Document No. 5449
DEPARTMENT OF ENVIRONMENTAL SERVICES
CHAPTER 61
Statutory Authority: 1976 Code Sections 13-7-40, 48-6-10 et seq., and 2023 Act No. 60, effective July 1, 2024

61-64. X-Rays (Title B).

Synopsis:

Pursuant to S.C. Code Ann. Section 13-7-40 et seq., the Department of Environmental Services (Department) has the authority to regulate radiation sources and to formulate, adopt, promulgate, and repeal rules and regulations relating to the control of ionizing radiation.

The Department is amending R.61-64, X-Rays (Title B), to incorporate the U.S. Food and Drug Administration's (FDA) amendments to the federal Mammography Quality Standards Act (MQSA) published on March 10, 2023, 88 FR 15126, and effective September 10, 2024.

The updates issued by the FDA, which became effective September 10, 2024, were to modernize the regulations by incorporating current science and mammography best practices. The Department's intent of its amendments to R.61-64, X-Rays (Title B), is to mirror the amendments of the federal MQSA by doing the following: improving the delivery of mammography services by strengthening the communication of healthcare information; allowing for more informed decision-making by patients and providers (by requiring facilities to provide them with additional health information); helping to ensure the availability of qualified mammography personnel; bolstering the medical outcomes audit to provide feedback to improve mammography interpretations; modernizing technological aspects of the standards; and adding additional tools to deal with noncompliant facilities.

The Administrative Procedures Act, S.C. Code Ann. Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department promulgates these amendments for compliance with federal law.

The Department had a Notice of Drafting published in the October 24, 2025, South Carolina State Register.

Section-by-Section Discussion:

Section	Type of Change	Purpose
R.61-64. PART V		
5.5.1	Revision	Amended to comply with federal requirements.
5.5.1.3	Revision	Amended to comply with federal requirements.
5.5.1.6	Revision	Amended to comply with federal requirements.
5.5.1.7	Revision	Revised to include new requirement based on federal requirements.
5.5.1.8	Addition	Addition to move the requirement previously contained within subsection 5.5.1.7 to 5.5.1.8.
5.9.4	Revision	Amended to retain the name of the section.
5.9.4.1	Addition	Addition to include new federal requirements for the retention of personnel records – requirement to maintain records for Department review.

5.9.4.2	Addition	Addition to include new federal requirements for the retention of personnel records – requirement to provide copies upon request.
5.9.4.3	Addition	Addition to include new federal requirements for the retention of personnel records – requirement for the timeframe to maintain these required records.
5.9.4.4	Addition	Addition to include new federal requirements for the retention of personnel records – requirement to provide required records.
5.9.4.5	Addition	Addition to include new federal requirements for the retention of personnel records – requirement for actions to take prior to facility closure or ceasing to perform mammography regarding personnel records.
5.10.2.1	Addition	Addition to include new federal requirement.
5.10.2.2	Addition	Addition to include new federal requirement.
5.10.11	Revision	Amended to include new federal requirements for facilities using screen-film units.
5.11.1	Revision	Amended to include new federal requirements for the examination presented for interpretation.
5.11.1.2	Revision	Amended to include new federal required information to be included on the mammography report.
5.11.1.4	Revision	Amended to include new federal requirement to clarify the assessment statement.
5.11.1.4.1	Revision	Amended to include new federal language that clarifies a “Negative” assessment.
5.11.1.4.2	Revision	Amended to include new federal language that clarifies a “Benign” assessment.
5.11.1.4.5	Revision	Amended for grammar.
5.11.1.4.6	Addition	Addition of new federally required assessment category and description – “Known Biopsy – Proven Malignancy”.
5.11.1.4.7	Addition	Addition of new federally required assessment category and description – “Post-Procedure Mammogram for Marker Placement”.
5.11.1.5	Revision	Amended to include new federal requirement for classification statements.
5.11.1.5.1	Addition	Addition of new federally required assessment category and description – “Incomplete; Need additional imaging evaluation”.

