

ENVIRONMENTAL PROTECTION

AIR QUALITY, ENERGY, AND SUSTAINABILITY

DIVISION OF CLIMATE, CLEAN ENERGY and RADIATION PROTECTION

COMMISSION ON RADIATION PROTECTION

Radiation Protection Programs

Proposed Amendments: N.J.A.C. 7:28-1.6, 19.1 through 19.10, 19.14, 24.11, 61.1, 64.2, and 64.10

Proposed Repeal and New Rule: N.J.A.C. 7:28-19.16

Proposed Recodification with Amendments: N.J.A.C. 7:28-19.17 as 19.18

Proposed Recodification: N.J.A.C. 7:28-19.18 as 19.19

Proposed New Rule: N.J.A.C. 7:28-19.17

Authorized By: Catherine McCabe, Commissioner, Department of Environmental Protection, and the Commission on Radiation Protection, Julie K. Timins, Chair.

Authority: N.J.S.A. 13:1B-1 et seq., 13:1D-1 et seq., 26:2D-1 et seq., and 26:2D-25 et seq.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

DEP Docket Number:

Proposal Number:

Submit comments by [60 days after publication], electronically at <http://www.nj.gov/dep/rules/comments>. Each comment should be identified by the applicable N.J.A.C. citation, with the commenter's name and affiliation following the comment.

The Department of Environmental Protection (Department) encourages electronic submittal of comments. In the alternative, comments may be submitted on paper to:

Alice A. Previte, Esq.
Attention: DEP Docket Number
Office of Legal Affairs
Department of Environmental Protection
401 East State Street, 7th Floor
Mail Code 401-04L
P.O. Box 402
Trenton, New Jersey 08625-0402

The rule proposal may be viewed or downloaded from the Department's website at <http://www.nj.gov/dep/rules>.

The agency proposal follows:

Summary

As the Commission on Radiation Protection (Commission) and the Department have provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

The Radiation Protection Act, N.J.S.A. 26:2D-1 et seq., and the Radiologic Technologist Act, N.J.S.A. 26:2D-24 et seq., govern the possession, handling, and use of sources of radiation

within the State of New Jersey. The Radiation Protection Act established the Commission and vested in that body the power to promulgate rules and regulations as may be necessary to prohibit and prevent unnecessary radiation. The Radiation Protection Act authorizes the Department to establish and charge fees, through the promulgation of rules, for any of the services it performs under the Radiation Protection Act. Therefore, both the Commission and the Department propose the within amendments, repeal, and new rules.

Through the Radiation Protection Act, the Radiologic Technologist Act, and the Radiation Protection Programs rules, N.J.A.C. 7:28, New Jersey has a comprehensive radiation protection program encompassing x-ray machines, naturally occurring or accelerator produced radioactive materials (known as NARM), radon, clean-up of radioactively contaminated sites, monitoring around nuclear power plants, emergency preparedness and response to radiological incidents including transportation accidents, and requirements for non-ionizing sources of radiation. The State also regulates facilities through participation in the Agreement State program. As an Agreement State, New Jersey has assumed responsibility for regulation of radioactive materials that are governed under the Atomic Energy Act (AEA) through an agreement with the Nuclear Regulatory Commission (NRC). (See 42 U.S.C. § 2021.) Additionally, the Department's rules contain requirements for licensure and certification of people – radiologic technologists, nuclear medicine technologists, radon testers and mitigators, and qualified medical physicists.

The Department and the Commission propose three general categories of amendments. The first category implements recent amendments to the Radiologic Technologist Act, N.J.S.A. 26:2D-24 et seq. (the Act), which created the new license category of radiologist assistant for licensed diagnostic radiologic technologists. The proposed amendments to N.J.A.C. 7:28-19 and

new rule establish the educational and licensing requirements and the scope of practice for this new license category and establish a fee schedule for initial and renewal licensing. The proposed rules also establish the recognition requirements for radiologist assistant schools and revisions or elimination of a few existing regulations that require change or are obsolete. The second category is to propose an amended fee schedule for nuclear medicine technologists and fusion imaging computed tomography technologists at N.J.A.C. 7:28-24.11(a) and (b). The third category of amendments relates to the NRC's requirements for Agreement States. The Department and the Commission propose to amend the provisions incorporating 10 CFR 35, Medical Use of Byproduct Material, and 10 CFR Part 71, Packaging and Transportation of Radioactive Materials; and provide general provisions that are applicable to all incorporations of the Federal regulations into the chapter by reference, and that otherwise make the State's rules consistent with the Agreement State rules. The Department and the Commission also propose clarifications and corrections to the fee schedule, cross-references, terminology, and the previous incorporations of Federal regulations by reference.

