R432. Health, Family Health and Preparedness, Licensing.
R432-950. Mammography Quality Assurance.
R432-950-1. Authority.

This rule is adopted pursuant to Section 26-21a-203.

R432-950-2. Compliance.

Facilities shall be in full compliance with R432-950 and 42 U.S.C. 263b, the Mammography Quality Standards Act of 1992.

R432-950-3. Definitions.

(1) "Diagnostic mammography" means performing a mammogram on a woman suspected of having breast cancer.

(2) "Facility" means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility that conducts breast cancer screening or diagnosis, including any or all of the following: operation of equipment to produce a mammogram, processing of film, initial interpretation of the mammogram, and the viewing conditions for that interpretation.

(3) "Image quality" means the overall clarity and detail of an x-ray including spatial resolution or resolving power, sharpness, and contrast.

(4) "Mammogram" means a radiographic image of the breast.

(5) "Mammogram unit" means an x-ray system designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression, and low dose exposure that can produce reproducible images of high quality.

(6) "Mammography" means radiography of the breast to diagnose breast cancer.

(7) "Phantom" means an artificial test object simulating the average composition of, and various structures within, the breast.

(8) "Screening mammography" means a standard readable two-view per breast low dose radiographic examination to detect unsuspected breast cancer using specifically designed equipment dedicated for mammography.

(9) "Quality assurance" means a program designed to achieve the desired degree or grade of care including evaluation and educational components to identify and correct problems in interpreting and obtaining mammogram.

(10) "Quality control" means the process of testing and maintaining the highest possible standards of equipment performance and acquisition of radiographic images.

R432-950-4. Facility Quality Assurance.

(1) The facility shall conduct a quality assurance program to assure the operation and the services provided are in accordance with R432-950.

(2) The facility shall correct identified deficiencies to produce desired results.

(3) The facility shall evaluate the corrections required for a systems change to update the quality assurance plan.

R432-950-5. Compliance with State and Local Rules.

(1) A supplier of mammography services shall comply with all applicable Federal, State, and local laws and regulations pertaining to radiological services and mammography services.

(2) The facility shall maintain documentation showing that it complies with all applicable state and local laws and rules pertaining to radiological and mammography services. This includes the following:

(a) Certification of the facility;

(b) Licensure or certification of the personnel;

(c) Documentation that the facility has been approved by the American College of Radiology (ACR).

R432-950-6. Facility Oversight.

(1) The facility is responsible for the overall quality of the mammography conducted.

(2) The facility shall have available, either on staff or through arrangement, sufficient qualified staff to meet patients' needs relating to mammography. Sufficient staff includes the following:

(a) A designated physician supervisor who meets the requirements for qualified physicians specified by the Utah Department of Commerce;

(b) A medical physicist who is certified by the American Board of Radiology in Radiological Physics or Diagnostic Radiological Physics, or who meets the requirements specified by the Department of Environmental Quality;

(c) One or more radiologic technologists who meet the requirements specified by the Utah Department of Commerce pursuant to Section 26-21a-203.

R432-950-7. Physician, Physicist and Radiologic Technologist Standards.

(1) A physician interpreting mammograms or supervising mammography, or both, shall provide documentation to the Department upon request showing he meets minimum qualifications specified by the Utah Department of Commerce and the Mammography Quality Standards Act. A qualified physician shall interpret the results of all mammograms. Diagnostic mammography shall be done under the direct on-site supervision of a qualified physician.

(2) A radiologic technologist shall meet the following requirements and the facility shall provide documentation to the Department upon request showing the radiologic technologist:

(a) Meets minimum qualifications specified by the Utah Department of Commerce and the Mammography Quality Standards Act;

(b) Obtains on-the-job training in mammography under the supervision of a qualified physician, or the supervising radiologic technologist, or both;

(c) Is competent in breast positioning and compression as determined from critiques by a qualified physician of mammogram films taken by the radiologic technologist;

(d) Is knowledgeable in facility policies concerning technical factors, radiation safety, radiation protection, and quality control as evaluated by the radiologic technologist's supervisor;

(e) Receives continuous supervision and feedback on image quality from the interpreting or supervising physician.

