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ENVIRONMENTAL PROTECTION

ENVIRONMENTAL MANAGEMENT

DIVISION OF ENVIRONMENTAL SAFETY AND HEALTH

COMMISSION ON RADIATION PROTECTION

Radiation Protection Programs

Adopted Amendments: N.J.A.C. 7:28-1.5, 2.3, 2.5, 2.8, 2.13, 3.2, 3.3, 3.12, 4.1, 4.3, 4.4 through 4.7, 4.9, 4.10, 4.16 through 4.18, 4.21, 4.22, 4.24, 4.26, 4.27, 6.1, 12.12, 18.1, 19.2, 19.10, 19.13 through 19.15, 19.17, 20.1, 20.6, 20.11, 20.12, 22.2 through 22.10, 22.12, 22.13, 24.8, 41.2, 41.3, 41.4, 48.7, 50.1, 51.1, 52.1, 53.1, 54.1, 55.1, 56.1, 57.1, 58.1, 59.1, 60.1, 61.1, 62.1, 63.1, 64.2, and 64.4

Adopted Repeals: N.J.A.C. 7:28-4.8 and 22.14

Proposed: April 15, 2013, at 45 N.J.R. 806(a).

Adopted: April 8, 2014, by Bob Martin, Commissioner, Department of Environmental Protection and April 3, 2014, by the Commission on Radiation Protection, Julie K. Timins, Chair.

Filed: April 9, 2014, as R.2014 d.083, **with substantial and technical changes** not requiring additional public notice (see N.J.A.C. 1:30-6.3).

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

DEP Docket Number: 03-13-03.

Effective Date: May 5, 2014.

Expiration Date: May 9, 2020.

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

The Department of Environmental Protection (Department) and the Commission on Radiation Protection (CORP) are adopting amendments and repeals to the Radiation Protection Programs rules at N.J.A.C. 7:28.

New Jersey has a comprehensive radiation protection program encompassing x-ray machines, naturally occurring or accelerator produced radioactive material (NARM), radon, cleanup 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. Additionally, there are requirements for licensure and certification of people – radiological technologists, nuclear medicine technologists, radon testers and mitigators, and qualified medical physicists.

New Jersey became an Agreement State on September 30, 2009. As part of the Agreement State process, the State promulgated rules to regulate users of source, special nuclear, and byproduct materials, which were previously regulated by the U.S. Nuclear Regulatory Commission (NRC). (See 40 N.J.R. 2309(a), 40 N.J.R. 5196(b), and 41 N.J.R. 3415(a).) The within adopted amendments correct errors that were made in the 2008 adoption and incorporate changes that have been made to NRC rules since 2008, in order that the State's rules remain compatible with the Federal rules. The amendments also adjust fees, update contact information and cross references, and modify financial assurance requirements related to diffuse NARM licensees and remediation of radiation-contaminated sites.

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Summary of Public Comments and Agency Responses:

1. Ira Garlick, M.S., DABR, St. Barnabas Medical Center
2. Pamela J. Henderson, US Nuclear Regulatory Commission
3. Charles Mateo, Hackensack University Medical Center
4. Thomas Piccoli, Monmouth Medical Center
5. Tod Richards, Hackensack University Medical Center
6. Robert Shomo, Atlanticare Cancer Care Institute
7. Eric Weiss, M.S., DABR, Hackensack University Medical Center

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

N.J.A.C. 7:28-2.5 Protective devices, systems, or mechanisms

1. COMMENT: N.J.A.C. 7:28-2.5(c) should allow facilities 30 days to repair a device, system, or mechanism that was designed for protection against radiation, instead of prohibiting use until the equipment is repaired. (6)

RESPONSE: The purpose of the rules is to ensure that people are not exposed to unnecessary radiation. If a device that is designed to protect people from exposure to radiation is not functioning, the facility must repair the device prior to its next use; continued use of the malfunctioning unit could result in exposure to unnecessary radiation.

N.J.A.C. 7:28-22 Quality Assurance Programs for Medical Diagnostic X-ray Installations

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2. COMMENT: If the intent of the proposed rule is for the Department's inspectors to eventually perform all of the quality control (QC) tests on medical radiation-producing equipment in the State, and determine their own tests results, then the proposed rule is appropriate. However, if the amendment is proposed for any other reason, it is an unnecessary waste of time and resources and serves to undermine the qualifying certification/credentials of the medical physicist performing these tests. (5)

RESPONSE: It is not clear to which provision of the rules the commenter refers; however, quality assurance (QA) and quality control (QC) provisions are in N.J.A.C. 7:28-22. It is not the purpose of the amendments to Subchapter 22 to have the Department inspectors perform the required QC tests, nor is the Department attempting to second-guess the medical physicist's review of a facility's tests. Responsibility to perform the tests at the required frequencies remains with the facility under the amended rules. The medical physicists' responses on the annual QC surveys required at N.J.A.C. 7:28-22.8, 22.9, and 22.10 ensure that QC tests are properly performed and that facilities are producing high quality radiological images at the lowest possible human exposure to radiation. The necessity of maintaining records is discussed in the Response to Comments 3 through 6 below.