5.11.1.5.2	Addition	Addition of new federally required assessment category and description – "Incomplete: Need prior mammograms for comparison".
5.11.1.6	Revision	Original requirement reorganized to new subpart. Amended to include new federal requirement for the inclusion of the appropriate breast density statement.
5.11.1.6.1	Addition	Addition of new federally required breast density category.
5.11.1.6.2	Addition	Addition of new federally required breast density category.
5.11.1.6.3	Addition	Addition of new federally required breast density category.
5.11.1.6.4	Addition	Addition of new federally required breast density category.
5.11.1.7	Addition	Requirement for recommendations reorganized to this new subpart.
5.11.2	Revision	Amended to include new federal requirements for the contents of the lay summary provided to the patient.
5.11.2.1	Revision	Amended to include new federal requirements for the timeframe for sending reports for patients who do not name a healthcare provider with an assessment of "Suspicious" or "Highly Suggestive of Malignancy".
5.11.2.2	Revision	Amended to clarify the new federal requirement to maintain a system to refer patients to a healthcare provider when clinically indicated.
5.11.2.3	Addition	Addition of the new federally required appropriate breast density statement language based on the breast density category identified on the mammography report.
5.11.2.4	Addition	Addition of the new federally required appropriate breast density statement language based on the breast density category identified on the mammography report.
5.11.3	Revision	Amended for grammar.
5.11.3.1	Revision	Amended for grammar.
5.11.3.2	Revision	Amended to include new federal requirements for the mammography report and the timeframe for the final interpretation.
5.11.4.1	Revision	Amended for clarification on the timeframes and new federally required procedures for the maintenance of original mammograms and mammography reports.

5.11.4.2	Revision	Amended to include new federal requirements for the transfer of the mammogram and the mammography reports when such request is received.
5.11.4.3	Revision	Original requirement reorganized to new subpart. Amended to include new federal requirements for the release of copies of mammograms or mammogram reports.
5.11.4.4	Addition	Requirement for fees charged reorganized to this new subpart.
5.11.4.5	Addition	Addition of new federal requirements for mammographic records if a facility closes or ceases to provide mammography services.
5.11.4.5.1	Addition	Addition of new federal requirements for access to mammographic records.
5.11.4.5.2	Addition	Addition of new federal requirements for access to mammographic records.
5.11.4.5.3	Addition	Addition of new federal requirements for notification of accrediting body and the Department in writing of arrangements to notify affected patients.
5.23.1	Revision	Amended to new federal requirements for the medical outcomes audit.
5.23.1.1	Addition	Addition of the new federal requirement of the positive predictive value in the medical outcomes audit.
5.23.1.2	Addition	Addition of the new federal requirement of the cancer detection rate in the medical outcomes audit.
5.23.1.3	Addition	Addition of the new federal requirement of the recall rate in the medical outcomes audit.
5.23.4	Addition	Addition of new federal requirement for the timeframe to maintain records and data to demonstrate compliance.
5.24 title	Revision	Amended to new federal requirement to add referring provider.
5.24.1	Revision	Amended to new federal requirements to clarify patient provider notification.
5.24.2	Revision	Amended to new federal requirements that allow the Department to notify patients and physicians as needed.
R.61-64. PART X		
10.6	Revision	Amended to include the language healthcare provider.
10.42	Revision	Amended to include the language healthcare provider.
10.137	Revision	Amended to include digital breast tomosynthesis and full field digital mammography.
10.151	Revision	Amended to align with federal regulation.

10.160	Revision	Amended to clarify definition of patient whether the person is healthcare provider or self-referred.
10.175	Revision	Amended for grammar.

Instructions:

Amend the regulation as shown below. All other items remain unchanged.

