Janda, Donna

From: Jenny Goodman [Jenny.Goodman@dep.state.nj.us]
Sent: Friday, August 01, 2008 9:17 AM
To: dennis.solenberger@nrc.gov; Donna Janda; Monica Orendi
Cc: Patricia Gardner; Richard Peros
Subject: Adoption
Attachments: adoption.nrc.doc

Folks,
Attached is our response to comment document and changes that we intend to make on adoption. Our filing date is August 21, 2008 for publication on September 15, 2008, but we will need any comments by Aug 8 so we can make changes if necessary. I will be out of the office until Sept 2, so please copy Pat Gardner and Rich Peros with any comments.
Thanks
Jenny

B/5

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ENVIRONMENTAL REGULATION

DIVISION OF ENVIRONMENTAL SAFETY AND HEALTH

COMMISSION ON RADIATION PROTECTION

Radiation Protection Programs

Adopted Repeals: **N.J.A.C. 7:28-3.5, 3.8, 3.11, 3.13, 4.19, 5.4, 6, 7.5, 8.3, 8.4, 9, 10.4, 10.5, and 11**

Adopted New Rules **N.J.A.C. 7:28-2.13, 4.16, 6, 12.10, 12.15, and 50 through 64**

Adopted Amendments N.J.A.C. 7:28-1.1, 1.4, 1.5, 3.1, 3.2, 3.6, 3.10, 4.1 through 4.18, 5.1 through 5.3, 7.1 through 7.3, 8.1, 8.2, 8.5, 10.6 through 10.9, 12.2 through 12.5, 12.7 through 12.13 and Appendix A, 13.1, 13.2, 17.1 through 17.6, 17.8, 18.1, and 48.2.

Proposed: May 19, 2008 at 40 N.J.R. 2309(a).

Adopted: by Lisa P. Jackson, Commissioner, Department of Environmental Protection and

Julie K. Timins, M.D., Chair, the Commission on Radiation Protection.

Filed: , **with substantive and technical 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. and 26:2D-1 et seq.

DEP Docket Number: 04-08-04/637

Effective Date: [publication]

Operative Date: Operative upon publication of notice by the Department of Environmental Protection that the US Nuclear Regulatory Commission and the State of

New Jersey have entered into an Agreement for the State to regulate source, certain special nuclear, and byproduct material.

Expiration Date: June 21, 2010

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

States have the option to assume responsibility for regulation of radioactive materials that are governed under the Atomic Energy Act (AEA) through an agreement between the Governor of the state and the United States Nuclear Regulatory Commission (NRC). (See 42 U.S.C. § 2021.) 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).)

Prior to the 2005 Energy Policy Act (42 U.S.C. § 13201 et seq.), the definition of byproduct material included any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material. This type of byproduct material includes

nuclear medicine produced by a reactor (instead of an accelerator). In August 2005, President Bush signed the Energy Policy Act (42 U.S.C. § 13201 et seq.)). By changing the definition of byproduct material to include discrete sources of NARM, the Energy Policy Act gives the NRC control over every aspect of almost all radioactive materials beginning in August 2009, unless a state enters into an Agreement with the NRC. In other words, the existing New Jersey program, except for a limited amount of material, will be Federally preempted, unless New Jersey becomes an Agreement State. In light of this approaching deadline, and mindful of the State's history and experience in regulating radioactive materials, the State notified the NRC of its decision to become an Agreement State by letter dated May 23, 2006, from Governor Corzine to NRC Chairman Nils J. Diaz.

New Jersey is seeking approval from the NRC to regulate source, certain special nuclear, and byproduct material. If the NRC grants New Jersey Agreement State status, New Jersey will have authority to regulate these materials instead of the NRC. The within rules establish New Jersey's regulation of source, certain special nuclear (states can only assume authority to regulate small quantities of special nuclear material), and byproduct material, in order that New Jersey can become an Agreement State.

When the NRC grants New Jersey Agreement State Status, which is anticipated to be in late summer 2009, a notice will be published in the New Jersey Register, advising that the within rules are operative. Until the new rules and amendments are operative, New Jersey will continue to rely on the Federal government to license and regulate source, special nuclear, and byproduct materials.

Summary of Public Comments and Agency Responses:

The following individuals, companies, organizations, and/or agencies submitted written comments on the proposal.