3. COMMENT: In the age of digital imaging, it is an unnecessary burden to maintain the images for quality control tests for the purpose of verifying the physicist's evaluation of the images reviewed. (1)

4. COMMENT: Images of all tests performed are not needed since the results are contained in the certified medical physicist's report. The reason for maintaining test images is to

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verify that tests were actually performed. The record keeping requirements would create a huge waste of film and digital space. The Department needs to trust certified medical physicists. (3, 7)

5. COMMENT: Maintaining the images of the quarterly light field/x-ray field alignment would be a burden to hospitals and large imaging centers and problematic to store and retrieve. The tests are performed quarterly, and the quantity of documentation per test is substantial. If the purpose of maintaining the images is to determine whether the quarterly test was performed, the State should not question board certified medical physicists. (1, 4, 6)

6. COMMENT: Only tests that failed should be maintained. (1)

RESPONSE TO COMMENTS 3 THROUGH 6: It is not clear to which provision of the rules the commenters refer; however, QA and QC provisions are in N.J.A.C. 7:28-22. The purpose of the amendments to the record retention provisions of N.J.A.C. 7:28-22 is to further specify what constitutes a test record and establish the length of time that images used in the evaluation of the quality control tests required in N.J.A.C. 7:28-22.5, 22.6, and 22.7 must be maintained.

The rules require facilities to perform QC tests at various frequencies throughout the year. These tests can be performed by persons other than New Jersey certified medical physicists, and in most facilities are performed by the facility employed staff. If a facility does not have a full-time medical physicist to perform the tests, the facility retains a medical physicist to perform the annual review, and relies on that review to identify deficiencies in the facility's QA program. In order to effectively evaluate a program, the medical physicist should review test images and the paperwork produced by the facility. The Department and CORP respect the

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expertise of the New Jersey certified medical physicist; the amendments to the rules should not be interpreted as questioning the ability of the medical physicists to perform the annual medical physicist quality control survey.

Maintaining the tests films/images for one year should not be burdensome to a facility. Images do not need to be kept in hard copy. Digital storage is available at a relatively low cost, and can be readily reused. If a facility uses digital images, the images can be stored on a computer, CD or external hard drive for retrieval at a later date. The Department and/or the medical physicist can review the image on the monitor to ensure that a test was properly performed. Of the four test items listed in N.J.A.C. 7:28-22.5(j)3, only item 8 (quarterly x-ray field/light field alignment test) would need to be performed if the facility has digital equipment. The remaining three test items are not applicable to digital equipment. Medical facilities that do not use digital images generally have very few pieces of x-ray equipment; therefore, although the facility is required to perform more test items under N.J.A.C. 7:28-22.5(j)3 than a facility that uses digital equipment, recordkeeping should not be burdensome, as the number of records the facility generates is correspondingly lower. The Department recognizes that there may be some inconvenience to facilities as a result of the record retention requirements; however, it is necessary that the medical physicist have the records available for the required annual review. As stated above, the annual review is a means by which a facility can identify deficiencies in its QA program. Moreover, record retention is necessary in order that the records are available for Department review, if needed.

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N.J.A.C. 7:28-22.6 Quality assurance program for medical diagnostic fluoroscopic equipment

7. COMMENT: A facility should not need to keep images (film or digital) of all monthly QC tests performed for phantom images (fluoro video monitor), as required at N.J.A.C. 7:28-22.6(i)3. The results are contained in the certified medical physicist's report. Since images of low contrast/high contrast tests require the results to be compared to a baseline created from past test readings, test images are not needed. The Department needs to trust New Jersey certified medical physicists. (3, 7)

8. COMMENT: The monthly fluoroscopic phantom image test is not necessary and not practicable in many institutions. Images should be evaluated on the monitor and not printed and stored. (6)

9. COMMENT: The monthly fluoroscopic phantom image is a test to evaluate the monitor and is not a recorded image test. The image on the monitor cannot be compared with the image that is stored on film or on digital media. The regulation limits the phantom image test to the monitor only. (1, 4)

RESPONSE TO COMMENTS 7 THROUGH 9: The Department agrees that maintaining the image of the fluoroscopic phantom image test is not an appropriate means of reviewing the accuracy of the test, since the image can be evaluated only while displayed on the fluoroscopic monitor. Saving the digital image to display it later, or printing the image on film to review in hard copy, may not show the same quality and results as when it the image was first

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evaluated on the monitor. Therefore, the Department is modifying the rule on adoption to delete proposed N.J.A.C. 7:28-22.6(i)3.

