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ENVIRONMENTAL PROTECTION

AIR QUALITY, ENERGY, AND SUSTAINABILITY

DIVISION OF ENERGY, SECURITY, AND SUSTAINABILITY

COMMISSION ON RADIATION PROTECTION

Radiation Protection Programs

Adopted Amendments: N.J.A.C. 7:28-1.5, 6.1, 24, 58.1, 60.1, and 61.1

Adopted Repeals: N.J.A.C. 7:28-24.10 and 24.11

Adopted New Rules: N.J.A.C. 7:28-1.6, 24.4, 24.6, 24.8, 24.13, 24.14, 24.16, 24.17, and 65

Proposed: October 19, 2015, at 47 N.J.R. 2589(a) (see also 47 N.J.R. 2695(a)).

Adopted: February 10, 2016, by Bob Martin, Commissioner, Department of Environmental Protection, and January 20, 2016, the Commission on Radiation Protection, Julie K. Timins, Chair.

Filed: February 11, 2016, as R.2016 d.022, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 13:1B-1 et seq., 13:1D-1 et seq., 26:2D-1 et seq., and 26:2D-24 et seq.

DEP Docket Number: 09-15-09.

Effective Date: March 7, 2016.

Operative Dates: March 7, 2016, Adopted Amendments to N.J.A.C. 7:28-24, Adopted New Rules N.J.A.C. 7:28-24.4, 24.6, 24.8, 24.13, 24.14, and 24.17, and Adopted Repeals N.J.A.C. 7:28-24.10 and 24.11;
March 19, 2016, Adopted Amendments to N.J.A.C. 7:28-1.5, 6.1, 58.1, 60.1, and 61.1, and Adopted New Rules N.J.A.C. 7:28-1.6 and 65.

Expiration Date: May 9, 2020.

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 on Radiation Protection 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 are adopting amendments, repeals, and new rules at N.J.A.C. 7:28, Radiation Protection Programs.

Through the Radiation Protection Act, the Radiologic Technologist Act, and the Radiation Protection Programs rules, 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 within adopted amendments, repeals, and new rules create a new license category of fusion imaging CT technology for licensed nuclear medicine technologists, establish the educational and licensing requirements and the scope of practice for this new category, and establish a new fee schedule for examination and licensing. Adopted amendments and new rules incorporate 10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, by reference into the State's rules, amend the provisions incorporating 10 CFR Part 71, Packaging and Transportation of Radioactive Materials, and provide general provisions 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 adopted amendments and rules also contain miscellaneous corrections to cross-references, terminology, and the previous incorporations of Federal regulations by reference.

Summary of Public Comments and Agency Responses:

The Commission and the Department accepted comments on the proposal through December 28, 2015. The following individuals provided written comments during the public comment period.

1. Callie Ascione
2. Darlene Baldassarre
3. Evelyn Borny
4. Barbara Bradway
5. Michele Carty
6. Seny Choulang
7. Carol Clark
8. Jason Colloton
9. Ed Campos
10. Jacqueline Crews
11. David Crincoli
12. Jonathan Crincoli
13. Lauren DeStefano
14. Maureen Dickerson

15. Jacob Dubroff
16. Elizabeth Dull
17. Roxanne Fagan
18. Michelle Falance
19. Michael Farwell
20. Liza Felice
21. Stephanie Fiore
22. Janelle Gallagher
23. Maria Gillis
24. Alena Gonzales
25. Shane Granitski
26. Rob H
27. Kayla Hatchell
28. Pamela Henderson, US Nuclear Regulatory Commission
29. Timothy Herbert
30. Roger Jensen, Jr.
31. Randy Jones
32. Dawn Juliana
33. Jamie Kelly
34. Danielle Leshik
35. Briana Lynn
36. Laura MacAulay
37. Mandy Malone
38. Richard Mandis
39. David Mankoff, MD
40. Eleanor Mantel
41. Jocelyn Mattingly
42. Jonathan Mota
43. Ilya Nasrallah
44. Katie Neal, Nuclear Medicine Technologist Certification Board
45. Ruthann Newcomb
46. Sabrina Ortiz-Cadorna
47. Jane Oyer
48. Joan Parks
49. Erica Payne
50. Nicole Petsis
51. Michelle Powelson
52. Daniel Pryma
53. Steve Regn
54. Alexis Rodriguez
55. Ram Shastri
56. Truxell Sherry
57. Irene Sinargridis
58. Kay Sjogren
59. Aaron Scott, Society of Nuclear Medicine and Molecular Imaging - Technologist Section
60. Christina Warner