Agreement State

New Jersey has assumed responsibility for regulation of radioactive materials that are governed under the Atomic Energy Act of 1954, 42 U.S.C. §§ 2011 et seq. (AEA), through an agreement with the Nuclear Regulatory Commission (NRC). This is known as becoming an Agreement State. The AEA requires that an Agreement State's regulations be compatible with the NRC's regulations, and that the state's regulations be adequate to protect the public health and safety, with respect to such materials. (See 42 U.S.C. § 2021(d).) In order that New Jersey's rules are "adequate and compatible" with the Federal regulations, the Department's rules incorporate by reference substantial portions of the Federal regulations.

Incorporation of the CFR by Reference

The Department and the Commission propose amendments to the general provisions at N.J.A.C. 7:28-1.6 to address two comments from the NRC, which were not provided to the Department until after adoption of the amended rule in 2016. (See 48 N.J.R. 409(b), March 7, 2016.) The NRC commented that existing N.J.A.C. 7:28-1.6(f) may cause confusion and be misinterpreted because it places on the licensee the burden of determining which set of requirements prevail. To address this comment, the Department and the Commission propose to identify the provisions of N.J.A.C. 7:28 that are substantially different from the NRC's rules. Therefore proposed amended N.J.A.C. 7:28-1.6(f) specifies that N.J.A.C. 7:28-12 substitutes for 10 CFR Part 20 Subpart E in its entirety. It also states that N.J.A.C. 7:28 also does not incorporate by reference provisions of the NRC rules that allow determination of dosage of unsealed byproduct material for medical use by methods that do not include direct measurements because N.J.A.C. 7:28-55.1(b)5 and 6 differ from the requirements of the NRC rules at 10 CFR 35.63(b)(2)(i) through (iii) and 10 CFR 35.63(c)(3)(i) and (ii), and are proposed to be identified in the amended rule. Existing N.J.A.C. 7:28-6.1(c)6 through 11, and (d)19 already identify the differences between 10 CFR Part 20 Subpart E and the Department's requirements. Existing N.J.A.C. 7:28-55.1(b) and (c) already identify the differences between 10 CFR Part 35 and the Department requirements.

The NRC recently amended 10 CFR Part 35, Medical use of byproduct material. The NRC published its revised regulations on July 16, 2018 (83 FR 33046). All of the NRC's amendments are incorporated by reference into N.J.A.C. 7:28 by operation of the incorporation provisions of existing N.J.A.C. 7:28-55.1. However, the Department and Commission propose new N.J.A.C.

7:28-1.6(h)5 to exclude from incorporation any reference to a master material license or permit issued by a master material licensee. A master material license is a multi-site, multi-regional material (byproduct, source, and/or special nuclear material) license issued to a Federal organization that authorizes the licensee to undertake a limited number of regulatory activities as specified in a joint Letter of Understanding with the NRC. The NRC has exclusive jurisdiction over Federal entities that possess and use radioactive materials, such as Veterans Administration hospitals and military bases.

Replacement terms for terms in CFR provisions incorporated by reference

Rather than identify in each subchapter a list of substituted terms or citations, the existing rules contains a table of the most common substitutions necessary when the Federal regulations are incorporated into N.J.A.C. 7:28. Each time an identified term appears in the Federal regulations, the incorporation by reference includes the corresponding substitution. For example, whenever the NRC regulations use “part 20 of this chapter,” the incorporation by reference substitutes “N.J.A.C. 7:28-6,” which is the subchapter that incorporates 10 CFR Part 20 by reference.

The existing Table 1 to N.J.A.C. 7:28-1.6 does not identify each of the subchapters related to the Agreement State program. The Department and the Commission propose to amend the table to identify the relevant CFR part and the replacement reference in the Department’s rules. The existing table does not identify all of the replacements, although to a large extent these substitutions are already included in the existing rules. For example, N.J.A.C. 7:28-51.1(c)8 replaces parts 30 and 32 with N.J.A.C. 7:28-51 and 53, but only in the incorporated 10 CFR 321(c)(8)(i). Because the existing rules, such as N.J.A.C. 7:28-51.1(c)8, are

so specific with their replacement, they may not necessarily capture all of the replacements as the NRC amends its rules. The proposed amended table provides a more complete replacement, reducing the likelihood that the Department and the Commission will need to amend the rules each time the NRC amends its rules.