N.J.A.C. 7:28-22.7 Quality assurance program for diagnostic computed tomography equipment

10. COMMENT: Maintaining all images for computed tomography QC test items 3 and 4 (CT number for water and field uniformity) for 30 days, as required by N.J.A.C. 7:28-22.7(j)2, and items 6 through 8 (low contrast resolution, high contrast spatial resolution, and noise) for one year, as required by N.J.A.C. 7:28-22.7(j), is a burden to hospitals. (1, 6)

RESPONSE: No facility in the State has more than three computed tomography (CT) units, and in most cases item number 2 of Table 3 (daily film processor QC test) does not apply. The test applies only to CT images processed through a film processor. At most facilities, CT images are never processed through a film processor; instead, CT images are electronically sent, viewed, and interpreted on a computer monitor. Maintaining the tests films or images should not be burdensome to a facility. Although items 3 and 4 are performed daily, and 6 through 8 are performed monthly, the images can be stored on CD or an external hard drive, thereby freeing space in the facility's network storage. These tests are required to be performed by the facility, and can be performed by persons other than New Jersey certified medical physicists; in most facilities, the tests are performed by the facility's staff. The purpose of maintaining the images is to verify that the tests were performed properly, and to assist the medical physicists in their review of a facility's QA program during the required annual medical physicist QC survey. In

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order to effectively evaluate a program, the medical physicist must be able to review test images and the paperwork produced by the facility.

Nuclear Regulatory Commission Compatibility Comments

11. COMMENT: New Jersey incorporated by reference certain rules that are categorized as Compatibility NRC, meaning that the NRC and not the Agreement State has jurisdiction. Therefore, they must be excluded from incorporation by reference. (2)

RESPONSE: The Department and CORP agree, and are modifying the rules on adoption to conform to the NRC requirements. The NRC citations that the commenter raised are identified in Table 1 below. The corresponding modifications being made to the rules on adoption are also shown in Table 1.

Table 1

**Modifications to N.J.A.C. 7:28 on adoption
to meet the NRC Compatibility Requirements**

NRC Citation	Modification to the Rules on Adoption
• 10 CFR 30.4 Definition: Commencement of Construction	Add “commencement of construction paragraph 2” to N.J.A.C. 7:28-51.1(b)2
• 10 CFR 30.4 Definition: Construction, paragraph 9(ii)	Add “construction paragraph 9(ii)” to N.J.A.C. 7:28-51.1(b)
• 10 CFR 36.2 Definition:	Add “Commencement of Construction - paragraph

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- Commencement of Construction, paragraph 2 2” to N.J.A.C. 7:28-56.1(b)
- 10 CFR 36.2 Definition: Add “Construction paragraph 9(ii)” to N.J.A.C. Construction, paragraph 9(ii) 7:28-56.1(b)
- 10 CFR 40.4 Definition: Add “Commencement of Construction - paragraph Commencement of Construction 2” to N.J.A.C. 7:28-58.1(b)
- 10 CFR 40.4 Definition: Add “Construction paragraph 9(ii)” to N.J.A.C. Construction, paragraph 9(ii) 7:28-58.1(b)
- 10 CFR 70.4 Definition: Add “Commencement of Construction - paragraph Commencement of Construction 2” to N.J.A.C. 7:28-60.1(b)2
- 10 CFR 70.4 Definition: Add “Construction paragraph 9(ii)” to N.J.A.C. Construction, paragraph 9(ii) 7:28-60.1(b)2
- 10 CFR 32.30 Certain industrial devices containing byproduct material: Add 10 CFR 32.30 as N.J.A.C. 7:28-53.1(b)20 Requirements for license to manufacture, process, produce, or initially transfer
- 10 CFR 32.31 Certain industrial devices containing Add 10 CFR 32.31 as N.J.A.C. 7:28-53.1(b)21

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byproduct material: Safety

criteria

- 10 CFR 32.32 Conditions of licenses issued under §32.30: Quality control, labeling, and reports of transfer Add 10 CFR 32.32 as N.J.A.C. 7:28-53.1(b)22
- 10 CFR 19.14(a) Presence of representatives of licensees and workers during inspections The State incorporated 10 CFR 19.14(a) by reference with changes, removing the language that made this section NRC Compatibility. However this section was also included in N.J.A.C. 7:28-50.1(b) making it not incorporated by reference. Therefore, 10 CFR 19.14(a) will be removed at N.J.A.C. 7:28-50.1(b)4 and left as incorporated with changes.
- 10 CFR 70.73 Renewal of licenses Add 10 CFR 70.73 as N.J.A.C. 7:28-60.1(b)33

12. COMMENT: NRC regulation 10 CFR 35.57(b)(2) was incorporated without changes, thereby leaving in the rule language regarding master materials licenses, over which New Jersey has no authority. Master materials licenses are issued to Federal facilities, which are not regulated by New Jersey. (2)

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RESPONSE: At N.J.A.C. 7:28-55.1, because the Department and CORP did not replace “Commission” with “US NRC,” the rule indicates that the Department issues master materials licenses. Master material licenses or permits are issued exclusively by the NRC to Federal facilities. The Department has no authority to regulate Federal facilities. The Department and CORP agree with the commenter and are modifying N.J.A.C. 7:25-55.1(c) on adoption to add paragraph 43, which replaces “Commission” with “U.S. NRC.” Adopted N.J.A.C. 7:25-55.1(c)43 also adds “or U.S. NRC” before each instance of “Agreement State,” as discussed in the Summary of Agency-Initiated Changes below.

