occur immediately;
(K) Availability and use of technique charts that shall include an indication of the kV-target-filter combination to be used with each image receptor shall be monitored at least annually;
(L) The use of kV-target-filter combination appropriate to the image receptor shall be monitored daily before patient irradiation;
(M) Darkroom integrity, for light-tight conditions and use of proper safelight, shall be monitored at least semiannually and whenever bulbs or filters are changed or when fog is suspected; darkroom fog levels shall have a variance of not greater than five-hundredths (0.05) density units between the fogged and unfogged film based on a two (2)-minute exposure to the darkroom safelight;
(N) Image quality, using one (1) of the following mammography phantoms; the RMI 152, the RMI 156, the CIRS, the Nuclear Associates phantom or other equivalent phantom acceptable to the Department of Health, which simulates the composition of the breast and provides indicators of disease conditions allowing objective analysis of clinical image quality, shall be monitored at least monthly and each time the mammographic equipment is moved or altered in any major way including the replacement of parts; a phantom image shall be made and evaluated for mobile units and vans at each location prior to the performance of mammography;
(O) Average glandular dose shall be determined at least annually based on measurements of estimated skin entrance exposure; the average glandular dose shall be calculated from those used for imaging a four and five-tenths centimeters (4.5 cm) compressed breast in the cranial caudal view and the measurement point shall be four and five-tenths centimeters (4.5 cm) from the surface of the grid or cassette as appropriate; and
(P) Film-screen contact shall be monitored at least semiannually and when new or repaired cassettes/screens are placed in service, using a contact test tool specifically designed for mammography; cassettes/screens shall be cleaned at least weekly; for xeroradiography, the photoreceptor plates shall be maintained in accordance with the manufacturer’s specifications.

(3) Evaluation of monitoring results—
(A) Standards of image quality giving acceptable ranges of value for each of the parameters tested shall be established to aid in the evaluation of monitoring results. The standards of image quality related to dose shall include a requirement that the average glandular dose for one (1) cranial caudal view of a four and five-tenths centimeters (4.5 cm) compressed breast fifty percent (50%) glandular/fifty percent (50%) adipose composition shall not exceed one hundred (100), three hundred (300) and four hundred (400) millirads (mrads) for film/screen units without grids, film/screen units with grids, and xeroradiography units, respectively; and
(B) The monitoring results shall be compared routinely to the standards of image quality established by the Department of Health. If the results fall outside the acceptable range, the test shall be repeated. If the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted.

(4) A program to analyze retakes shall be established to detect and correct problems affecting image quality or exposure. This analysis shall be performed at least quarterly or after two hundred fifty (250) patients, whichever comes first.

(5) All quality assurance test equipment shall be in good operating order and calibrated according to the manufacturer’s specifications.


19 CSR 30-11.090 Maintenance of Mammography Records

PURPOSE: This rule establishes requirements for maintenance of quality assurance records by the supplier.

(1) Records of all quality assurance tests for mammography X-ray equipment shall include the following:
   (A) The initial mammographic equipment performance evaluation and subsequent evaluations and testing;
   (B) Verification that the mammographic X-ray equipment is in safe operating order; and
   (C) Quality assurance test results.

(2) Records or written logs of maintenance and any repairs of mammographic X-ray equipment shall be kept for at least three (3) years.

(3) Film processor control charts used to regulate proper processor function shall be kept for at least two (2) years.

(4) Film processor maintenance logs shall include all of the following records and these records shall be kept for at least two (2) years: preventive maintenance; corrective maintenance; and cleaning and replacement of chemicals.

(5) Each film processor record entry shall be dated and signed or initialed by the individual who performed the quality assurance test.

(6) Records of calibration, monitoring results, the radiation physicist’s on-site consultation and the physician consultant’s annual review shall be documented in the supplier’s records and shall be readily available for review by agents of the Department of Health.


Appendix A
Topics to be Covered in Mammography Instruction

A. Anatomy and Physiology of the Female Breast
   1. Mammary glands
   2. External anatomy
   3. Subdivision for localization
   4. Retromammary space
   5. Central portion
   6. Cooper’s ligament
   7. Vessels, nerves, lymphatics
   8. Breast tissue

B. Classification of Breast Tissue
   1. Fibro-granular
   2. Fibro-fatty
   3. Fatty
   4. Lactating

C. Epidemiology of the Breast, Breast Cancer Detection Methods and Information Sources

D. Influence of Technical Factors

E. Positioning of the Breast
   1. Cranio-caudad
   2. Medial lateral oblique
   3. Axillary
   4. Magnification
   5. Errors in positioning
   6. Special techniques for mammography for the postoperative breast and the augmented breast
   7. Special radiographic techniques for breast localization and specimen radiography

F. Film or Image Evaluation, or both, and Critique

1. What constitutes optimum quality mammography radiographs or images
2. “Scanning” radiographs and images
3. Detection of pathology
4. Benign and malignant lesions
5. Mass lesion borders
   a. Smooth
   b. Irregular
   c. Calcification

G. Radiation Biology and Radiation Protection

H. Quality Assurance

19 CSR 30-11.100 Right of Entry to Mammography Suppliers for Enforcement

PURPOSE: This rule authorizes the right of entry by agents of the Department of Health.