1. Laurence Bernson - Alcatel-Lucent
2. J. Russell Cerchiaro - Schering-Plough
3. Michael J. Drzyzga - Hoffmann-La Roche Inc.
4. Sue M. Dupre - Princeton University Environmental Health and Safety
5. Michael Egenton - New Jersey State Chamber of Commerce
6. Hoy E. Frakes, Jr. - Shieldalloy Metallurgical Corporation
7. Halim A. Hasan - Lundbeck Research USA, Inc.
8. Debra Hrabinski
9. Tony Russo - Chemistry Council of New Jersey
10. Vincent Williams- Merck Research Laboratories

General

1. COMMENT: The comment period should be extended 60 days because the length and complexity of the proposal and the time of year has made it difficult to complete a review of the 472 page proposal and develop appropriate comments. (1, 2, 3, 4, 5, 7,8, 9, 10)

RESPONSE: Although the proposal was lengthy, the substance of the proposal was very straightforward. As stated in the Summary, 40 N.J.R. 2309(a) at 2310, New Jersey regulations must be compatible with the Nuclear Regulatory Commission (NRC) regulations so the Department of Environmental Protection (Department) and the

Commission on Radiation Protection (Commission) have elected to incorporate the NRC's regulations by reference. NRC licensees in New Jersey had the opportunity to review and comment on NRC regulations when they were proposed. If a facility is in compliance with NRC regulations, the facility should have no difficulty complying with the New Jersey rules. The difference is that the regulator will now be the Department instead of the NRC. No licensees holding only a New Jersey license asked for an extension of the comment period (although some may be included in the industry wide group associations).

It is not practical for the Department and the Commission to extend the comment period, in light of the NRC's schedule for becoming an Agreement State. Appendix C from the NRC's Office of Federal and State Materials and Environmental Management (FSME) Programs State Agreement procedure on Processing an Agreement (SA-700), includes a schedule for processing a new Agreement (http://nrc-stp.ornl.gov/procedures/sa700hb_appc.pdf). The amount of time projected by the NRC to process an Agreement once the NRC receives New Jersey's formal Agreement application request is 39 weeks (between 9 and 10 months), provided New Jersey's application is nearly perfect, the Commission reviews and votes on the two papers in a timely manner (the NRC staff submit a paper to the Nuclear Regulatory Commission members on the proposed Agreement and another paper on the final Agreement), and New Jersey has the required number of employees hired and trained. If the Agreement is to be in place by August 2009, New Jersey should submit its application no later than September 2008, which gives the NRC eleven months. Part of a complete application is adopted rules. If the comment period were extended, the rules would likely not be in

place to submit a complete application to the NRC and allow them enough time to review and approve it by August 2009.

As was discussed in the summary of the proposal, 40 N.J.R. 2310, if New Jersey does not become an Agreement State by August 2009, the NRC could assume authority over all NARM, which is regulated by New Jersey. The NARM waiver expires on August 8, 2009. However, because of the possibility that the application will not be perfect, that the NRC Commission may take longer to review and vote, that the Department does not have sufficient staff hired and trained, the Department and the Commission believe that the adoption should be published as soon as possible. The Department is committed to making this transition as seamless as possible. Extending the comment period by 60 days, or even 30 days would make it less likely that New Jersey will become an Agreement State by August 2009.

Extending the comment period will also have a negative economic effect on the regulated community. If the Agreement goes into effect on August 8, 2009, New Jersey licensees will avoid NRC fees for Fiscal Year 2010. If the Agreement goes into effect at anytime between October 1, 2009 and March 31, 2010, NRC will charge one half of the annual fee. NRC is not flexible in its ability to prorate fees (see 10 CFR 171.17(b)(2)). After April 1, 2010, the annual fee for the full year will be collected.

2. COMMENT: Many current NRC licensees in New Jersey are not currently licensed by the Department, and do not have access to the existing Department regulations. An outdated and incomplete version of N.J.A.C. 7:28 (2005) is available "on-line." The rules must be purchased as part of the entire Department code at a cost of

over ($500.00). In order for the proposed new rules to be effectively evaluated by those New Jersey based NRC licensees, they must obtain the current N.J.A.C. 7:28. This purchase process significantly delays the review, and therefore supports extending the comment period. (3, 7, 8)

RESPONSE: The Department's website on regulations makes it clear that the statutes and regulations on the website are "courtesy copies" of the documents, and that they might not be the most current or accurate versions. The link on how to get copies of the Departmental rules states that to get official copies, the current versions of the code must be purchased from Lexis Nexis. Lexis Nexis is not affiliated with the State, and the State does not control the price that Lexis Nexis charges. As an alternative, the New Jersey Register and the New Jersey Administrative Code are available for review at public and university libraries throughout the State.