Nuclear Regulatory Commission Waiver Comments

13. COMMENT: The Department listed 10 CFR 32.1(c)(2) in N.J.A.C. 7:28-53.1(b) as not incorporated by reference, but also listed it under N.J.A.C. 7:28-53.1(c) as incorporated with changes. This creates a conflict in the rules. (2)

RESPONSE: When the NRC changed the Atomic Energy Act to include discrete sources of radium-226 and accelerator-produced radioactive materials under the definition of byproduct material, there was a waiver issued to states that were not yet Agreement States so that they could continue to regulate these materials until August of 2009. The Federal rule at 10 CFR 32.1(c)(2) relates to the waiver. As New Jersey became an Agreement State in September 2009, and August 2009 has passed, there is no need to incorporate rule sections that reference the waiver date. The inclusion of 10 CFR 32.1(c)(2) under N.J.A.C. 7:28-53.1(c) as incorporated by reference with changes was in error; therefore, N.J.A.C. 7:28-53.1(c)6 is deleted on adoption.

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The Department and CORP reviewed other subchapters for similar errors and found that 10 CFR 30.3(b) through (d) was proposed under N.J.A.C. 7:28-51.1(b) as not incorporated by reference and also under N.J.A.C. 7:28-51.1(c) as incorporated by reference with changes. In addition, 10 CFR 35.13(a) was included in N.J.A.C. 7:28-55.1(b) as not incorporated by reference, when only 10 CFR 35.13(a)(1) and (2) should be identified as not incorporated. The Department and CORP have corrected these errors, as explained in the Summary of Agency-Initiated Changes below.

Dose Calibrator

14. COMMENT: N.J.A.C. 7:28-55.1(b) states that New Jersey does not incorporate 10 CFR 35.63(b)(2)(i) through (iii) and (c)(3)(i) through (iii) regarding dose calibrators. However, in N.J.A.C. 7:28-55.1(c), New Jersey appears to adopt those same sections by reference with changes (2).

RESPONSE: The provisions were mistakenly incorporated with changes. The Federal Standards Analysis of the September 2008 proposal of rules as part of the initial Agreement State process (40 N.J.R. 2309(a) at 2366) stated why 10 CFR 35.63(b)(2)(i) through (iii) and (c)(3)(i) through (iii) were not incorporated by reference. The NRC rule requires the use of a dose calibrator for only certain administrations to humans. Dose calibrators provide a check on the prescribed dose, as well as the prescribed radionuclide of radiopharmaceuticals. The Department and CORP considered an actual example of a misadministration of a dose of radiopharmaceuticals to demonstrate that the benefits of using a dose calibrator outweigh the costs. Therefore, the Department did not incorporate the Federal rule, but require licensees to

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use a dose calibrator before administering radiopharmaceuticals. N.J.A.C. 7:28-55.1 is modified on adoption to delete N.J.A.C. 7:28-55.1(c)42 through 45, thus leaving these sections as not incorporated by reference, which was the original intent.

Summary of Agency-Initiated Changes:

In addition to the modifications on adoption discussed above in response to comments, and modifications to update addresses, the Department and CORP are modifying the rules on adoption to make changes of three types. The first type relates to those facilities and materials over which the State has no authority, such as discussed in response to Comment 11 above, and in the proposal Summary at 45 N.J.R. at 812. The second type of modification relates to the incorporation of the Federal rules by reference, and is necessary in order that the incorporated rule makes sense as applied to the regulated community. For instance, when the NRC rule says “an equivalent Agreement State license,” the rule as incorporated into the State’s rules by reference has been modified to add “or NRC” after “Agreement State,” as explained in the proposal Summary (45 N.J.R. at 812). Other modifications on adoption remove “of this chapter” after specific NRC regulation citations. For example, the revised NRC rule at 10 CFR 30.32(g)(1)(ii) states “Contain the information identified in §32.210(c) of this chapter.” The Department and CORP have deleted “of this chapter,” because “this chapter” refers to the Code of Federal Regulations, rather than N.J.A.C. 7:28. The modifications on adoption make similar replacements. The modifications on adoption allow the regulated community to follow the correct citations as explained in the proposal Summary (45 N.J.R. 812-813).

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The third type of modification on adoption addresses instances in the State rules where citations to NRC rules that have not been incorporated by reference into the State's rules have been inadvertently retained. For example, as written, the State's rules incorporate by reference Federal rules that refer to 10 CFR 20.1402 or 1403, which are the NRC's decommissioning regulations. The NRC's decommissioning regulations are not incorporated by reference into the State's rules, so certain modifications on adoption replace citations to the NRC's decommissioning regulations with N.J.A.C. 7:28-12, the Department's decommissioning regulation. Also, when the NRC rules reference 10 CFR 20.1403, which is the NRC's restricted use citation that has not been incorporated by reference into the State rules, the Department and CORP replace this citation with the term "restricted use." Similarly, certain modifications on adoption correct cross-references to citations that were not incorporated by reference into the State's rules.

N.J.A.C. 7:28-6.1(d) is modified on adoption to add paragraph 21, deleting "of this part." from 10 CFR 20.1501(b). The Department does not use the word "part" to describe its regulations.