Text:

PART V
QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR FACILITIES PERFORMING MAMMOGRAPHY

RHB 5.5.1 shall be revised as follows:

5.5.1 Except as provided in RHB 5.5.2, the Department may suspend or revoke a certificate if the Department finds that the facility, owner, operator, or any employee of the facility:

RHB 5.5.1.3 shall be revised as follows:

5.5.1.3 Has failed to comply with reasonable requests of the Department or the accreditation body for records, information, reports, or materials, including clinical images for an additional mammography review as required by RHB 5.24, 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 5.24;

RHB 5.5.1.6 shall be revised as follows:

5.5.1.6 Has failed to comply with prior sanctions imposed by the Department, including a Corrective Action Plan or a patient and referring physician notification;

RHB 5.5.1.7 shall be revised as follows:

5.5.1.7 Has failed to comply with requests of current or former facility personnel for records of their training or experience relevant to their qualification under MQSA as required by RHB 5.9.4; or

RHB 5.5.1.8 shall be added as follows:

5.5.1.8 Has failed to pay any required fees.

RHB 5.9.4 shall be revised as follows:

5.9.4 Retention of personnel records.

RHB 5.9.4.1 shall be added as follows:

5.9.4.1 Facilities shall maintain records of training and experience relevant to their qualification under MQSA for personnel who work or have worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the Department.

RHB 5.9.4.2 shall be added as follows:

5.9.4.2 The facility shall provide copies of these personnel records to current interpreting physicians, radiologic technologists, and medical physicists upon their request.

RHB 5.9.4.3 shall be added as follows:

5.9.4.3 Records of personnel no longer employed by the facility must be maintained for no less than twenty-four (24) months from the date of the departure of an employee, and these records must be available for review at the time of any inspection occurring during those twenty-four (24) months.

RHB 5.9.4.4 shall be added as follows:

5.9.4.4 Facilities must provide personnel records to former employees if the former employees communicate their request within twenty-four (24) months of the date of their departure. If it has been greater than twenty-four (24) months and the facility has maintained those records, the facility must provide those records to former employees upon request.

RHB 5.9.4.5 shall be added as follows:

5.9.4.5 Before a facility closes or ceases to provide mammography services, it must make arrangements for access by current and former personnel to their MQSA personnel records. This access may be provided by the permanent transfer of these records to the personnel or the transfer of the records to a facility or other entity that will provide access to these records for no less than twenty-four (24) months from the date of facility closure or cessation of mammography services.

RHB 5.10.2.1 shall be added as follows:

5.10.2.1 All devices used in mammography must have met the applicable FDA premarket authorization requirements for medical devices of that type with that intended use.

RHB 5.10.2.2 shall be added as follows:

5.10.2.2 A mammography unit that is converted from one mammographic modality to another is considered a new unit at the facility under this part and must, prior to clinical use, undergo a mammography equipment evaluation demonstrating compliance with applicable requirements. The facility must also follow its accreditation body’s procedures for applying for accreditation of that unit.

RHB 5.10.11 shall be revised as follows:

5.10.11 Film. For facilities using screen-film units, the facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography. For facilities using hardcopy prints of digital images for transfer, retention or final interpretation purposes, the facility shall use a type of film designated by the film manufacturer as appropriate for these purposes and compatible with the printer being used.

RHB 5.11.1 shall be revised as follows:

5.11.1 Contents and terminology. Each facility shall prepare a written report of the results of each mammographic examination performed under its certificate. The mammographic examination presented for interpretation must be in the original mammographic modality in which it was performed, and must not consist of digital images produced through copying or digitizing hardcopy original images. The mammography report shall include the following information:

RHB 5.11.1.2 shall be revised as follows:

5.11.1.2 Date of examination, facility name, and location. At a minimum, the location shall include the city, State, ZIP code, and telephone number of the facility;

RHB 5.11.1.4 shall be revised as follows:

5.11.1.4 Overall final assessment of findings, classified in one of the following categories (the assessment statement is only the word or phrase within the quotation marks):

RHB 5.11.1.4.1 shall be revised as follows:

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

RHB 5.11.1.4.2 shall be revised as follows:

5.11.1.4.2 "Benign." Also a normal result, with benign findings present, but no evidence of malignancy (if the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be documented and addressed);

RHB 5.11.1.4.5 shall be revised as follows:

5.11.1.4.5 "Highly Suggestive of Malignancy." Finding(s) has a high probability of being malignant;

RHB 5.11.1.4.6 shall be added as follows:

5.11.1.4.6 "Known Biopsy – Proven Malignancy." Reserved for known malignancies being mammographically evaluated for definitive therapy; and

RHB 5.11.1.4.7 shall be added as follows:

5.11.1.4.7 "Post-Procedure Mammogram for Marker Placement." Reserved for a post-procedure mammogram used to confirm the deployment and position of a breast tissue marker.