(3) A medical physicist must:

(a) be certified in an acceptable specialty by one of the bodies approved by the FDA to certify medical physicists;

(b) be licensed or approved by a State to conduct evaluations of mammography equipment as required by State law; or

(c) for those medical physicists associated with facilities that apply for accreditation before October 27, 1997, who meet training and experience requirements of Mammography Quality Standards Act and its implementing regulations.

R432-950-8. Personnel Requirements.

(1) The facility shall document that new staff orientation and ongoing in-service training is based on current written facility policies and procedures.

(2) Personnel shall have access to the facility's written policies and procedures when on duty.

(3) The facility shall implement a standardized orientation program for each employment position including the time for completing training.

(4) A written in-service training program shall identify the topics and frequency of training including an annual review of facility policies and procedures.

(5) The facility shall maintain personnel records documenting that each employee is qualified and competent to perform respective duties and responsibilities by means of appropriate licensure or certification, experience, orientation, ongoing in-service training, and continuing education.

(6) The facility shall retain personnel records for terminated employees for a minimum of four years following the final date of termination.

R432-950-9. Equipment Standards.

(1) Mammogram units shall be designed specifically for mammography and shall have a compression device and the capability for placement of a grid.

(2) The facility shall maintain current written policies and procedures for operating equipment.

(3) Prior to initiating operation of a mammogram unit it shall be registered with the Utah Department of Environmental Quality.

R432-950-10. Safety Standards.

(1) The facility shall maintain documentation that the mammogram unit is safe and that proper radiation safety practices are being followed.

(2) The facility shall maintain documentation that employees have been trained on safety standards for radiation.

(3) The facility shall maintain procedure manuals and logs for equipment quality control.

(4) The facility shall maintain documentation that the quality control program complies with ACR quality control manuals for mammography or the equivalent.

(a) Equivalent programs shall include a quality control program for equipment, mammogram unit performance, and film processors, approved by the Utah Department of Environmental Quality.

(b) Equivalent programs shall contain stated objectives achieved by procedures comparable to objectives and procedures in the American College of Radiology Quality Control Manuals for Mammography.

(5) Accreditation by the American College of Radiology Mammography Program documents compliance with mammogram unit quality control requirements in R432-950-10(1).

R432-950-11. Technical Specifications for Mammography.

(1) The facility shall have available a phantom for use in the facility's ongoing quality control program.

(2) The facility shall evaluate image quality at least monthly using a phantom that produces measurements satisfactory to the supervising physician.

(3) The facility's evaluation of clinical images shall include the following:

(a) Positioning;

(b) Compression;

(c) Exposure level;

(d) Resolution;

(e) Contrast;

(f) Noise;

(g) Exam Identification;

(h) Artifacts.

R432-950-12. Physician Supervisor Responsibility.

(1) A physician supervisor is responsible for general oversight of the quality control program of the facility. Oversight responsibilities include:

(a) Annual review of the policy and procedure manual;

(b) Verification that the equipment and facility personnel meet applicable federal, state and local licensure and registration requirements;

(c) Verification that equipment is performing properly;

(d) Verification that safe operating procedures are used to protect facility personnel and patients;

(e) Verification that all other requirements of R432-950 are being met.

(2) The physician shall document annually that he provides oversight for the quality control of the mammography service.

R432-950-13. Mammography Records.

(1) A medical record shall be maintained for each patient on whom screening or diagnostic mammography is performed.

(a) Provision shall be made for the filing, safe storage and accessibility of medical records.

(b) Records shall be protected against loss, defacement, tampering, fires, and floods.

(c) Records shall be protected against access by unauthorized individuals.

(d) All records shall be readily available upon the request of:

(i) The attending physician,

(ii) Authorized representatives of the Department for determining compliance with licensure rules;

(iii) Any other person authorized by written consent.