N.J.A.C. 7:28-51.1(c) is modified on adoption to specify that "Commission" means U.S. NRC in 10 CFR 30.15(a)(2)(iii) and 30.32(g)(1) and (2); to delete the phrase "of this chapter" in 10 CFR 30.19(b), 30.20(b), 30.22(a) and (b), and 30.32(g); and to replace NRC parts with Department subchapters in 10 CFR 30.22(a) .

N.J.A.C. 7:28-51.1(c) is modified on adoption to delete paragraphs 3 through 6 because 10 CFR 30.3(b) through (d) pertain only to entities under NRC jurisdiction. The State does not have authority to regulate Federal agencies or Indian tribes.

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The Federal rule at 10 CFR 30.35(c)(6) references the NRC decommissioning regulations at 10 CFR 20.1402, which the Department did not incorporate in the 2008 adoption, so the NRC citation was replaced with the citation for the Department's decommissioning regulations, N.J.A.C. 7:28-12.1, in N.J.A.C. 7:28-51.1(b). Section 10 CFR 30.35(e)(1)(B) references 10 CFR 20.1403, which is the NRC's restricted use criteria and were not incorporated by the Department in the original 2008 adoption. The Department's restricted use criteria are also in N.J.A.C. 7:28-12.1, so the NRC section was reworded to specify that the decommissioning funding plan should cover the cost of either unrestricted or restricted use. N.J.A.C. 7:28-51.1(c)49 also adds "or restricted" after "unrestricted," so that "provided that if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria" could be deleted. The NRC requires applicants or licensees to demonstrate that further reductions in residual radioactivity necessary to comply with the unrestricted release criteria would result in net public harm or were not being made because the residual levels associated with restricted conditions are "as low as reasonably achievable" (ALARA). The Department does not require such a demonstration.

N.J.A.C. 7:28-53.1(b) is modified on adoption to add 10 CFR 32.30, 32.31, 32.32, and 32.211. These NRC regulations are categorized as NRC compatibility and thus the Department and CORP have no authority to adopt them.

N.J.A.C. 7:28-53.1(c) is modified on adoption to add "or the U.S. NRC" after "Agreement State" at 32.15(b), 32.55, 32.56(b), and 32.62(e), and delete "of this chapter" at 32.15(b), 32.56(b), and 32.62(e). In addition, N.J.A.C. 7:28-53.1(c) is modified on adoption to ensure that any manufacturer and/or distributor of generally licensed tritium or promethium

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devices in New Jersey must report distribution to any Agreement State or NRC State. An NRC State is a state that is not an Agreement State and, therefore, is regulated by the NRC. Delaware is an example of an NRC State. Therefore, 10 CFR 32.56(b) was modified appropriately.

N.J.A.C. 7:28-55.1(b) is modified on adoption at paragraph (b)4 to include 10 CFR 35.13(a)(1) and (2) as not adopted by reference. 10 CFR 35.13(a)(1) refers to Federal facilities and Indian tribes, which the Department does not regulate. The Federal rule at 10 CFR 35.13(a)(2) refers to a waiver provision that has since expired. When the NRC changed the Atomic Energy Act to include discrete sources of radium-226 and accelerator-produced radioactive materials under the definition of byproduct material, there was a waiver issued to states that were not yet Agreement States so that they could continue to regulate these materials until August of 2009. As New Jersey became an Agreement State in September 2009, and August 2009 has passed, there is no need to incorporate rule sections that reference the waiver date.

N.J.A.C. 7:28-55.1(c) is modified on adoption to delete “except that –” because this refers to subsections 35.13(a)(1) and (2), which were not incorporated by reference. (See discussion above.) N.J.A.C. 7:28-55.1(c) is further modified on adoption to add “or the U.S. NRC” after “Agreement State” at 10 CFR 35.51(b)(2).

N.J.A.C. 7:28-58.1(b) is modified on adoption to add 10 CFR 40.52 and 10 CFR 40.53 as not incorporated by reference. The NRC recently adopted amendments to 10 CFR Part 40, at which time licensees had the opportunity to comment on them. The NRC amendments are compatibility NRC and, as such, are outside of the State’s jurisdiction. (See Comment 11.) The amendments to the Federal rules were published on May 29, 2013, which was after the April 15,

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2013, publication of the proposal to amend N.J.A.C. 7:28. Because of NRC amendments are designated compatibility NRC, the State has no authority; however, in the absence of a modification on adoption, the NRC amendments would be incorporated into the State's rules by reference. (See proposal Summary, 45 N.J.R. 806(a) at 812.) Accordingly, the rule is modified on adoption to prevent the improper incorporation.

N.J.A.C. 7:28-58.1(c) is modified on adoption to add paragraphs 22 and 23, which replace the reference to the NRC decommissioning regulation (10 CFR 20.1402) at 10 CFR 40.36(c)(5) and 10 CFR 40.36(d)(1)(B) with the State's decommissioning regulation citation, N.J.A.C. 7:28-12.1. References to 10 CFR 20.1403, the NRC's restricted use criterion, which were not incorporated in the 2008 adoption, were reworded to specify that the decommissioning funding plan should cover the cost of either unrestricted or restricted use. The State's restricted use criteria are at N.J.A.C. 7:28-12.1.