- 61. Jessica Williams
- 62. Nikole Zallie

The comments received and the Commission's and Department's responses are summarized below. The number(s) in parentheses after each comment identify the respective commenter(s) listed above.

Comments Related to Fusion Imaging CT Technology Licensing Provisions

1. COMMENT: Licensed nuclear medicine technologists who will be licensed in fusion imaging computed tomography (CT) technology are not sufficiently trained in radiologic technology to conduct the radiologic technology portion of a Positron Emission Technology/Computed Tomography (PET/CT) or Single Photon Emission Tomography/Computed Tomography (SPECT/CT) procedure. Two years of education in diagnostic radiography is needed. Nuclear medicine technologists do not receive education in cross-sectional anatomy, radiation protection, radiation biology, or CT. These individuals could put patient safety at risk. (1, 9, 11, 12, 14, 22, 25, 30, 31, 50, 60)

RESPONSE: The adopted rules establishing the license category of fusion imaging CT technologist are in response to amendments to the Radiologic Technologist Act, N.J.S.A. 26:2D-27.1, that authorize the Radiologic Technology Board of Examiners to issue additional limited licensure to an already licensed nuclear medicine technologist who has completed additional education and demonstrated competency in CT. The additional licensure provides additional privileges limited to the performance of the CT portion of a fusion imaging procedure (PET/CT

or SPECT/CT). Currently, only five CT procedures are commonly performed as part of a fusion imaging procedure.

The Department and Commission have determined that the adopted requirements will ensure patient safety and competency in CT procedures performed as part of fusion imaging procedures by licensed nuclear medicine technologists who are also licensed in fusion imaging CT technology. In order to ensure patient safety, the adopted rules require nuclear medicine technologists seeking licensure to perform fusion imaging CT technology to undergo training specifically related to the non-nuclear portion of a fusion image. Moreover, the curricula of all schools of nuclear medicine technology in New Jersey include instruction in cross-sectional anatomy, radiation protection, radiation biology, and CT imaging.

A nuclear medicine technologist seeking licensing in fusion imaging CT technology can qualify to apply for the additional license in one of three ways. Under the first method, he or she may demonstrate competency by completing the required coursework, including demonstrating clinical experience and competency in performing a minimum of 125 CT procedures, and pass the American Registry of Radiologic Technologists (ARRT) CT certification examination. These are the same requirements already completed by 1,575 New Jersey diagnostic radiologic technologists who are certified by the ARRT in CT. The second method is to complete the required coursework, including demonstrating clinical experience and competency in performing a minimum of 500 hours in CT procedures, and pass the Nuclear Medicine Technologist Certification Board's (NMCTB) CT certification examination. The third method is to complete the required coursework in the five CT content areas at N.J.A.C. 7:28-24.6(a)1, competently perform a minimum of 20 fusion imaging CT procedures as required at N.J.A.C. 7:28-24.6(a)2, and pass the State examination in fusion imaging CT technology. Both ARRT and NMTCB CT

certifications are recognized by the Federal government under the 2008 Medicare Improvement for Patients and Providers Act (MIPPA) as evidence of competency in performing CT procedures.

2. COMMENT: The proposed fusion imaging CT technology licensing requirements are appropriate and reasonable and will improve patient care and efficiency while decreasing costs, since only one licensed technologist will be required to perform the entire fusion imaging procedure. (2-8, 10, 13, 15-21, 23, 24, 26, 27, 32-40, 42-45, 47-49, 52-54, 56-59, 61, 62)

RESPONSE: The Department and Commission acknowledge the commenters' support for the adopted rules.