Packaging and Transportation of Radioactive Materials

After the NRC reviewed the 2016 amendments to N.J.A.C. 7:28-61, Packaging and Transportation of Radioactive Materials, which incorporated by reference 10 CFR Part 71, the NRC distributed a clarification letter (STC-17-060) to Agreement States. Other Agreement States were in the process of submitting their proposed regulations to incorporate NRC amendments to 10 CFR Part 71 for an NRC compatibility review and were asking the NRC's Office of Nuclear Material Safety and Safeguards staff about the Agreement States' authority and responsibilities under 10 CFR 71.17 and 71.101(c) for approving general licensees' quality assurance programs. The essential requirement of 10 CFR 71.101(c)(1) is that each licensee who uses a Type B package shall, prior to the use of any package for the shipment of any material subject to the regulation, obtain approval of its quality assurance program by the regulatory agency. Although the approval requirement may previously have been contained in the individual state's department of transportation regulations, the agency that administers the state's Agreement State program may not have been aware of the requirement.

Also, the NRC changed the classification of the approval requirement in 10 CFR 71.101(c)(1) from a compatibility category D or C designation to a C designation. Provisions that the NRC identifies as compatibility categories A, B, or C must be incorporated by Agreement States in order that the state's rules are compatible with the Federal regulations.

Provisions that the NRC identifies as compatibility category D do not need to be adopted by Agreement States for compatibility, although New Jersey does incorporate some such sections by reference. Previously, an Agreement State was required to adopt compatible regulations only if it had users of Type B packages other than industrial radiography. However, as the NRC explained in its Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Transportation Requirements, 80 FR 33988, 34009, “If a [s]tate does not have a user of a Type B package, the [s]tate is able to seek an exemption from the requirement to make their requirement compatible.” The letter also clarified that NRC compatibility reviews of the Agreement States’ equivalent regulations incorporating these NRC rules may not have identified these issues, which was the case with the NRC review of the New Jersey regulations. While there currently are no Type B package users in New Jersey, the Department will not seek an exemption from the NRC, but is choosing to incorporate the appropriate regulations in case New Jersey receives an application for a Type B package user in the future.

When it incorporated 10 CFR Part 71 (80 FR 33987 and 80 FR 48683) by reference into N.J.A.C. 7:28-61.1, the Department inadvertently omitted 10 CFR 71.70, 71.85(a) through (c) and 71.91(b) from the list of sections that are not incorporated by reference. In addition, the Department included 10 CFR 71.17 in its entirety as a section where NRC would not be replaced by the Department. The proposed amendment correctly lists only 10 CFR 71.17(e) where NRC is not replaced by the Department. This means that the Department will issue a general license to a Type B container user in the state, with the exception of industrial radiographers. In addition, the Department did not delete the words “certificate holder, and applicant for a Certificate of Compliance,” as only the NRC can issue Certificates of Compliance for Type B

containers. The proposed amendments delete these words from 71.101 (a) and (b), 71.103(a), and 71.135.

Radioactive Materials License Fees

Existing N.J.A.C. 7:28-64 establishes fees for radioactive materials licenses. The Department proposes to amend Table 1 of N.J.A.C. 7:28-64.2, Schedule of fees, to make it clear that when a reciprocity fee is calculated by taking 50 percent of the annual license fee, that it is rounded either up or down to the nearest multiple of \$5.00 using standard rounding techniques. For example, at existing N.J.A.C. 64.2 Table 1: 3.O. Licenses for possession and use of byproduct material for industrial radiography operations, the annual fee is \$11,085. A reciprocity license would be $\$11,085/2$ which is equal to \$5,542.50. Rounding to the nearest increment of \$5.00 would make the reciprocity fee equal to \$5540.

For ease of calculation and payment the Department is making a similar amendment to N.J.A.C. 7:28-64.10(a), which provides for an annual adjustment of fees in Tables 1 and 2 in N.J.A.C. 7:28-64.2. The existing rule does not specify that the adjusted fee is rounded when it is adjusted by the inflation factor. The fees in the tables are of a magnitude that rounding up or down to an increment of \$5.00 is a relatively small percent difference from what would otherwise result from application of the inflation factor.