N.J.A.C. 7:28-58.1(c) is modified on adoption by the addition of paragraph (c)34 to delete "or Appendix A to this part." from 10 CFR 40.46(b). The Department and CORP did not incorporate Appendix A in the 2008 adoption, so this cross-reference is not applicable.

N.J.A.C. 7:28-60.1(c) is modified on adoption to add paragraphs 13 and 14, delete the NRC decommissioning regulation citation 10 CFR 20.1402 at 10 CFR 70.25(c)(5) and 70.25(e)(1)(B), which the Department did not incorporate, and add the State's decommissioning regulation citation, N.J.A.C. 7:28-12.1. References to 10 CFR 20.1403, the NRC's restricted use criterion, which were not incorporated in the 2008 adoption, were reworded to specify that the decommissioning funding plan should cover the cost of either unrestricted or restricted use. The State's restricted use criteria are at N.J.A.C. 7:28-12.1.

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Federal Standards Analysis

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.

The adopted amendments and repeals, except as discussed below, are promulgated in order to comply with the Federal requirements for Agreement States. Accordingly, except as discussed below, the rules do not exceed Federal standards.

As discussed in the summary of proposed amendments to Subchapter 12, Remediation Standards for Radioactive Materials (45 N.J.R. at 810), the incorporation by reference of 10 CFR 20.1403(c), which mandates a one percent real rate of return on investments for financial assurance for decommissioning, is amended. Adopted N.J.A.C. 7:28-12.12(b)2 allows the Department flexibility to use a one percent real rate of return for short-lived radionuclides, but a declining real rate of return for longer-lived radionuclides. The provision in the Federal rule is among those that Agreement States are given discretion on whether to incorporate. The policy rationale for N.J.A.C. 7:28-12.12(b)2 is discussed in the proposal Summary, 45 N.J.R. at 810.

It is not possible at this time to determine the economic impact of adopted N.J.A.C. 7:28-12.12(b)2. For facilities containing short-lived nuclides, the amendment is the same as the Federal rule. For facilities with long-lived radionuclides, the rate of return on investments for financial assurance in the decommissioning of a facility will be based on site-specific conditions.

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Thus, there is no accurate way to determine whether or not the adopted amendment relating to long-lived radionuclides is more stringent than the Federal standard.

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

7:28-4.17 Requests for an adjudicatory hearing

(a) – (b) (No change.)

(c) All requests for a contested case hearing shall be submitted in writing to the Department, at Office of Legal Affairs, ATTENTION: Adjudicatory Hearing Requests, Department of Environmental Protection, Mail Code 401-04L, P.O. Box 402, ***401 East State Street, 7th Floor***, Trenton, New Jersey 08625-0402. The request shall contain:

1. -4. (No change.)

(d) (No change.)

7:28-6.1 Incorporation by Reference

(a) – (c) (No change from proposal.)

(d) The following provisions of 10 CFR 20 are incorporated by reference with the specified changes:

1. – 20. (No change from proposal.)

21. 10 CFR 20.1501(b), delete “of this part”;

Recodify proposed 21. – 29. as ***22. -30.*** (No change in text from proposal.)

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(e) (No change.)

7:28-19.17 Procedures for requesting and conducting adjudicatory hearings

(a) –(d) (No change.)

(e) The applicant or violator shall send the request for an adjudicatory hearing to:

The Office of Legal Affairs

New Jersey Department of Environmental Protection

Mail Code 401-04L

401 East State Street, *[Fourth]* ***Seventh*** Floor

PO Box 402

Trenton, New Jersey 08625-0402

Attention: Hearing Request; and

New Jersey Department of Environmental Protection

Bureau of X-ray Compliance

Mail Code 25-01

25 Arctic Parkway

PO Box 420

Trenton, New Jersey 08625-0420

Attention: Hearing Request

(f) (No change.)

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7:28-22.6 Quality assurance program for medical diagnostic fluoroscopic equipment

(a) – (h) (No change from proposal.)

(i) The registrant shall ensure that:

1. All results of QC tests performed for items 2 through 6 in Table 2, Fluoroscopic Quality Control Requirements, are recorded on forms available from the Department at www.xray.nj.gov, or a comparable form containing the same information, and maintained for at least one year; ***and***

2. All images (film or digital) produced and relied upon in the performance of QC tests for items 2, 3, and 5 are maintained for at least 30 days*[, and]**.*

[3. All images (film or digital) produced and relied upon in the performance of QC tests for item 4 are maintained for at least one year.]

(j) – (k) (No change.)

SUBCHAPTER 48. FEES FOR THE REGISTRATION OF NONIONIZING RADIATION PRODUCING SOURCES

7:28-48.7 Initial registration fee and annual renewal fee for nonionizing radiation producing sources

(a) – (d) (No change.)

(e) The registration of an owner who fails to submit an annual renewal fee within 60 calendar days after the owner's receipt of the bill shall be considered expired.

1. (No change.)

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2. Requests for hearings shall be sent to the Office of Legal Affairs, ATTENTION:

Adjudicatory Hearing Requests, Department of Environmental Protection, *Mail Code 401-04L,* P.O. Box 402, *401 East State Street, 7th Floor,* Trenton, NJ 08625-0402.