3. COMMENT: Existing technologists who hold licenses in both diagnostic radiologic technology and nuclear medicine technology should be grandfathered under the new license category, so that they may continue to perform the complete fusion imaging procedure. Those individuals who already hold both a nuclear medicine and diagnostic technology license should not be required to obtain another sub-specialty license. The sub-specialty license in fusion imaging CT technology is unnecessarily restrictive and a financial burden. (29)

RESPONSE: Individuals who hold licenses in both nuclear medicine technology and diagnostic radiologic technology have been able to perform a complete fusion imaging procedure, and will continue to be able to conduct the complete fusion imaging procedure under the new rules without additional training, examination, or licensing. Under the new rules, a fusion imaging

procedure may be performed by one licensed fusion imaging CT technologist, or a person licensed in nuclear medicine technology and a person licensed in radiologic technology. Under the second option, one person with both a nuclear medicine technology license and a diagnostic radiologic technology license may perform both roles. The new license category does not reduce the pool of professionals who may perform the fusion imaging procedure, but rather expands it.

4. COMMENT: The proposed rule will flood the market, affecting jobs and salary with less experienced personnel. (25, 30)

RESPONSE: The adopted rules creating the new license category of fusion imaging CT technologist will increase the number of licensed technologists who can perform the CT portion of a fusion imaging procedure; however, the licensed fusion imaging CT technologists will not be less experienced in performing fusion imaging procedures. See the Response to Comment 1 for a discussion of the education, experience, and certifications required as prerequisites to licensure. As discussed in the Economic Impact, 47 N.J.R. at 2600, there may be an impact on salaries of licensed radiologic technologists in those facilities that no longer require a radiologic technologist to perform a PET/CT or SPECT/CT, if the facilities do not have other procedures for the radiologic technologists to perform. However, to the extent that the radiologic technologist will be available to perform more radiologic procedures, a facility may be able to increase the number of such procedures it schedules, thereby eliminating any negative impact on the salaries of the radiologic technologists. As stated in the Response to Comment 8, nuclear medicine technologists licensed in fusion imaging CT cannot perform standalone CT procedures for diagnostic purposes.

5. COMMENT: The license in fusion imaging CT technology is a good idea, but why should a nuclear medicine technologist, who has completed CT training as part of his or her education and has passed the NMTCB entry level nuclear medicine examination that included questions on CT, need to pass another examination to be licensed in fusion imaging CT technology? (41)

RESPONSE: The Radiologic Technologist Act at N.J.S.A. 26:2D-31.a requires a person to pass a licensing examination in his or her specialty. The NMTCB's Components of Preparedness (www.nmtcb.org/exam/cops.php) is a detailed description of the basic tasks that are tested in the NMTCB examination. The most recent Components of Preparedness contains only limited examination content in CT, which the Department and the Commission find insufficient to ensure competency. The NMTCB also recognized that a more comprehensive examination in CT is needed and, in November 2014, started to offer an advanced skill certifying examination in CT. An individual who has passed the advanced skill certifying examination in CT is eligible to apply for licensing in fusion imaging CT technology.

6. COMMENT: The rule should allow a diagnostic radiologic technologist with proper training be licensed to perform the PET or SPECT portion of a fusion imaging procedure. (25, 46)

RESPONSE: The Radiologic Technologist Act provides that a nuclear medicine technologist with additional training may be licensed to perform the CT portion of a fusion imaging

procedure. The Act does not allow a licensed diagnostic radiologic technologist to be licensed in fusion imaging CT technology, unless he or she is also a licensed nuclear medicine technologist.