RHB 5.11.1.5 shall be revised as follows:

5.11.1.5 In cases where no final assessment category can be assigned due to incomplete work-up, one of the following classification statements shall be assigned as an assessment and reasons why no final assessment can be made shall be stated by the interpreting physician;

RHB 5.11.1.5.1 shall be added as follows:

5.11.1.5.1 "Incomplete: Need additional imaging evaluation." Reserved for examinations where additional imaging needs to be performed before an assessment category identified in RHB 5.11.1.4 can be given; or

RHB 5.11.1.5.2 shall be added as follows:

5.11.1.5.2 "Incomplete: Need prior mammograms for comparison." Reserved for examinations where comparison with prior mammograms should be performed before an assessment category identified in RHB 5.11.1.4 can be given. If this assessment category is used, a follow-up report with an assessment category identified in RHB 5.11.1.4.1 through 5.11.1.4.5 must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained.

RHB 5.11.1.6 shall be revised as follows:

5.11.1.6 Overall assessment of breast density classified in one of the following categories:

RHB 5.11.1.6.1 shall be added as follows:

5.11.1.6.1 “The breasts are almost entirely fatty.”

RHB 5.11.1.6.2 shall be added as follows:

5.11.1.6.2 “There are scattered areas of fibroglandular density.”

RHB 5.11.1.6.3 shall be added as follows:

5.11.1.6.3 “The breast are heterogeneously dense, which may obscure small masses.”

RHB 5.11.1.6.4 shall be added as follows:

5.11.1.6.4 “The breasts are extremely dense, which lowers the sensitivity of mammography.”

RHB 5.11.1.7 shall be added as follows:

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

RHB 5.11.2 shall be revised as follows:

5.11.2 Communication of mammography results to the patient. Each facility shall provide each patient a summary of the mammography report written in lay terms within thirty (30) calendar days of the mammographic examination which shall, at a minimum, include the name of the patient; the name, address, and telephone number of the facility performing the mammographic examination; and an assessment of breast density as described in RHB 5.11.2.3 and RHB 5.11.2.4. If the assessment of the mammography report is “Suspicious” or “Highly Suggestive of Malignancy,” the facility shall provide the patient a summary of the mammography report written in lay language within seven (7) calendar days of the final interpretation of the mammograms.

RHB 5.11.2.1 shall be revised as follows:

5.11.2.1 Patients who do not name a healthcare provider to receive the mammography report shall be sent the report described in RHB 5.11.1 within thirty (30) calendar days, in addition to the written notification of results in lay terms. If the assessment of the mammography report is “Suspicious” or “Highly Suggestive of Malignancy,” the facility shall send this report to the patient within seven (7) calendar days of the final interpretation of the mammograms.

RHB 5.11.2.2 shall be revised as follows:

5.11.2.2 Each facility that accepts patients who do not have a healthcare provider shall maintain a system for referring such patients to a healthcare provider when clinically indicated, which shall include when such patients’ mammogram assessment is either probably benign, suspicious, or highly suggestive of malignancy.

RHB 5.11.2.3 shall be added as follows:

5.11.2.3 If the mammography report identifies the patient's breast density as "The breasts are almost entirely fatty" or "There are scattered areas of fibroglandular density," the lay summary shall include the statement "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is not dense. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

RHB 5.11.2.4 shall be added as follows:

5.11.2.4 If the mammography report identifies the breast density as "The breasts are heterogeneously dense, which may obscure small masses" or "The breasts are extremely dense, which lowers the sensitivity of mammography," the lay summary shall include the statement "Breast tissue can be either dense or not dense. Dense tissue makes it harder to find breast cancer on a mammogram and also raises the risk of developing breast cancer. Your breast tissue is dense. In some people with dense tissue, other imaging tests in addition to a mammogram may help find cancers. Talk to your healthcare provider about breast density, risks for breast cancer, and your individual situation."