(f) –(g) (No change.)

7:28-50.1 Incorporation by reference

(a) (No change.)

(b) The following provisions of 10 CFR Part 19 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. – 2. (No change from proposal.)

3. 10 CFR 19.11(b), Posting of notices to workers; * **and***

[4. 10 CFR 19.14(a), Presence of representatives of licensees and regulated entities, and workers during inspections; and]

[5.] *4.* (No change in text from proposal.)*

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

7:28-51.1 Incorporation by reference

(a) (No change.)

(b) The following provisions of 10 CFR Part 30 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. (No change from proposal.)

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2. 10 CFR 30.4, Definitions, the following definitions are not incorporated by reference:

“Act,” “alert,” ***“commencement of construction – paragraph 2,” “construction, paragraph 9(ii),”*** “Department and Department of Energy,” “production facility,” “site area emergency,” and “utilization facility”;

3. – 14. (No change to proposal.)

(c) The following provisions of 10 CFR Part 30 are incorporated by reference with the specified changes:

1. – 2. (No change to proposal.)

*[3. 10 CFR 30.3(b)(1), replace “parts 19, 20, 21 and 71 of this chapter” with “N.J.A.C. 7:28-6, 50, and 61” and replace “10 CFR parts 33, 34, 36 or 39” with “N.J.A.C. 7:28-54, 56, 57, or 63”;

4. 10 CFR 30.3(b)(1), (2) and (3), delete “or Federally recognized Indian Tribe”;

5. 10 CFR 30.3(b)(3), delete “or Indian Tribe”;

6. 10 CFR 30.3(c)(1), replace “parts 19, 20, 21 and 71 of this chapter” with “N.J.A.C. 7:28-6, 50, and 61” and replace “10 CFR parts 33, 34, 36, or 39” with “N.J.A.C. 7:28-54, 56, 57, or 63”];*

Recodify proposed 7. - 23. as ***3. - 19.*** (No change in text from proposal.)

20. 10 CFR 30.15(a)(2)(iii), “Commission” shall mean the U.S. Nuclear Regulatory Commission;

Recodify proposed 24. - 27. as ***21. - 24.*** (No change in text from proposal.)

[28.] ***25.*** 10 CFR 30.19(b), add “or U.S. NRC” after “Agreement State” ***and delete both instances of “of this chapter”***;

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[29.]* *26. (No change in text from proposal.)

[30.]* *27. 10 CFR 30.20(b), add “or the U.S. NRC” after “Agreement State” ***and delete both instances of “of this chapter”***;

[31.]* *28. (No change in text from proposal.)

***29.** 10 CFR 30.22(a), delete “section 81 of” and replace “19, 20, 21, 30 through 36, and 39 of this chapter” with N.J.A.C. 7:28-6, 20, 51 through 57 and 63”; and delete “of this chapter” after “§32.30”;

30. 10 CFR 30.22(b), delete both instances of “of this chapter”;

Recodify proposed 32. - 35. as ***31. - 34.*** (No change in text from proposal.)

***35.** 10 CFR 30.32(g), delete all seven instances of “of this chapter”;

36. 10 CFR 30.32(g)(1) ***and (2)***, “Commission” shall mean the U.S. Nuclear Regulatory Commission;

37. - 47. (No change from proposal.)

***48.** 10 CFR 30.35(c)(6), replace “10 CFR 20.1402” with “N.J.A.C. 7:28-12.1”;

49. 10 CFR 30.35(e)(1)(B), replace “10 CFR 20.1402” with “N.J.A.C. 7:28-12” and add “or restricted” after “unrestricted,” and delete “, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria”;

Recodify proposed 48. - 74. as ***50. - 76.*** (No change in text from proposal.)

(d) – (g) (No change from proposal.)

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(a) (No change.)

(b) The following provisions of 10 CFR Part 32 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. – 19. (No change from proposal.)

***20. 10 CFR 32.30, Certain industrial devices containing byproduct material:**

Requirements for license to manufacture, process, produce, or initially transfer;

21. 10 CFR 32.31, Certain industrial devices containing byproduct material: Safety criteria;

22. 10 CFR 32.32, Conditions of licenses issued under §32.20: Quality control, labeling, and reports of transfer;*

[20.]* *23.* 10 CFR 32.210, Registration of product information; *[and]

24. 10 CFR 32.211, Inactivation of certificates of registration of sealed sources and devices; and

***[21.]* *25.* (No change in text from proposal.)**

(c) The following provisions of 10 CFR Part 32 are incorporated by reference with the specified changes:

1. – 5. (No change from proposal.)

[6. 10 CFR 32.1(c)(2), replace “part 31 of this chapter” with “N.J.A.C. 7:28-52”];

Recodify proposed 7. - 9. as ***6. - 8.*** (No change in text from proposal.)

9. 10 CFR 32.15(b) delete “of this chapter” and add “the U.S. NRC or” before “an Agreement State”;

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10. – 18. (No change from proposal.)