There are additional reasons to allow only a nuclear medicine technologist with the additional license in fusion imaging CT technology to perform the entire fusion procedure. The American Society of Radiologic Technologists analyzed the educational curricula of schools of diagnostic radiography and nuclear medicine. That analysis revealed that a diagnostic radiologic technologist would need to undergo much more training to competently perform the nuclear medicine tasks associated with PET or SPECT imaging than a nuclear medicine technologist would need in order to competently perform the CT portion of a fusion imaging procedure. Further, there are several radiation hazards involved in the handling and administration of radioactive materials, especially positron emitters such as F-18. Handling and administering these radioactive materials are among the routine tasks of a nuclear medicine technologist. Limiting the handling of nuclear materials to the licensed nuclear medicine technologist reduces the risk of radiation contamination and lessens the risk of unnecessary radiation exposure to technologists, patients, and the public. There are fewer than 100 fusion imaging units in New Jersey, most of which are located in nuclear medicine departments of hospitals. It is not likely that a nuclear medicine department would employ a diagnostic radiologic technologist who holds the limited license that the commenter suggests, since the only nuclear medicine procedures that the person could perform would be the PET or SPECT portion of a fusion imaging procedure.

7. COMMENT: The proposed rules will allow unlicensed persons to operate x-ray equipment. (51, 55)

RESPONSE: The rules related to the new license category of fusion imaging CT technologist do not allow unlicensed people to operate x-ray equipment. In order to perform the CT portion of a fusion imaging procedure, the licensed nuclear medicine technologist must also hold a separate license in fusion imaging CT technology. The fusion imaging CT technology license does not permit a nuclear medicine technologist to perform standalone CT procedures for diagnostic purposes. CT procedures that are not part of a fusion imaging procedure must still be performed by a licensed diagnostic radiologic technologist.

Comments on Agreement State Provisions

8. COMMENT: The language in N.J.A.C. 7:28-1.5(b) requiring that “all communications regarding radioactive materials...be addressed to the New Jersey Department of Environmental Protection...” conflicts with Federal regulations that require communications be addressed to the Nuclear Regulatory Commission (NRC), such as in 10 CFR 37.27(a). Similarly, proposed N.J.A.C. 7:28-1.6(m) replaces any NRC contact information with the Department contact information in N.J.A.C. 7:28-1.5(b). In some cases, the NRC contact information must be retained, such as in 10 CFR 71.97. In contrast, proposed 10 CFR 40.22(c) and 40.55(d)(1) should contain State contact information, rather than the “Director of the Office of Nuclear Material Safety and Safeguards.” (28)

RESPONSE: N.J.A.C. 7:28-1.5 is modified on adoption to correct the conflict between the State’s rules and 10 CFR 37.27(a). The Federal regulation relates to the requirements for criminal history records checks of individuals granted unescorted access to category 1 or

category 2 quantities of radioactive material. As proposed, the rule would direct communication regarding criminal history records checks to the Department, rather than to the NRC. One purpose of the Federal regulation is to enable the NRC to transmit fingerprints of individuals who have unescorted access to category 1 or category 2 quantities of radioactive material to the Federal Bureau of Investigation. N.J.A.C. 7:28-1.5(b) as modified on adoption requires that communications under 10 CFR 37.27 continue to be directed to the NRC, rather than to the Department. New Jersey licensees that are subject to fingerprinting must also send correspondence and checks to the NRC at the NRC addresses and/or emails specified in 10 CFR 37.27(c)(1) and (2). In order to ensure that the State's rules direct correspondence to the NRC where appropriate, adopted N.J.A.C. 7:28-1.6(m) clarifies that if the incorporation by reference replaces "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission" with NRC, then the corresponding contact information is also replaced. Consequently, if "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission" are not being replaced, then the contact information, if indicated, remains the NRC contact information.

N.J.A.C. 7:28-1.6(i) Table 1 is modified on adoption to add "Director of the Office of Nuclear Material Safety and Safeguards" to the list of terms in the Federal regulations incorporated into the Department's rules by reference that are replaced with the "Bureau of Environmental Radiation at the address specified in N.J.A.C. 7:28-1.5(b)." This modification on adoption will address the commenter's concern with regard to 10 CFR 40.22(c) and 40.5(d)(1), and other regulations that refer to the Director of the Office of Nuclear Material Safety and Safeguards.

