

**Fiscal Impact Analysis of
Permanent Rule Amendment, Repeal, and Repeal Through
Readoption without Substantial Economic Impact**

Agency: Department of Health and Human Services
Division of Health Service Regulation
Radiation Protection Section

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Impact Summary

Federal Government: No Impact
State Government: No Impact
Local Government: No Impact
Regulated Community: Minimal
Substantial Impact: No

Rule Citation(s)

Rule Amendment: 10A NCAC 15 .0501 Industrial Radiographic Operations of Electronic
Radiation Machines for Non-Human Use

Rules for Repeal: 10A NCAC 15 .0502 .0506, .0509, .0510, .0511, .0512, .0513, .0514, .0515,
.0516, .0517, .0519, .0520, .0522, .0523, .0525

Rule Repeal Through
Readoption: 10A NCAC 15 .0503, .0504, .0505, .0507, .0508, .0521, .0524

*See text in Appendix

Rulemaking Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b); 104E-12(a)(1); 104E-12(a)(2);
10 CFR 34

Background

The rules in 10A NCAC 15 regulate the use of radioactive materials and radiation machines in the State of North Carolina pursuant to G.S. 104E. Rules in Section .0500 of Chapter 15 regulate industrial radiographic activities.

Pursuant to G.S. 150B-21.3A, Periodic Review and Expiration of Existing Rules, all rules are reviewed at least every 10 years, or they shall expire. As a result of the periodic review of the rules in Chapter 10A NCAC 15, Radiation Protection, seven rules, Rules 10A NCAC 15 .0503 - .0505, .0507 - .0508, .0521, and .052. were determined to be “Necessary with Substantive Public Interest” and will be repealed

through readoption with this rulemaking action. Seventeen rules, Rules 10A NCAC 15 .0501- .0502, .0506, .0509 - .0520, .0522 - .0523, and .0525 .1003, .1005 and .1006 were determined to be “Necessary Without Substantive Public Interest” and will be repealed with this rulemaking action. One rule, Rule 10A NCAC 15 .0501 was determined to be “Necessary Without Substantive Public Interest” and will be amended with this rulemaking action.

As mandated by G.S. 150B-19. (4) the agency may not adopt a rule that repeats the content of a law, a rule, or a federal regulation. Prior to this rule making effort, Rules 10A NCAC 15 .0501 - .0517 and .0519 - .0525 found in Section .0500 repeated the federal regulations found in 10 CFR 34. To comply with this mandate, the federal regulations in 10 CFR 34 will be adopted by reference, including subsequent amendments and editions to make compliance easier for the regulated community. This will result in a single rule for all registrants conducting industrial radiographic operations using radiation machines for non-human use.

Rule 10A NCAC 15 .0501 is proposed for amendment to incorporate by reference the federal Code of Federal Regulations (CFR) for industrial radiography found in 10 CFR 34. The amendment will bring that Rule into compatibility with the federal regulations found in 10 CFR 34 for persons conduction industrial radiographic operations using radiation machines for non-human use.

Rule Changes and Anticipated Fiscal Impact

10A NCAC 15 .0501 Industrial Radiographic Operations of Electronic Radiation Machines for Non-Human Use

The Radiation Protection Commission is proposing to amend this rule. The amended rule removes the scope and applicability statements from the existing rule and is reorganized into Paragraphs with subdivisions where appropriate to improve readability.

- Paragraph (a) incorporates the regulations in 10 CFR 19 by reference, including subsequent amendments and editions, except those references to and requirements for activities conducted under 10 CFR 34.
- Subparagraph (a)(2) provides substitute definitions for terms used in 10 CFR 34 so the regulations are easier to understand and more meaningful to persons registered with the agency pursuant to the Rules in Section .0200 of Chapter 15.
- Subparagraph (a)(3) clarifies the term “radioactive material” used in 10 CFR 34.25 to mean the same as “radiation machine” in G.S. 104E-5(13).
- Subparagraph (a)(5) clarifies the term “radioactive source” used in 10 CFR 34.25 to mean the same as “radiation machine” in G.S. 104E-5(13).
- Subparagraphs (a)(10) and (a)(11) clarify that workers should send requests for inspections of registered and licensed activities to the agency and not the USNRC.
- Subparagraph (a)(14) is administrative in nature and specifies the minimum information the agency requires to issue an exemption from the regulations in 10 CFR 19 and directs those requests to the agency and not the USNRC.

- Paragraph (b) provides a web address where copies of 10 CFR 34 may be obtained.

The regulations in 10 CFR 34 that are being incorporated by reference apply to the same regulated parties and are identical to the requirements being struck from the Rule 10A NCAC 15 .0501, and all the requirements in the rest of the rules in Section .0500 of Chapter 15. Accordingly, there will be no change to the requirements the regulated community must meet because of this proposed rule change.