Existing N.J.A.C. 7:28-58, Domestic Licensing of Source Material, incorporates by reference 10 CFR Part 40, Domestic Licensing of Source Material. The incorporated rules include the definition of unimportant quantities of source material, 10 CFR 40.4. Prior to the NRC's amendments to its rules, these unimportant quantities were issued a general license; the NRC's amended rules require a small class of users of source material to obtain a radioactive materials license.

The existing fee provisions at N.J.A.C. 7:28-64.2, Table 1, do not expressly provide for these licensees; therefore, the existing rule categorize these users under “All other source material licenses,” with a corresponding fee of \$10,300. Proposed amended Table 1 includes “licenses that authorize possession, storage and use of reference sources containing source material for calibration, proficiency testing, quality assurance and/or in the manufacturing of exempt devices” in the existing category with “licenses that authorize only the possession, use, and/or installation of source material for shielding,” with a corresponding fee of \$600.00. This fee is more appropriate for users of these small quantities of source material.

Existing Table 2 identifies at fee category C.2. a fee for a “[r]equest to amend a license requiring review and a site visit, but not limited to, facility move or addition of a process.” The existing description states that the fee applies when the amendment requires both a review and a site visit. As amended, the fee applies when a technical review is required, whether or not a site visit is also required. The proposed amendment divides the description into two sentences, for clarity.

Full text of the proposed amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

7:28-1.6 Incorporation of the Code of Federal Regulations by reference

(a)-(e) (No change.)

(f) In the event that there are inconsistencies or duplications in the requirements of the provisions incorporated by reference from the CFR and the rules set forth in this chapter, the provisions incorporated by reference from the CFR shall prevail, except [where the rules set

forth in this chapter are more stringent] at **N.J.A.C. 7:28-12, Remediation Standards for Radioactive Materials, which replaces 10 CFR 20, Subpart E, in its entirety, and N.J.A.C. 7:28-55.1(b)5 and 6, which specifically exclude provisions of the CFR that allow determination of dosage of unsealed byproduct material for medical use by methods that do not include direct measurements.** The foregoing notwithstanding, as to subparts the NRC identifies as compatibility categories A or B, in the event of inconsistencies or duplications, the provisions of the CFR shall prevail, **except as provided in Table 1 below and the non-substantive substitutions identified in individual subchapters of this chapter.**

(g) (No change.)

(h) The following provisions of the CFR are not incorporated by reference:

1. – 4. (No change.)

5. Any reference to a master material license or a permit issued by a master material licensee.

(i) The following words and terms in the CFR shall be replaced as indicated in Table 1 below, except as otherwise indicated in this chapter:

Table 1: Replacement terms for terms in CFR provisions incorporated by reference

<u>Terms in CFR</u>	<u>Replacement Terms</u>
Of this part	Of this subchapter
To this part	To this subchapter
By this subpart	By this subchapter
Subject to this subpart	Subject to this subchapter

Under this subpart	Under this subchapter
In this subpart	In this subchapter
Agreement State or Agreement State agency	Agreement State or the NRC
Any non-Agreement State	The State of New Jersey, where the Department maintains jurisdiction
Commission	Department
NRC	
Nuclear Regulatory Commission	
U.S. NRC	
Act	Radiation Protection Act
Atomic Energy Act	
Atomic Energy Act of 1954	
Section __ of the Act	the Act
Part 19	N.J.A.C. 7:28-50
Part 20	N.J.A.C. 7:28-6
Part 30	N.J.A.C. 7:28-51
Part 31	N.J.A.C. 7:28-52
Part 32	N.J.A.C. 7:28-53

Part 33	N.J.A.C. 7:28-54
Part 34	N.J.A.C. 7:28-63
Part 35	N.J.A.C. 7:28-55
Part 36	N.J.A.C. 7:28-56
Part 37	N.J.A.C. 7:28-65
Part 39	N.J.A.C. 7:28-57
Part 40	N.J.A.C. 7:28-58
Part 61	N.J.A.C. 7:28-59
Part 70	N.J.A.C. 7:28-60
Part 71	N.J.A.C. 7:28-61
Part 150	N.J.A.C. 7:28-62
NRC Operations Center (301-816-5100)	Department of Environmental Protection’s hotline 1-877 WARNDP (1-877-927-6337)
Written interpretation by the General Counsel	Written interpretation signed and approved by the Commissioner of the Department
NRC regional office or Director of the office of Federal and State Materials and Environmental Management Programs or Director, Division of Security Policy, Office of Nuclear Security and Incident Response	Bureau of Environmental Radiation at the address specified in N.J.A.C. 7:28-1.5(b)
10 CFR 20.1401	N.J.A.C. 7:28-12

10 CFR 20.1402	
10 CFR 20.1403	
10 CFR 20.1404	
10 CFR 20.1405	

(j)-(n) (No change.)