9. COMMENT: Proposed N.J.A.C. 7:28-1.6(f) states that if there are inconsistencies between the State's rules and the Federal regulations incorporated by reference, the Federal regulations will prevail unless the State's rules are more stringent. This provision could result in the State's rules regarding provisions designated compatibility category A or B being more stringent than the Federal regulations, which an Agreement State's rules may not be. (28)

RESPONSE: At present, there are no State rules regarding provisions identified as compatibility categories A or B that are more stringent than the Federal regulations. Nevertheless, as an Agreement State, New Jersey may not promulgate rules regarding compatibility categories A or B that are more stringent than the Federal regulations. Accordingly, N.J.A.C. 7:28-1.6(f) is modified on adoption to ensure that the State's rules do not violate the Agreement State requirements as to compatibility categories A or B.

10. COMMENT: Proposed N.J.A.C. 7:29-1.6(h)1 refers to a specific NRC website to determine the compatibility category of a provision of the NRC regulations. If that web address is changed, the State's rules would be incomplete. The correct reference is to the Federal Register. When the NRC promulgates an Agreement State-related regulation, it provides in the Federal Register a table showing each rule provision and the assigned compliance category. Courtesy copies of the tables are provided at the web address in the proposed rules; however, the Federal Register contains the official record. (28)

RESPONSE: N.J.A.C. 7:28-1.6(h)1 is modified on adoption to refer to the Federal Register, rather than the NRC website, in order to prevent the difficulty the commenter raises.

11. COMMENT: Proposed N.J.A.C. 7:28-60.1(a) incorporates Appendix A, 10 CFR Part 70 by reference. The Appendix is compatibility category NRC, which remains within the jurisdiction of the NRC, not the Agreement States. Similarly, proposed N.J.A.C. 7:28-61.1 incorporates 10 CFR 71.85(c) by reference. This provision is also identified as compatibility category NRC, and should not be incorporated into the State's rules. (28)

RESPONSE: As stated in the summary of proposed N.J.A.C. 7:28-1.6, if the NRC regulations identify an item as compatibility category NRC, then the section remains within the jurisdiction of the NRC, and it is not incorporated into N.J.A.C. 7:28 (47 N.J.R. at 2594). N.J.A.C. 7:28-60.1(b)38 is added and N.J.A.C. 7:28-61.1(b)1iii is deleted on adoption to exclude Appendix A of 10 CFR Part 70, and 10 CFR Part 71.85, respectively, as not incorporated by reference.

12. COMMENT: By operation of N.J.A.C. 7:28-1.6(i), the State's rules mistakenly substitute the term "Department" for "NRC" in 10 CFR 71.17, incorporated by reference at N.J.A.C. 7:28-61.1(c)1. Also, at 10 CFR 71.106, incorporated by reference at N.J.A.C. 7:27-61.1, "NRC" should be replaced with "Department." (28)

RESPONSE: As modified on adoption, N.J.A.C. 7:28-61.1(c)1iii identifies 10 CFR 71.17 as a regulation for which "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission" are not replaced with "Department." Proposed N.J.A.C. 7:28-61.1(c)1ix would have resulted in the term "Nuclear Regulatory Commission" remaining in the Federal regulation as incorporated by reference. As the commenter states, in this instance the

term in the Federal regulation should be replaced with “Department”; accordingly, the rule is modified on adoption to delete N.J.A.C. 7:28-61.1(c)lix. By operation of N.J.A.C. 7:28-1.6(i), under the adopted rule, “NRC” is replaced with “Department” at 10 CFR 71.106.