RHB 5.11.3 shall be revised as follows:

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

RHB 5.11.3.1 shall be revised as follows:

5.11.3.1 Provide a written report of the mammography examination, including the items listed in subsection 5.11.1 of this Section, to that healthcare provider as soon as possible, but no later than thirty (30) calendar days after the date of the mammography examinations; and

RHB 5.11.3.2 shall be revised as follows:

5.11.3.2 If the assessment is "Suspicious" or "Highly Suggestive of Malignancy," the facility shall provide a written report of the mammographic examination, including the items listed in RHB 5.11.1, to the referring healthcare provider, or if the referring healthcare provider is unavailable, to a responsible designee of the referring healthcare provider within seven (7) calendar days of the final interpretation of the mammograms.

RHB 5.11.4.1 shall be revised as follows:

5.11.4.1 Shall, except as provided in RHB 5.11.4.2, maintain the original mammograms and mammography reports in a permanent medical record of the patient for the longest of the following: a period of not less than five (5) years, or a period of not less than ten (10) years if no additional mammograms of the patient are performed at the facility. Facilities shall implement policies and procedures to minimize the possibility of loss of these records. The original mammograms must be retained in retrievable form in the mammographic modality in which they were produced. They cannot be produced by copying or digitizing hardcopy originals.

RHB 5.11.4.2 shall be revised as follows:

5.11.4.2 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, a physician or healthcare provider of the patient, or to the patient directly during the time specified in RHB 5.11.4.1. Transfer of the mammograms and the mammography reports must take place within fifteen (15) calendar days of the facility receiving such request. The transferred mammograms must be in the mammographic modality in which they were produced, and cannot be produced by the copying or digitizing hardcopy originals. For digital mammograms or digital

breast tomosynthesis, if the examination is being transferred for final interpretation purposes, the facility must be able to provide the recipient with original digital images electronically;

RHB 5.11.4.3 shall be revised as follows:

5.11.4.3 Shall upon request by, or on behalf of, the patient, provide copies of mammograms or copies of mammogram reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly during the time specified in RHB 5.11.4.1. Release of the copies must take place within fifteen (15) calendar days of the facility receiving such request. For digital mammograms or digital breast tomosynthesis, if the copies are being released for final interpretation purposes, the facility must be able to provide the recipient with digital images electronically;

RHB 5.11.4.4 shall be added as follows:

5.11.4.4 Any fee charged to the patient for providing the services in RHB 5.11.4 shall not exceed the documented costs associated with this service; and

RHB 5.11.4.5 shall be added as follows:

5.11.4.5 Before a facility closes or ceases to provide mammography services, it must make arrangements for access by patients and healthcare providers to their mammographic records.

RHB 5.11.4.5.1 shall be added as follows:

5.11.4.5.1 This access may be provided by the permanent transfer of mammographic records to the patient or the patient's healthcare provider or the transfer of the mammographic records to a facility or other entity that will provide access to patients and healthcare providers. Access to the records must be provided by such other facility or entity for the remainder of the time periods specified in RHB 5.11.4.1.

RHB 5.11.4.5.2 shall be added as follows:

5.11.4.5.2 If a facility ceases to perform mammography but continues to operate as a medical entity, and is able to satisfy the recordkeeping requirements of RHB 5.11.4.1, it may choose to continue to retain the medical records rather than transfer them to another facility, unless such a transfer is requested by, or on behalf of, the patient.

RHB 5.11.4.5.3 shall be added as follows:

5.11.4.5.3 The facility must notify its accreditation body and the Department in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients.

