

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).

**Preamble:**

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 proposes 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 proposal to amend 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 proposes 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.

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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

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5.11.4.3	Revision	mammogram and the mammography reports when such request is received. 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.

**Notice of Public Hearing and Opportunity for Public Comment:**

Interested persons may submit written comments on the proposed amendments to Ms. Chrissy Chavis of the Bureau of Land and Waste Management, South Carolina Department of Environmental Services, 2600 Bull Street, Columbia, South Carolina 29201; or via email at [Chrissy.Chavis@des.sc.gov](mailto:Chrissy.Chavis@des.sc.gov). To be considered, the Department must receive comments no later than 5:00 p.m. on Monday, March 30, 2026, the close of the comment period.

Should a public hearing on the proposed regulations be requested by qualifying entities or the requisite number of persons pursuant to Section 1-23-110(A)(3) of the 1976 Code, as amended, the South Carolina Administrative Law Court will conduct a public hearing on Monday, April 13, 2026, beginning at 1:30 p.m. at the South Carolina Administrative Law Court, Edgar Brown Building, Second Floor, 1205 Pendleton Street, Columbia, S.C. 29201. If a qualifying request pursuant to Section 1-23-110(A)(3) is not received by 5:00 p.m. on March 30, 2026, the hearing will be cancelled.

**Statement of Need and Reasonableness:**

The following presents an analysis of the factors listed in 1976 Code Sections 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION: R.61-64, X-Rays (Title B).

Purpose: The Department proposes amendment to R.61-64, X-Rays (Title B), for federal compatibility with the Mammography Quality Standards Act (MQSA). R.61-64 Part V “Quality Standards and Certification Requirements for Facilities Performing Mammography” and Part X “Definitions” will be amended to adopt language from the recent revisions to the federal MQSA regulations that were published in the Federal Register on March 10, 2023, and became effective September 10, 2024.

Legal Authority: 1976 Code Sections 13-7-40, 48-6-10 et seq., and 2023 Act No. 60, effective July 1, 2024.

Plan for Implementation: The Department currently enforces the requirements of recently revised MQSA regulations via Administrative Order 24-06-RP that was executed November 14, 2024. Implementation guidance and information resources are currently available via websites and annual inspections.

**DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:**

The proposed amendments are necessary for federal compatibility with MQSA regulations. As stated in the Federal Register, these revisions were issued to “modernize the regulations by incorporating current science and mammography best practices..., to improve the delivery of mammography services by strengthening the communication of healthcare information..., [to allow] for more informed decision making by patients and providers (by requiring facilities to provide them with additional health information)..., [to help] ensure the availability of qualified mammography personnel..., [to bolster] the medical outcomes audit to provide feedback to improve mammography interpretations..., [to modernize] technological aspects of the standards..., and [to add] additional tools to deal with noncompliant facilities.”

**DETERMINATION OF COSTS AND BENEFITS:**

Implementation of these proposed amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any requirements of these amendments.

There is no anticipated additional cost to stakeholders and members of the regulated community.

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### **UNCERTAINTIES OF ESTIMATES:**

There are no uncertainties of estimates relative to the costs to the state or its political subdivisions.

### **EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:**

Adoption of the recent changes in federal regulations through the proposed amendments to R.61-64 will provide continued protection of the environment and public health.

### **DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:**

There is no anticipated detrimental effect on the environment. If the proposed amendments are not implemented, the state of South Carolina may lose the qualification to administer the MQSA 42 U.S. Code Section 263b certification program.

### **Text:**

The full text of this regulation is available on the South Carolina General Assembly Home Page: <http://www.scstatehouse.gov/regnsrch.php>. Full text may also be obtained from the promulgating agency.