None of the proposed changes to Rule 10A NCAC 15 .0501 impose burdens on the regulated community that are not already required by the collection of rules in Section .0500 of Chapter 15, or require any changes to the operations of federal, state, or local government. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community during the registration process as well as less time spent by regulatory staff providing technical assistance or on enforcement actions because a registrant failed to apply the correct rules while conducting industrial radiographic operations using radiation machines for non-human use, resulting in a violation issued by the agency. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

Summary

The proposed rule changes are largely for the purpose of updating the rules to comply with current federal regulations for persons conducting industrial radiographic operations using radiation machines for non-human use. None of the proposed changes will result in additional burdens to the regulated community, nor will they result in changes to operations for local, state, or federal government. The improved clarity of the rules could result in time savings related to the application process for the regulated community and state regulators; however, these time savings are expected to be very minimal.

Appendix

10A NCAC 15 .0501 is proposed for amendment as follows:

SECTION .0500 - ~~SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY OPERATIONS~~ X-RAY MACHINES

Codifier's Note: 10 NCAC 03G .2600 was transferred to 15A NCAC 11 .0500 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0501 ~~PURPOSE AND SCOPE~~ INDUSTRIAL RADIOGRAPHIC OPERATIONS OF ELECTRONIC RADIATION MACHINES FOR NON-HUMAN USE

~~(a) The rules in this Section establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this Section are in addition to and not in substitution for the other requirements of this Chapter.~~

~~(b) The rules in this Section apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however that nothing in this Section shall apply to the use of sources of radiation in the healing arts.~~

(a) Persons conducting industrial radiographic operations using radiation machines shall comply with the following provisions of 10 CFR 34, which are hereby incorporated by reference including subsequent amendments and editions, except references to and the requirements of 10 CFR 30, 37, 71, 150 and 171 contained therein shall not apply:

(1) 10 CFR 34.1, "Purpose and Scope;"

(2) 10 CFR 34.3, "Definitions;" except that the definition of becquerel, control (drive) cable, control drive mechanism, control tube, exposure head, field station, guide tube (projection sheath), S-tube, source assembly, source changer, and storage container, shall not apply. Prior to using industrial radiography all persons shall be registered in accordance with Rules in Section .0200 of this Chapter. The following terms apply:

(A) "agreement state" shall have the same meaning as "agency" as defined in G.S 104E-5(2);

(B) "license" shall have the same meaning as "registration" as defined in Rule .0104(131) of this Chapter;

(C) "licensed" shall have the same meaning as "registered" pursuant to the Rules in Section .0200 of this Chapter;

(D) "licensee" shall have the same meaning as "registrant" as defined in Rule.0104(130) of this Chapter;

(E) "radiation source" shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

(F) "radiographic exposure device" shall have the same meaning as "radiation machine" in G.S 104E-5(13); and

(G) "sealed source" shall have the same meaning as "radiation machine" in G.S 104E-5(13).

- (3) 10 CFR 34.25, "Radiation survey instruments." The term "radioactive material" used in 10 CFR 34.25 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);
- (4) 10 CFR 34.31(a), (b)(1), and (c), "Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments;"
- (5) 10 CFR 34.33, "Permanent radiographic installations." The term "radioactive source" used in 10 CFR 34.33 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);
- (6) 10 CFR 34.35(c), "Labeling, storage, and transportation;"
- (7) 10 CFR 34.41, "Conducting industrial radiographic operations;"
- (8) 10 CFR 34.42, "Radiation Safety Officer for industrial radiograph;"
- (9) 10 CFR 34.43, "Training;"
- (10) 10 CFR 34.45(a)(1) through (a)(3), (a)(5), (a)(7) through (a)(11), (a)(13), and (b), "Operating and emergency procedure;"
- (11) 10 CFR 34.46, "Supervision of radiographers' assistants;"
- (12) 10 CFR 34.47, "Personnel monitoring;"
- (13) 10 CFR 34.49, "Radiation surveys;"
- (14) 10 CFR 34.51, "Surveillance;"
- (15) 10 CFR 34.53, "Posting;"
- (16) 10 CFR 34.61, "Records of the specific license for industrial radiography;"
- (17) 10 CFR 34.65, "Records of radiation survey instrument;"
- (18) 10 CFR 34.71, "Utilization logs;"
- (19) 10 CFR 34.73, "Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments;"
- (20) 10 CFR 34.75, "Record of alarm system and entrance control checks at permanent radiographic installations;"
- (21) 10 CFR 34.79, "Records of training and certification;"
- (22) 10 CFR 34.81, "Copies of operating and emergency procedures;"
- (23) 10 CFR 34.83, "Records of personnel monitoring procedures;"
- (24) 10 CFR 34.85, "Records of radiation surveys;"
- (25) 10 CFR 34.87, "Form of records;"
- (26) 10 CFR 34.89(a), (b)(1 through 10), "Location of documents and records;" and
- (27) Appendix A to 10 CFR 34-Radiographer Certification.

(b) Copies of these regulations are available free of charge at <https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/index.html>.

