



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEV DUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

MEMORANDUM

DATE: April 1, 2025

TO: Interested Parties

FROM: Shanah Black, Rule Review Manager *SFB*

RE: Proposed Readoption/Amendment/Repeal of Radiation Protection Commission Rules
10A NCAC 15 .0501, .0608-.0609, .0802-.0803, .0901-.0910, .1001, .1601, .1901-.1911,
.2001-.2011

GS 150B-21.2 requires a rule-making body to notify certain individuals of its intent to adopt a rule. It also requires notification of the date, time and location of the public hearing on the rule and any fiscal analysis that has been prepared in connection with the proposed rule. There are 39 rules in this rulemaking action. With input from advisory committees, working groups of the N.C. Radiation Protection Commission and stake holders, substantive changes are proposed for 10 rules for readoption with substantive changes, 5 rules for amendment, 2 rules for repeal through readoption, and 22 rules are proposed for adoption.

These rules are necessary to regulate the therapeutic use of accelerators (radiation generating devices) used to treat cancer and disease in people and in animals. Currently, the State regulates accelerators by blending outdated accelerator rules with the practice of applying and interpreting the Federal regulations used to regulate teletherapy machines using radioactive materials found in 10 CFR Part 35.600 for this purpose. The existing accelerator rules, 10A NCAC 15 .0608, .0609, and Section .0900 are inadequate and have not been updated since 1994. A couple have not been updated since 1980 when the rules were first enacted. Many changes in technology and therapy techniques have been developed over the last thirty-plus years. Using outdated accelerator rules to regulate the use of modern accelerators and applying rules developed for regulating the use of radioactive materials in an entirely different type of device is inefficient, confusing, and contrary to NC General Statute 150B-18: the agency is using a policy, interpreting rules from one technology to apply to a different technology, in lieu of rules for the technology being regulated.

The North Carolina Radiation Protection Commission has submitted form 0300 to the Codifier of Rules, Office of Administrative Hearings, indicating its intent to proceed with the following rule-making actions:

10A NCAC 15 Radiation Protection

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

OFFICE OF THE DIRECTOR

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

10A NCAC 15 .0501	Industrial Radiographic Operations Of Electronic Radiation Machines For Non-Human Use (Amend)
10A NCAC 15 .0608	Therapeutic X-Ray Installations: Less Than One Mev (Repeal Through Readopt)
10A NCAC 15 .0609	X-Ray And Electron Therapy Installations One Mev and Above (Repeal Through Readopt)
10A NCAC 15 .0802	Definitions (Amend)
10A NCAC 15 .0803	Personnel Requirements (Amend)
10A NCAC 15 .0901	Purpose and Scope (Readopt)
10A NCAC 15 .0902	Licensing Requirements (Readopt)
10A NCAC 15 .0903	Requirements For Issuance Of A License For Accelerators (Readopt)
10A NCAC 15 .0904	Limitations (Readopt)
10A NCAC 15 .0905	Shielding and Safety Design (Readopt)
10A NCAC 15 .0906	Controls and Interlock System (Readopt)
10A NCAC 15 .0907	Warning Devices (Readopt)
10A NCAC 15 .0908	Operating Procedures (Readopt)
10A NCAC 15 .0909	Radiation Monitoring Requirements (Readopt)
10A NCAC 15 .0910	Ventilation Systems (Readopt)
10A NCAC 15 .1001	Notices, Instructions, and Reports To Employees (Amend)
10A NCAC 15 .1601	Standards For Protection Against Radiation (Amend)
10A NCAC 15 .1901	Purpose and Scope (Adopt)
10A NCAC 15 .1902	Definitions (Adopt)
10A NCAC 15 .1903	General Administrative Requirements For Facilities Using Therapeutic Radiation Machines (Adopt)
10A NCAC 15.1904	General Technical Requirements For Facilities Using Therapeutic Radiation Machines (Adopt)
10A NCAC 15.1905	Quality Management Program (Adopt)
10A NCAC 15.1906	Therapeutic Radiation Machines of Less Than 500 KV (Adopt)
10A NCAC 15.1907	Therapeutic Radiation Machines OF 500 Kev and Above (Adopt)
10A NCAC 15.1908	Calibration of Survey Instruments and Dosimetry Systems (Adopt)
10A NCAC 15.1909	Shielding and Safety Design Requirements (Adopt)
10A NCAC 15.1910	Other Use of Electronically-Produced Radiation To Deliver Therapeutic Radiation Dosage (Adopt)
10A NCAC 15.1911	Emerging Technologies (Adopt)
10A NCAC 15.2001	Purpose and Scope (Adopt)
10A NCAC 15.2002	Definitions (Adopt)
10A NCAC 15.2003	General Administrative Requirements For Veterinary Facilities Using Therapeutic Radiation Machines (Adopt)
10A NCAC 15.2004	General Technical Requirements For Facilities Using Veterinary Therapeutic Radiation Machines (Adopt)
10A NCAC 15.2005	Quality Management Program (Adopt)
10A NCAC 15.2006	Veterinary Therapeutic Radiation Machines of Less Than 500 KV (Adopt)
10A NCAC 15.2007	Veterinary Therapeutic Radiation Machines of 500 Kev and Above (Adopt)
10A NCAC 15.2008	Calibration of Survey Instruments and Dosimetry Systems (Adopt)
10A NCAC 15.2009	Shielding and Safety Design Requirements (Adopt)
10A NCAC 15.2010	Other Use Of Electronically-Produced Radiation To Deliver Therapeutic Radiation Dosage (Adopt)

Approval of the fiscal analysis for these rules was obtained from the Office of State Budget and Management on February 27, 2025, in accordance with G.S. 150B-21.4.

The proposed rule text is attached to this memo. The rules were published in today's April 1, 2025 edition of the N.C. Register which can be found at the Office of Administrative Hearings web site at <https://www.oah.nc.gov/rules-division/north-carolina-register>.

A public hearing is scheduled for May 1, 2025, at 10:00 a.m. in Room 026, Edgerton Building, 809 Ruggles Drive, Raleigh, NC 27603. The building is in Dorothea Dix Park. Ms. Shanah Black, DHSR Rule-Review Manager, is accepting public comments on these rules and fiscal analysis from April 1, 2025 through June 2, 2025, close of business. Comments will also be accepted in person at the public hearing. The proposed effective date of these rules is October 1, 2025.

A copy of the proposed rules, fiscal analysis, and instructions for submitting comment can be found at the Division of Health Service Regulation web site at <https://info.ncdhhs.gov/dhsr/ruleactions.html>.

Please feel free to contact the Radiation Protection Section at (919) 814-2250, should you have questions related to this memorandum or the proposed rule text and fiscal note.

Enclosures

cc: Mark Payne, Director, Health Service Regulation
Emery Milliken, Deputy Director, DHSR
Raj Premakumar, Assistant General Counsel, DHHS
James Albright, Radiation Protection Section
Louis Brayboy, Section Chief, Radiation Protection Section
Dr. Carmine Plott, PhD, CHP, Chair, N.C. Radiation Protection Commission