RHB 5.23.1 shall be revised as follows:

5.23.1 General Requirements. For the purposes of these audit requirements, a mammographic examination consisting of routine views of an asymptomatic patient shall be termed a screening mammogram, while a mammographic examination consisting of individualized view of a patient with breast symptoms, physical signs of breast disease, or abnormal findings on a screening mammogram shall be termed a diagnostic mammogram. Each facility shall establish a system to collect and review outcome data for all mammographic examinations performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. In addition, for cases of breast cancer among patients imaged at the facility that subsequently become known to the facility, the facility shall promptly initiate follow-up on surgical and/or pathology results and review of the mammographic examinations taken prior to the

diagnosis of a malignancy. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians and, at a minimum, shall consist of a determination of the following:

RHB 5.23.1.1 shall be added as follows:

5.23.1.1 Positive predictive value – percent of patients with positive mammograms who are diagnosed with breast cancer within one (1) year of the date of the mammographic examination.

RHB 5.23.1.2 shall be added as follows:

5.23.1.2 Cancer detection rate – of patients initially examined with screening mammograms who receive an assessment of "Incomplete: Need additional imaging evaluation," "Suspicious," or "Highly Suggestive of Malignancy" on the screening mammogram or on a subsequent diagnostic mammogram, the number of patients who are diagnosed with breast cancer within one (1) year of the date of the initial screening mammogram, expressed arithmetically as a ratio per one thousand (1,000) patients.

RHB 5.23.1.3 shall be added as follows:

5.23.1.3 Recall rate – percentage of screening mammograms given an assessment of "Incomplete: Need additional imaging evaluation."

RHB 5.23.4 shall be added as follows:

5.23.4 The records and data required to demonstrate compliance with the requirements in RHB 5.23.1, RHB 5.23.2 and RHB 5.23.3 must be retained until the annual inspection that follows the facility's analysis of that information.

RHB 5.24 title shall be revised as follows:

RHB 5.24. Additional Mammography Review and Patient and Referring Provider Notification.

RHB 5.24.1 shall be revised as follows:

5.24.1 If the Department believes that mammographic quality at a facility has been compromised and may present a significant 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 whether there is a need to notify affected patients, their referring physicians or other healthcare providers, and/or the public there is a significant risk to human health.

RHB 5.24.2 shall be revised as follows:

5.24.2 Based on the results of the additional mammography review, the facility's failure to comply with the terms of the additional mammography review, or other information, the Department may determine that the quality of mammography performed by a facility, whether or not certified under RHB 5.4, was so inconsistent with the quality standards established in this Part as to present a significant risk to human health, the Department may require such a facility to notify all patients who received mammograms at the facility or those patients who are determined to be at risk due to the quality of their mammography, and their referring physicians or other healthcare providers, of the deficiencies and resulting potential harm, appropriate remedial measures, and such other relevant information as the Department may require. Such notification shall occur within a timeframe and in a manner specified by the Department. If the facility is unable or unwilling to perform such notification, the

Department may notify patients and their referring physicians or other healthcare providers individually or through the mass media.

PART X
DEFINITIONS

RHB 10.6 shall be revised as follows:

10.6 "Adverse event" means an undesirable experience associated with mammography activities that include, but are not limited to: poor image quality; failure to send mammography reports within thirty (30) calendar days to the referring healthcare provider or in a timely manner to the self-referred patient; and use of personnel that do not meet the requirements.

RHB 10.42 shall be revised as follows:

10.42 "Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring healthcare provider).

RHB 10.137 shall be revised as follows:

10.137 "Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography, digital breast tomosynthesis, and full field digital mammography.

RHB 10.151 shall be revised as follows:

10.151 "MQSA" means the Mammography Quality Standards Act.

RHB 10.160 shall be revised as follows:

10.160 "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment, including a mammography evaluation in a facility regardless of whether the person is referred by a healthcare provider or is self-referred.

RHB 10.175 shall be revised as follows:

10.175 "Positive mammogram" means a mammogram that has an overall assessment of findings that are either "Suspicious" or "Highly Suggestive of Malignancy."