History Note: Authority G.S. 104E-7;

Eff. February 1, 1980;

Amended Eff. May 1, 1993;

Transferred and Recodified from 15A NCAC 11 .0501 Eff. February 1, 2015;

*Pursuant to G.S.150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~
2019;*
Amended Eff. May 1, 2024.

10A NCAC 15 .0502 is proposed for repeal as follows:

10A NCAC 15 .0502 DEFINITIONS

History Note: Authority G.S. 104E-7; 10 CFR 34.3;
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989;
*Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule
becomes effective, whichever is sooner;*
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0502 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~
2019;*
Repealed Eff. May 1, 2024.

10A NCAC 15 .0503 - .0505 are proposed for repeal through readoption as follows:

10A NCAC 15 .0503 EQUIPMENT RADIATION LEVEL LIMITS
10A NCAC 15 .0504 RADIOGRAPHIC EXPOSURE DEVICES AND STORAGE CONTAINERS
10A NCAC 15 .0505 STORAGE, LABELS AND TRANSPORTATION PRECAUTIONS

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Amended Eff. May 1, 1992;
*Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the
permanent rule becomes effective, whichever is sooner;*
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0503 - .0505 Eff. February 1, ~~2015~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0506 is proposed for repeal as follows:

10A NCAC 15 .0506 SURVEY INSTRUMENTS

History Note: Authority G.S. 104E-7; 104E-12(a)(1);
 Eff. February 1, 1980;
 Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
 Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994;
 Transferred and Recodified from 15A NCAC 11 .0506 Eff. February 1, 2015;
 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~
2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0507 - .0508 are proposed for repeal through readoption as follows:

10A NCAC 15 .0507 LEAK TESTING AND REPLACEMENT OF SEALED SOURCES
10A NCAC 15 .0508 QUARTERLY INVENTORY

History Note: Authority G.S. 104E-7; 104E-12(a)(1);
 Eff. February 1, 1980;
 Amended Eff. June 1, 1993;
 Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
 Amended Eff. April 1, 1999; May 1, 1995;
 Transferred and Recodified from 15A NCAC 11 .0507 - .0508 Eff. February 1, ~~2015~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0509 - .0517 are proposed for repeal as follows:

10A NCAC 15 .0509 UTILIZATION LOGS
10A NCAC 15 .0510 LIMITATIONS
10A NCAC 15 .0511 INSPECTION AND MAINTENANCE
10A NCAC 15 .0512 PERSONNEL MONITORING
10A NCAC 15 .0513 OPERATING AND EMERGENCY PROCEDURES
10A NCAC 15 .0514 SECURITY
10A NCAC 15 .0515 RADIATION SURVEYS AND SURVEY RECORDS
10A NCAC 15 .0516 POSTING
10A NCAC 15 .0517 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS

History Note: Authority G.S. 104E-7;104E 12(a)(1); 104E-12(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540; 10 C.F.R. 34.43; 10 C.F.R. Appendix A; Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1993; June 1, 1989; October 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. January 1, 2005; April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0509 - .0517 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0519 is proposed for repeal as follows:

10A NCAC 15 .0519 SUBJECTS TO BE COVERED DURING INSTRUCTION OF RADIOGRAPHERS

History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0519 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0520 is proposed for repeal as follows:

10A NCAC 15 .0520 PERMANENT RADIOGRAPHIC INSTALLATIONS

History Note: Authority G.S. 104E-7; 104E-12(a)(1);
Eff. October 1, 1980;
Amended Eff. January 1, 1994;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0520 Eff. February 1, 2015;

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~
2019;*
Repealed Eff. May 1, 2024.

10A NCAC 15 .0521 is proposed for repeal through readoption as follows:

10A NCAC 15 .0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT

History Note: Authority G.S. 104E-7;
*Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule
becomes effective, whichever is sooner;*
Eff. May 1, 1995;
Amended Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0521 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0522 - .0523 are proposed for repeal through readoption as follows:

10A NCAC 15 .0522 REPORTING REQUIREMENTS
10A NCAC 15 .0523 RECORDS OF INDUSTRIAL RADIOGRAPHY

History Note: Authority G.S. 104E-7;
*Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule
becomes effective, whichever is sooner;*
Eff. May 1, 1995;
Amended Eff. January 1, 2005; April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0522 - .0523 Eff. February 1, 2015;
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~
2019;*
Repealed Eff. May 1, 2024.

10A NCAC 15 .0524 is proposed for repeal through readoption as follows:

10A NCAC 15 .0524 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY

*History Note: Authority G.S. 104E-7; 104E-10(b);
Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0524 Eff. February 1, ~~2015~~; 2015;
Repealed Eff. May 1, 2024.*

10A NCAC 15 .0525 is proposed for repeal as follows:

10A NCAC 15 .0525 RADIOGRAPHER CERTIFICATION

*History Note: Authority G.S. 104E-7; 104E-10(b); 10 C.F.R. 34.43; 10 C.F.R. 34, Appendix A;
Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0525 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019~~;
2019;
Repealed Eff. May 1, 2024.*