13. COMMENT: In the word and term replacements in N.J.A.C. 7:28-1.6(i) Table 1, change the definition of Agreement State in 10 CFR 37.5 so that it does not meet the compatibility category B designation assigned to it. New Jersey should include the definition of Agreement State at 10 CFR 37.5 in the list of regulations in N.J.A.C. 7:28-65.1(c)1 and 3 for which substitutions are not made. (28)

RESPONSE: Adopted N.J.A.C. 7:28-65.1 incorporates by reference the Federal regulations at 10 CFR Part 37. As proposed, the operation of adopted N.J.A.C. 7:28-1.6(i) would replace the terms “Commission,” “Nuclear Regulatory Commission,” “NRC,” and “U.S. Nuclear Regulatory Commission” with “Department,” and “Act” with “Radiation Protection Act.” The Federal regulation at 10 CFR 37.5 defines “Agreement State” as “any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b of the Act.” Replacing “U.S. Nuclear Regulatory Commission” with “Department” and “Act” (meaning the Atomic Energy Act) with “Radiation Protection Act” in the definition would not make sense. Moreover, the definition is one that the NRC has identified as compatibility category B, meaning that with regard to that item the rules of an Agreement State (such as New Jersey) should be essentially identical to those of the NRC. Therefore, N.J.A.C. 7:28-65.1(c)1 and 3 are modified on adoption to indicate the definition of

“Agreement State” as an exception to the replacements otherwise applicable under N.J.A.C. 7:28-1.6(i).

14. COMMENT: The Federal regulation at 10 CFR 37.43(d)(1) no longer contains a reference to 10 CFR 37.43(d)(9); therefore, N.J.A.C. 7:28-65.1(c)7, which deletes the phrase “Except as provided in paragraph (d)(9) from the Federal rule incorporated by reference,” is unnecessary. (28)

RESPONSE: On adoption, N.J.A.C. 7:28-65.1(c)7 is deleted and the remaining paragraphs are recodified.

15. COMMENT: The definition of “special form radioactive material” at 10 CFR 71.4 refers to past versions of 10 CFR Part 71. These references to 10 CFR Part 71 should not be replaced with N.J.A.C. 7:28-61, as they would be by operation of N.J.A.C. 7:28-1.6(i) Table 1. (28)

RESPONSE: As proposed, N.J.A.C. 7:28-61.1 incorporates by reference 10 CFR Part 71. “Special form radioactive material” is defined at 10 CFR 71.4 as a radioactive material that satisfies three identified conditions. The third condition is that the material “satisfies the requirements of § 71.75. A special form encapsulation designed in accordance with the requirements of § 71.4 in effect on June 30, 1983 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of § 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was

successfully tested before September 10, 2015 in accordance with the requirements of § 71.75(d) of this section in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition.”

By operation of N.J.A.C. 7:27-1.6(i), references in the incorporated Federal regulation to “Part 71” would be replaced with “N.J.A.C. 7:28-61.” As the commenter indicates, the substitution would render the third condition in the definition of “special form radioactive material” meaningless. On adoption, N.J.A.C. 7:28-61.1(c) is modified to add paragraph 5, which states that references to past versions of 10 CFR Part 71 in the definition of “special form radioactive material” are not replaced by “N.J.A.C. 7:28-61.”

16. COMMENT: In N.J.A.C. 7:28-65.1(c)lix, New Jersey incorporates 10 CFR 37.77 by reference while maintaining that all references to the “NRC” in 10 CFR 37.77 mean the “U.S. Nuclear Regulatory Commission.” However, the notifications required in the introductory paragraph to 10 CFR 37.77 and in 10 CFR 37.77(a)(1), (a)(3), (c)(1), (c)(2), and (d) should be provided to New Jersey, not the NRC. (28)

RESPONSE: As proposed, N.J.A.C. 7:28-65.1(c)lix would result in references to “NRC” and “U.S. Nuclear Regulatory Commission” in 10 CFR 37.77 remaining as “NRC” and “U.S. Nuclear Regulatory Commission,” rather than being replaced with “Department,” meaning that the NRC would continue to receive advance notification of shipments of category 1 quantities of radioactive material. New Jersey relied upon the guidance document from the NRC (NUREG 2155 Rev. 1 Interpretation Guidance of Part 37) to interpret 10 CFR 37.77. The guidance

document stated that both the NRC and the Agreement State should be provided advanced notification of shipment of category 1 quantities of radioactive materials. The NRC clarified in its comment on the proposal that the NRC need not be notified.