The majority of the amendments to the rules incorporate the NRC regulations by reference. The NRC regulations are available on the NRC website, http://www.nrc.gov/reading-rm/doc-collections/cfr/, through the Federal Government Printing Office website at http://www.gpoaccess.gov/CFR/INDEX.HTML, and at public and university libraries throughout the State.

3. COMMENT: There were an insufficient number of stakeholder meetings about the proposed rules. (3, 10)

RESPONSE: There were six public stakeholder meetings held over the past 19 months. Department representatives gave presentations about the rules at:

Meeting of New Jersey Chapter of the Health Physics Society, Somerset, December 5, 2006;

The noticed March 21, 2007 meeting of the Commission on Radiation Protection;

Meeting with the Medical Physicists, and other industry groups, Radiation Protection office, Ewing, July 17, 2007;

Mid-Atlantic States and New Jersey Health Physics Society Joint Meeting, Lambertville, October 16, 2007;.

Special meeting with radiological remediation consultants and contaminated facilities to discuss Decommissioning Regulations, Radiation Protection office, Ewing, December 6, 2007; and

Meeting of the New Jersey Society of Nuclear Medical Technologists, Atlantic City, March 7, 2008.

In addition, the Department posted a link to Agreement State issues on its website, which included a list of Frequently Asked Questions. There were ample opportunities for stakeholders to meet with the Department and the Commission, to learn about the proposed rules and to discuss the rules with Department representatives.

Sewerage Discharge Limits

4. COMMENT: There is an inconsistency between the Summary and the rule text regarding release limits for H-3 and C-14. The Summary at 40 N.J.R. 2317 states that a limit of 1 Curie would apply to both H-3 and C-14, but the rule incorporates the NRC regulation by reference. The NRC discharge limits are 5 Curies per year for H-3 and 1 Curie per year for C-14. (3, 4, 8, 10)

RESPONSE: The Summary mistakenly states that the limit will be 1 Curie for H-3 and C-14. The rule text is correct, in which 10 CFR 20.1301 is incorporated by reference, replacing the term "sanitary sewer" with "domestic treatment works." There is no change from the current NRC discharge limits, which are 5 Curies per year for H-3 and 1 Curie per year for C-14.

Throughout the Summary, the Department and Commission indicated that the intention is to be adequate and compatible with the Federal rules. Moreover, the Federal Standards Analysis, 40 N.J.R. 2366, in which the State describes the rule provisions that are more stringent than the Federal rules, does not indicate that the proposed discharge limits for H-3 are more stringent than the Federal rules. Thus, the error in the Summary at 40 N.J.R. 2317 was evident.

Personnel Monitoring

5. COMMENT: Proposed Subchapter 7 no longer contains any reference to personnel monitoring and, therefore, cross references from different subchapters are no longer valid. (4)

RESPONSE: The Department and Commission proposed no amendments to N.J.A.C. 7:28-7.4, Use of personnel-monitoring equipment. The section remains in the rules and cross references to it are valid.

Decommissioning

6. COMMENT: The rules should contain a definition of real property, since the term is used in the decommissioning subchapter (N.J.A.C. 7:28-12). (4)

RESPONSE: Real property is clear as is it customarily used. It includes land and things permanently attached to the land, such as buildings, and stationary mobile homes. Anything that is not real property would be materials and equipment. In this context, the rules' dose criterion applies to the land and buildings. The contribution from residual radioactivity from buildings and land together must not exceed 15 millirem per year.