SUBCHAPTER 61. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIALS

7:28-61.1 Incorporation by reference

(a) (No change.)

(b) The following provision of 10 CFR 71 are not incorporated by reference. If there is a cross reference to a Federal citation specifically entirely excluded from incorporation, then the cross-referenced citation is not incorporated by virtue of the cross reference.

1.-20. (No change.)

21. 10 CFR 71.70, Incorporation by reference;

Renumber 21.-25. to 22.-26.

27. 10 CFR 71.85 (a)-(c);

28. 10 CFR 71.91(b);

Renumber 26. – 36. to 29. 38.

(c) In addition to the changes outlined in N.J.A.C. 7:28-1.6, the following provisions of 10 CFR 71 are incorporated by reference with the specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 71 of the Code of Federal Regulations that are incorporated by reference, means the Department, except at:

i.-ii. (No change.)

iii. 10 CFR 71.17 **(e)**;

iv.-viii. (No change.)

2.-12. (No change.)

13. 10 CFR 71.17(c)(3), Do not replace the address as otherwise indicated in N.J.A.C. 7:28-1.6 Table 1;

14. 10 CFR 71.85 (d), replace “in paragraphs (a) through (c) of this section,” with “of paragraphs (a) through (c) of 10 CFR 71.85”;

15. 10 CFR 91(c) and (d), delete “certificate holder, and an applicant for a CoC”;
Renumber 13. to 16.

17. 10 CFR 71.101(a) delete “Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of packaging subject to this subpart.”;

18. 10 CFR 71.101(b) delete “certificate holder, and an applicant for a CoC”;
Renumber 15 – 16 to 19-20.

21. 10 CFR 71.103(a) delete “certificate holder, and applicant for a Certificate of Compliance” in both instances;

22. 10 CFR 71.135 delete “certificate holder, and applicant for a Certificate of Compliance”;

(d) – (e) (No change.)

SUBCHAPTER 64 RADIOACTIVE MATERIALS LICENSE FEES

7:28-64.2 Schedule of fees

(a) through (h) (No change.)

Table 1

Schedule of Source, Special Nuclear, and Byproduct Material Annual Fees

<u>FEE CATEGORY</u>	<u>LICENSE TYPE</u>	<u>ANNUAL FEE (\$)</u>
1. (No change.)		
2.	Source Material	
A. (No change.)		
B.	Licenses that authorize only the possession, use, and/or installation of source material for shielding, or licenses that authorize possession, storage and use of reference sources containing source material for calibration, proficiency testing, quality assurance and/or in the manufacturing of exempt devices.	600

C. (No change.)

3. through 15. (No change.)

16.	Reciprocity	50 percent of annual fee of applicable category, rounded to the nearest \$5.00.
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17. through 18. (No change.)

Table 2

Schedule of Radioactive Materials Annual Fees

<u>FEE CATEGORY</u>	<u>LICENSE TYPE</u>	<u>ANNUAL FEE (\$)</u>
1. (No change.)		
2.	Amendments	
A. through B. (No change.)		
C.		
1. (No change.)		
2.	[Request to amend a license requiring review and a site visit, but not limited to, facility move or addition of a process.] Request to amend a license requiring a technical review, whether or not a site visit is also required. This	\$410

**includes, but is not limited to, a
facility move or the addition of
a process.**

3. through 8. (No change.)

7:28-64.10 Annual adjustment of fees

(a) Each year the annual fees in Tables 1 and 2 in N.J.A.C. 7:28-64.2 will be adjusted by the previous 12-month inflation factor. The inflation factor is calculated from the Consumer Price Index, all urban consumers, U.S. city average (CPI-U), published monthly by the U.S. Department of Labor, Bureau of Labor Statistics. The CPI-U for purposes of calculating the inflation factor shall be the CPI-U for the 12-month period ending May 31. **The resulting fee will be rounded up or down to the nearest increment of \$5.00.**

(b) – (d) (No change.)