



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEVPUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

MEMORANDUM

TO: Office of State Budget & Management

FROM: Shanah Black, DHSR Rule-making Coordinator

DATE: July 7, 2025

RE: Federal Certification for Radiation Protection Rule Readoptions and Repeals

Rule-making Coordinator's Certificate

As Required by GS 150B-19.1(g)
For Proposed Permanent and Temporary Rules Adopted to
Implement a Federal Law or which upon Receipt of Federal Funds is Conditioned

The attached rule-making package applies to Rules 10A NCAC 15 .0601- .0608, and .0610-.0611. These rules are proposed for readoption, amendment, and repeal for all registrants who use electronic radiation machines in the State of North Carolina.

The readoption and repeal of these rules are necessary for compliance with the federal regulations in 21 CFR Subchapter J that govern the use of x-ray imaging systems. The federal Regulations are being incorporated by reference into one rule for readoption, Rule 10A NCAC 15 .0607.

The specific federal regulations for Rule .0607 are 21 CFR Chapter I Subchapter J- Parts 1000, 1002, 1003, 1010, and 1020, which include General Provisions, Applicability, Performance Standards for Electronic Products-General, and Performance Standards for Ionizing Radiation Emitting Products.

The readoption of Rule .0607 is necessary to come into compliance with the Code of Federal Regulations for Radiologic Health in Title 21 Chapter I Subchapter J, which governs the assemblers' responsibility for compliance in Parts 1000 through 1003, and imaging systems that must comply with radiation safety performance standards for compliance in Parts 1010 and 1020.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

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