***19. 10 CFR 32.55, add “or U.S. NRC” after “Agreement State”;**

20. 10 CFR 32.56(b), delete “of this chapter,” add “or the U.S. NRC” after “Agreement State agency,” add “or the U.S. NRC” before “during the reporting period,” add “or the U.S. NRC” before “upon request,” and delete “of the agency”;*

Recodify proposed 19. - 22. as ***21. - 24.*** (No change in text from proposal.)

25. 10 CFR 32.62(e), delete “of this chapter,” and add “of U.S. NRC” after “Agreement State”;

Recodify proposed 23. - 31. as ***26. - 34.*** (No change in text from proposal.)

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

SUBCHAPTER 55. MEDICAL USE OF BYPRODUCT MATERIAL

7:28-55.1 Incorporation by reference

(a) (No change.)

(b) The following provisions of 10 CFR Part 35 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. – 3. (No change from proposal.)

4. 10 CFR 35.13(a)***(1) and (2)****[, License amendments]*;

5. – 7. (No change from proposal.)

(c) The following provisions of 10 CFR Part 35 are incorporated by reference with the specified changes:

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1. – 12. (No change from proposal.)

13. 10 CFR 35.13(a), delete “except that –” ;

Recodify proposed 13. – 32. as ***14. - 33.*** (No change in text from proposal.)

34. 10 CFR 35.51(b)(2), add “or U.S. NRC” after “Agreement State” ;

*Recodify proposed 33. - 40. as ***35. - 42.*** (No change in text from proposal.)

43. 10 CFR 35.57(b)(2), add “or U.S. NRC” after both instances of “Agreement State”; and replace “Commission” with “U.S. NRC” before each instance of master material license;

[41.] ***44.*** (No change in text from proposal.)

*[42. 10 CFR 35.63(b)(2)(ii), add “or U.S. NRC” after “Agreement State”;

43. 10 CFR 35.63(b)(2)(iii), add “or U.S. NRC” after “Agreement State”;

44. 10 CFR 35.63(c)(3)(i), add “or U.S. NRC” after “Agreement State”;

45. 10 CFR 35.63(c)(3)(ii), add “or U.S. NRC” after “Agreement State” ;]*

Recodify proposed 46. - 94. as ***45. - 93.*** (No change in text from proposal.)

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

7:28-56.1 Incorporation by reference

(a) (No change.)

(b) The following provisions of 10 CFR Part 36 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:

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1. 10 CFR 36.2, Definitions, the following definitions are not incorporated by reference: “commencement of construction, paragraph 2” and “construction, paragraph 9(ii)”;

Recodify proposed 1. and 2. as ***2. and 3.*** (No change in text from proposal.)

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

7:28-58.1 Incorporation by reference

(a) (No change.)

(b) The following provisions of 10 CFR Part 40 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. (No change.)

2. 10 CFR 40.4, Definitions. The following definitions in 10 CFR 40.4 are not incorporated by reference: ***“byproduct material,” “commencement of construction, paragraph 2,”* “Commission,” *and “construction, paragraph 9(ii)”*** *[and “byproduct material”]*;

3. – 17. (No change from proposal.)

***18. 10 CFR 40.52, Certain items containing source material; requirements for license to apply or initially transfer.**

19. 10 CFR 40.53, Conditions of licenses issued for initial transfer of certain items containing source material: Quality control, labeling, and records and reports.;*

Recodify proposed 18. - 23. as ***20. - 25.*** (No change in text from proposal.)

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(c) The following provisions of 10 CFR 40 are incorporated by reference with the specified changes:

1. – 21. (No change from proposal.)

***22. 10 CFR 40.36(c)(5) replace “20.1402” with “N.J.A.C. 7:28-12.1”;**

23. 10 CFR 40.36(d)(1)(B) replace “20.1402” with “N.J.A.C. 7:28-12.1,” add “or restricted” after “unrestricted,” and delete “, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria”;*

Recodify proposed 22. - 31. as ***24. - 33.*** (No change in text from proposal.)

34. 10 CFR 40.46(b) delete “or Appendix A to this part”;

Recodify proposed 32. - 35. as ***35. - 38.*** (No change in text from proposal.)

(d)– (g) (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. (No chang.)

2. 10 CFR 70.4, definition of ***“commencement of construction, paragraph 2,”***
“Commission”*, and “construction, paragraph 9(ii)”*;

3. – 32. (No change from proposal.)

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33. 10 CFR 70.73, Renewal of licenses;

Recodify proposed 33. - 36. as ***34. - 37.*** (No change in text from proposal.)*

(c) The following provisions of 10 CFR Part 70 are incorporated by reference with the specified changes:

1. – 12. (No change from proposal)

***13. 10 CFR 70.25(c)(5) replace “20.1402” with “N.J.A.C. 7:28-12.1”;**

14. 10 CFR 70.25(e)(1)(B) replace “20.1402” with “N.J.A.C. 7:28-12.1,” add “or restricted” after “unrestricted,” and delete “, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria”;*

Recodify proposed 13. - 24. as ***15. - 26.*** (No change in text from proposal.)

(d) – (f) (No change from proposal.)