As the commenter indicates, proposed N.J.A.C. 7:28-65.1(c)1ix is incorrect. However, deleting N.J.A.C. 7:28-65.1(c)1ix and relying on the replacements required under N.J.A.C. 7:28-1.6(i) is also incorrect. Not all references in the Federal regulation to “NRC” and “U.S. Nuclear Regulatory Commission” should be replaced with “Department.” 10 CFR 37.77(a)(1) uses the terms “NRC” and “U.S. Nuclear Regulatory Commission” in the context of identifying where a licensee may obtain contact information for “the office of each appropriate governor or governor’s designee” for purposes of providing advance notice of the shipment of licensed material in a category 1 quantity through or across the boundary of a state. As modified on adoption, N.J.A.C. 7:28-65.1(c)1ix does not replace “NRC” or “U.S. Nuclear Regulatory Commission” with “Department” for purposes of obtaining governors’ office contact information. In all other provisions of 10 CFR 37.77, N.J.A.C. 7:28-1.6(i) will result in appropriate replacements.

Federal Standards Statement

Executive Order No. 27 (1994) and N.J.S.A. 52:14B-1 et seq. require State agencies that adopt, readopt, or amend State regulations that exceed any Federal standards or requirements to include in the rulemaking document a Federal standards analysis. Adopted amendments to N.J.A.C. 7:28-24 include the educational and licensing requirements and scope of practice for

the new license category in fusion imaging CT technology, which was created pursuant to State law at N.J.S.A. 26:2D-24 et seq. The Federal regulations contain no comparable licensure requirement. Although the United States Department of Health and Human Services regulations at 45 CFR Part 75 require individuals who operate ionizing radiation-producing equipment or perform nuclear medicine procedures at Federally owned or operated facilities to meet certain educational requirements, neither the adopted amendments and new rules nor any of the Department's rules governing ionizing radiation-producing equipment apply to Federal facilities.

Adopted amendments to N.J.A.C. 7:28-61, Packaging and Transportation of Radioactive Materials, are promulgated in order to comply with the Federal requirements for Agreement States. Therefore, they are consistent with and do not exceed Federal standards.

Adopted new N.J.A.C. 7:28-65, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, is promulgated in order to comply with the Federal requirements for Agreement States. The Federal regulations are incorporated into the Department's rules by reference, and are therefore consistent with and do not exceed Federal standards.

Full text of the adopted amendments and new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

7:28-1.5 Communications

(a) (No change.)

(b) *[All communications]* ***Communications*** regarding radioactive materials including byproduct, source, special nuclear materials less than a critical mass, or diffuse

naturally occurring radioactive materials ***except those communications related to 10 CFR 37.27, Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material,*** shall be addressed to the New Jersey Department of Environmental Protection, Bureau of Environmental Radiation, Mail Code 25-01, PO Box 420, Trenton, NJ 08625-0420. Telephone: (609) 984-5400, Fax: (609) 984-5595. The physical location of the office is 25 Arctic Parkway, Ewing, NJ 08638.

(c) (No change from proposal.)

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

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

(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. ***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.***

(g) (No change from proposal.)

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

1. ***[Each subpart that is designated as “NRC” in the compatibility category column of the “Regulation Toolbox: Review Summary Sheets for Regulation Adoption for New Agreement States/Programs (10 CFR_),” http://nrc-stp.ornl.gov/regsumsheets_newregs.html]***

***Each subpart that the NRC identifies as compatibility category “NRC.” The compatibility category of a subpart is published in the Federal Register when the regulation is promulgated*;**

2. through 4. (No change from proposal.)

(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>
...	
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*; or Director of the Office of Nuclear Material Safety and Safeguards*	Bureau of Environmental Radiation at the address specified in N.J.A.C. 7:28-1.5(b)
...	