(e) The facility shall establish a system to assure that the patient's mammogram is accessible for clinical follow-up when requested.

(i) A copy of the mammogram and other appropriate information shall be sent to the requesting party responsible for subsequent medical care of the patient no later than 14 working days from the request for information. This shall include the full notification and follow up required under Utah Code 26-21a-206 and Administrative Code R432-950-14.

(ii) Medical information may be released only upon the written consent of the patient of her legal representative.

(2) The facility shall attempt to obtain a prior mammogram for each patient if the prior mammogram is necessary for the physician to properly interpret the current exam.

(3) The interpreting physician shall prepare and sign a written report of his interpretation of the results of the screening mammogram.

(a) The written report shall include a description of detected abnormalities and recommendations for subsequent follow-up studies.

(b) The interpreting physician shall render the report as soon as reasonably possible.

(c) The interpreting physician or his designee shall document and communicate the results of the report to the referring physician or his designated representative by telephone, by certified mail, or in such a manner that receipt of the report is assured.

(d) The interpreting physician or his designee shall notify self-referred patients, that is, patients who have no referring physician, of the results of the screening study in writing and in lay language.

(4) The interpreting physician or his designee shall document and communicate the results of all diagnostic reports in the high probability category with suspicion of breast cancer to the referring physician or his designated representative by telephone, by certified mail, or in such a manner that receipt of the report is assured.

(5) The physician shall document and communicate in person in lay language, by certified mail, or in such a manner that receipt of the diagnostic report is assured to all self-referred patients within the high probability category with a suspicion of breast cancer. The report shall indicate whether the patient needs to consult with a physician.

(a) The interpreting physician or his designee shall attempt to make a follow-up contact with the patient to determine whether she has consulted a physician for follow-up care.

(b) The interpreting physician or his designee shall document in the patient's medical record attempts to communicate the results to the patient.

(6) The facility shall retain the original and subsequent mammograms for a period of at least five years from the date of the procedure.

R432-950-14. Education and Notification Requirements.

(1) A patient has the right to be treated with dignity and afforded privacy during the examination.

(2) The facility shall establish an education system to ensure that the patient understands:

(a) The purpose of the mammogram and how it is used to screen for breast cancer;

(b) The process required to obtain the mammogram;

(c) The importance of the screening mammography to her ongoing health.

(3) As required in Utah Code 26-21a-206, the facility shall include the following notification and information with a mammography result provided to a patient with dense breast tissue: "Your mammogram indicates that you have dense breast tissue. Dense breast tissue is common and is found in as many as half of all women. However, dense breast tissue can make it more difficult to fully and accurately evaluate your mammogram and detect early signs of possible cancer in the breast. This information is being provided to inform and encourage you to discuss your dense breast tissue and other breast cancer risk factors with your health care

provider. Together, you can decide what may be best for you. A copy of your mammography report has been sent to your health care provider. Please contact them if you have any questions or concerns about this notice."

(4) The copy of the mammography report provided to the patient and the health care provider shall include the dense breast tissue notification required under Utah Code 26-21a-206.

R432-950-15. Collecting and Reporting Data.

(1) The facility shall establish a system for collecting and periodic reporting of mammography examinations and clinical follow-up as provided below:

(a) Clinical follow-up data shall include the follow-up on the disposition of positive mammographic findings, and the correlation of the surgical biopsy results with mammogram reports.

(b) The facility shall maintain records correlating the positive mammographic findings to biopsies done and the number of cancers detected.

(c) The facility shall report the results of the outcomes annually to the Department or its designated agent, on forms furnished by the Department. The report shall include as a minimum:

(i) The number of individuals receiving screening mammograms;

(ii) Total number of patients recommended for biopsy based on a screening mammogram;

(iii) Total number of patients diagnosed with breast cancer based on a screening mammogram;

(iv) The number and names of individuals with positive mammographic findings lost to follow-up.