(j) - (l) (No change from proposal.)

(m) *[Replace]* ***If the incorporation by reference replaces “Commission,” “NRC,” “Nuclear Regulatory Commission,” or “U.S. NRC” with “Department,” replace*** any NRC contact information with the contact information in N.J.A.C. 7:28-1.5(b).

(n) (No change from proposal.)

7:28-24.14 School of nuclear medicine technology; process for approval and termination

(a)-(d) (No change from proposal.)

(e) Schools that are approved by the Department on or before *[(one day prior to the operative date of the rules)]* ***March 6, 2016*** are deemed approved.

(f)-(g) (No change from proposal.)

7:28-24.16 Adjudicatory hearings

(a) Subject to the limitation on third-party hearing rights at (e) below, an applicant for examination, initial license, or license renewal; a licensed technologist; a school of nuclear medicine technology; or any person aggrieved by any Department or Board finding or administrative order may contest the finding or administrative order and request an adjudicatory hearing. The request shall be made in writing to the Department at the address at (d) below no later than 20 calendar days after receipt of the Department's or Board's findings or administrative order. The person or school requesting the hearing shall include the following information in each hearing request:

1.7. (No change from proposal)

8. A request, if necessary, for a barrier-free hearing location for physically disable***d*** persons.

(b)-(e) (No change from proposal.)

7:28-60.1 Incorporation by reference

(a) (No change.)

(b) The following provisions of 10 CFR Part 70 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.-35. (No change.)

36. 10 CFR 70.91, Violations; *[and]*

37. 10 CFR 70.82, Suspension and operation in war or national emergency*[*]**;

and

38. Appendix A.*

(c) - (f) (No change from proposal.)

7:28-61.1 Incorporation by reference

(a) - (b) (No change.)

(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 71.85(c), Preliminary determinations;]

iii. 10 CFR 71.17;

iv - vi. (No change.)

vii. 10 CFR 71.97(c)(1), (c)(3)(iii), and (f), Advance notification of shipment of irradiated reactor fuel and nuclear waste; ***and***

viii. 10 CFR 71.101(f), Quality assurance requirements; *[and

ix. 10 CFR 71.106;]*

2.- 4. (No change.)

***5. 10 CFR 71.4, in definition of special form radioactive material, N.J.A.C.**

7:28-1.6(i) shall not apply to replace references to past versions of Part 71 with

N.J.A.C. 7:28-61;*

Recodify existing 5. – 15. as ***6. – 16.*** (No change in text.)

(d) – (e) (No change.)

7:28-65.1 Incorporation by reference

(a) - (b) (No change from proposal.)

(c) In addition to the changes in N.J.A.C. 7:28-1.6, the following provisions of 10 CFR

Part 37 are incorporated by reference with the specified changes:

1. “Commission,” “Nuclear Regulatory Commission,” “NRC,” and “U.S. Nuclear Regulatory Commission,” as used in the following provisions of Part 37 of the Code of Federal Regulations that are incorporated by reference, mean the “U.S. Nuclear Regulatory Commission”:

i. 10 CFR 37.5 in definition*s* of ***“Agreement State” and* “fingerprint orders”**;

ii.– viii. (No change from proposal.)

ix. 10 CFR 37.77*(a)(1), **limited to the NRC website and address for obtaining contact information for the office of each appropriate governor or governor's designee***.

2. (No change from proposal.)

3. 10 CFR 37.5 Definitions, “Atomic Energy Act of 1954,” or “Act” shall mean “Atomic Energy Act of 1954” in the following instances:

i. 10 CFR 37.5 in definition of “Agreement State”;

Recodify proposed i.-iii. as ***ii.-iv.*** (No change in text from proposal.)

4.- 6. (No change from proposal.)

[7. 10 CFR 37.43(d)(1), delete “Except as provided in paragraph (d)(9)”];

Recodify proposed 8.-9. as ***7.-8.*** (No change in text from proposal.)