(2) The Department or its designated agent shall provide each reporting facility, on a schedule determined by the Department, summary statistical reports which permit each facility to compare its results to statewide and other comparative statistics.

R432-950-16. State Certification.

(1) No facility, person or governmental unit acting severally or jointly with any other person, may establish, conduct or maintain a mammography unit without first obtaining a state certificate from the Department.

(2) An applicant for state certification shall file a Request for Agency Action/Certification Application with the Utah Department of Health on forms furnished by the Department.

(3) Each facility shall comply with all zoning, building and licensing laws, rules and ordinances and codes of the city and county in which the facility is located. The applicant shall submit the following to the Department:

(a) Verification of participation and quality control by the American College of Radiology for monitoring mammography services in the facility;

(b) Verification of licensure or certification of required personnel;

(c) Fees established by the Utah State Legislature pursuant to Section 63-38-3.

(4) The Department shall render a decision on the initial certification within 60 days of receipt of a completed application packet or within 6 months of date that the first component of an application packet was received.

(a) Upon verification of compliance with state certification requirements, the Department shall issue a provisional certificate.

(b) The Department shall issue a notice of agency decision under the procedures for informal adjudicative proceedings denying a state certification if the applicant is not in compliance with the applicable laws or rules. The notice shall state the reasons for denial.

(5) Certificate Contents and Provisions. The state certificate shall include the name of the mammography facility, owner, supervising physician, address, issue and expiration dates of the state certificate and the certificate number.

(b) The state certificate may be issued only to the owner and for the premises described in the application and shall not be assignable or transferable.

(c) Each state certificate is the property of the Department and shall be returned within five days if the certification is suspended, revoked, or if the operation of the facility is discontinued.

(d) The state certificate shall be prominently displayed where it can be easily viewed by the public.

(6) Certification periods shall be for 24 months, and expire at midnight 24 months from the date of issuance.

(a) A request for renewal and applicable fees shall be filed with the Department 15 days before the state certificate expires.

(b) Failure to make a timely renewal shall result in assessment of late fees as established by the Utah State Legislature pursuant to Section 26-21a-203.

(7) The owner shall submit a Request for Agency Action/Application to amend or modify state certification status at least 30-days before any of the following proposed or anticipated changes occur:

(a) Change in the name of the facility;

(b) Change in the supervising physician;

(c) Change in the owner of the facility.

(8) The owner who wants to cease operation shall complete the following:

(a) Notify the patients within 30 days before the effective date of closure.

(b) Make adequate provision for the safekeeping of records and notify the department where those records will be stored.

(c) Return the state certificate to the Department within five days after the facility ceases operation.

(9) The Department may issue a provisional state certificate to a facility as an initial certification and may issue a provisional state certification to a facility that does not fully comply with the requirements for a standard certification but has made acceptable progress towards meeting the requirements.

(a) In granting a provisional state certification, the Department must be assured that the lack of full compliance does not harm the health, safety, and welfare of the patients.

(b) A provisional state certificate is nonrenewable and shall be issued for no more than 6 months.

R432-950-17. Inspections.

Upon presentation of proper identification, authorized representatives of the Department shall be allowed to enter a facility at any reasonable time without a warrant and be permitted to review records including medical records, when it is determined by the Department to be necessary to ascertain compliance with state law and rules promulgated under Section 26-21a-205.

(1) Each facility may be inspected by the Department or its designee to determine compliance with minimum standards and the applicable rules.

(2) Upon receipt of the survey results of the ACR, the facility shall submit copies of the certificate and the survey report and recommendations.

(3) The accreditation documents are open to the public.

(4) The Department may conduct periodic validation inspections of facilities accredited by the ACR for the purpose of determining compliance with state requirements.

R432-950-18. Enforcement and Appeal Process.

Whenever the Department has reason to believe that the facility is in violation of Section 26-21a-203 or any of the rules adopted pursuant to Title 26, Chapter 21, the Department shall issue a written Statement of Findings/Plan of Correction to the certified facility.

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