7. COMMENT: Subchapter 12 is not clear with regard to release levels for building surfaces and materials and equipment. The NRC does not include such levels in its rules; however, the NRC refers to Regulatory Guidance documents to support a licensees "free release" of buildings and equipment. The rule should be clarified or supplemented by cross referencing the NRC guidance upon adoption. (3)

RESPONSE: As stated in the response to Comment 6, the Department and Commission's dose criterion of 15 mrem per year at N.J.A.C. 7:28-12.8 applies to land and buildings. The NRC guidance documents related to "free release" of materials and equipment are not part of the Federal rules, and are not incorporated into the State's rules; however, because the State's rules incorporate the NRC's rules, the NRC's guidance is useful for interpretation. Therefore, the Commission and the Department will use the NRC's current approach for "free release" of materials and equipment outlined in NUREG 1757, Vol.1, Rev. 2, Consolidated Decommissioning Guidance, which is to review specific cases on an individual basis.

NUREG 1757 provides a description of the current NRC approach to releasing of solid materials, which is on a case by case basis. For materials and equipment with surface contamination, the NRC uses either the criteria in Regulatory Guide 1.86,

"Termination of Operating Licenses for Nuclear Reactors," or the criteria in Fuel Cycle Policy and Guidance Directive FC 83-23, entitled "Guidelines for Decontamination for Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Byproduct, Source or Special Nuclear Materials Licenses." Both guidance documents can be found on the NRC website (www.nrc.gov).

The release of materials and equipment with volumetric contamination is implemented by the NRC under the provisions of the December 27, 2002, NRC Memorandum, "Update on Case-Specific Licensing Decisions on Controlled Release of Concrete from Licensed Facilities" (referenced in STP-03-003). This memorandum indicates that controlled releases of volumetrically contaminated concrete may be approved under an annual dose criterion of a "few mrem." NUREG 1757 goes on to state that a few mrem means zero to five mrem per year total effective does equivalent (TEDE).

8. COMMENT: The Department and Commission propose to delete text referencing acceptable testing procedures for water and soil at N.J.A.C. 7:28-12.5(c) and (d), and replace it with certification by the Department's Office of Quality Assurance. This could be interpreted to mean that the only acceptable testing methods would be laboratory analysis. Would surveys by hand held instruments still be allowed for determining building surface contamination? (3)

RESPONSE: In 1999, when the Department and the Commission proposed amendments to Subchapter 12, the Department's Office of Quality Assurance did not certify laboratories for radionuclides in soil analyses. Therefore, the Department was

compelled to propose and adopt N.J.A.C. 7:28-12.5(c) and (d), which contain requirements on acceptable procedures and intercomparison testing. (See (31 N.J.R. 1723(a) at 1730, 32 N.J.R. 2866(a) at 2884.) Since then, the Office of Quality Assurance has updated its laboratory certification process to include certification of radiological analyses in soil, which make the specific language in the previous rules at N.J.A.C. 7:28-12.5(c) and (d) unnecessary

The Department's existing rule at N.J.A.C. 7:28-12.5(e) addresses surveys, requiring surveying with hand held instruments to be done in accordance with the Department's Field Sampling Procedures Manual. The Department and Commission did not propose amendments to N.J.A.C. 7:28-12.5(e), other than to renumber it as (d). Thus, surveys by hand instruments are allowed, as under the previous rules.

9. COMMENT: The method for calculating compliance with radiological decommissioning criteria in the proposed rule is overly restrictive and that nationwide, radiation control programs have found it appropriate for efficient and timely radiological decommissioning to provide flexibility in the analysis approach to address the wide variation in the regulated facilities. Specifically, analyzing dose from radiological decommissioning sites for more than 1000 years into the future is meaningless and that the Department misinterpreted the NRC's response to comment document regarding calculations beyond 1000 years being valuable for long-lived radioactive material. The NRC has stated that modeling should be specific to each radionuclide as:

> Unlike analyses of situations where *large quantities* of long-lived radioactive material may be involved (e.g. *a high-level waste*

> *repository*) and where distant future calculations may provide some insight into consequences, in the analysis for decommissioning...long term modeling thousands of years into the future of doses that are near background may be virtually meaningless. (Emphasis added by commenter)

52 Fed. Reg. 39058, 39083 (July 21, 1997) (Response F.7.3)

If the peak dose occurs in less than 1000 years, there is no rational basis to analyze for a thousand year period. (6)

RESPONSE: On July 6, 1999, the Department and the Commission proposed Soil Remediation Standards for Radioactive Materials, which was mandated by the Brownfields and Contaminated Site Remediation Act (Act), N.J.S.A.58:10B et seq. (See 31 N.J.R. 1723) The Act required the Department to publish remediation standards for both residential and commercial use. In the summary to that proposal, the Department stated:

> The proposed new soil standards facilitate compliance by increasing the likelihood that planned remediations are technically and financially feasible. Persons conducting remediations will be afforded latitude, depending on site characteristics and contaminant concentrations, in selecting remedies for meeting the dose standard. [For example] rather than removing all contaminated soil to a disposal facility, the allowed dose may be attainable by removing part of the contamination and placing uncontaminated surface soil over the residual

contamination, thus reducing the overall costs while maintaining public health and safety. (31 N.J.R.1723)

This demonstrates the Department's and Commission's intention was, and still is, to facilitate cleanups by providing options for remediation and putting land back into productive use. Nationwide, some states do not even have restricted release provisions or their dose criterion is less than New Jersey's.

The NRC decommissioning regulation at 10 CFR 20.1401(d) requires that when calculating the total effective dose equivalent to the average member of the critical group, the licensee shall determine the peak annual total effective does equivalent (TEDE) expected within the first 1000 years after decommissioning. The commenter's interpretation of the NRC's response to a comment on making the time period correlate with the half-life of the specific nuclide is different than the Department and the Commission's interpretation. A clear point that the NRC made is that the 1000-year modeling requirement does not apply to long-lived nuclides. Specifically, the NRC responded:

> As previously discussed in the preamble to the proposed rule, the [Nuclear Regulatory] Commission believes use of 1000 years in its calculation of maximum dose is reasonable based on the nature of the levels of radioactivity at decommissioned sites and the potential for changes in the physical characteristics at the site over long periods of time. Unlike analyses of situations where large quantities of long-lived radioactive material may be involved (e.g., a high-level waste repository) and where distant future calculations

> may provide some insight into consequences, in the analysis for decommissioning, where the consequences of exposure to residual radioactivity at levels near background are small and *peak doses for radionuclides of interest in decommissioning occur* <u>*within*</u> *1000 years*, long term modeling thousands of years into the future of doses that are near background may be virtually meaningless.

52 Fed. Reg. 39058, 39083 (July 21, 1997) (Response F.7.3) (emphasis added).

Long-lived radionuclides such as uranium and thorium have half-lives in the millions and billions of years and peak doses may well occur after 1000 years. The Department and Commission believe it is vital to consider the peak dose, whenever it occurs, to ensure that adequate measures are taken to protect the public health and safety. Also, the NRC did not object to the proposed language requiring modeling to the time of peak dose beyond 1000 years and agreed that this language met the compatibility requirements for becoming an Agreement State.

As far as the provision in N.J.A.C. 7:28-12.10(d) that requires modeling to the time of peak dose or 1000 years, whichever is longer, one will not know when peak dose occurs unless it can be demonstrated that the dose decreases over time. For these reasons, the Department and the Commission do not agree that N.J.A.C. 7:28-12.10(d) needs to be modified or deleted.

10. COMMENT: The Department and the Commission's requirement for decommissioned sites to meet the surface water quality standards would prohibit surface

water discharges because of the "anti-backsliding" provisions in the surface water rules. Specifically, N.J.A.C. 7:9B-1.5(d) would preclude detectable radioactivity releases above background, even if the levels are significantly below those required to protect the health and safety of the public, because provisions of the Surface Water Quality Standards do not allow measurable changes in water quality. Exceptions to the backsliding provisions apply only if some change in ambient water quality should be allowed because of necessary and justifiable social or economic development, and that a decommissioned facility may not be able to demonstrate that.

The proposed rule does not consider that the NRC rules allow radioactive discharges to surface waters, provided that all pathways for exposure are considered and resulting doses are within limits and that they are minimized to the extent reasonable considering a balance of costs and benefits. The Department and the Commission have proposed a ban on any radioactive discharges to surface waters from remediation sites and this is an impractical standard for radioactivity that is not related to a rational public health and safety goal.

The proposal does not explain the equivalence between its proposed impractical ban on discharges with the NRC approach of minimizing discharges consistent with a balance of cost and benefits. Application of the Surface Water Quality Standards to radioactivity should be deleted from the rules. The proposed provision has a discriminatory impact on the one facility that would be affected by this provision. (6)

RESPONSE: The intent of N.J.A.C. 7:28-12.8(c) is to ensure that decommissioned facilities with residual material present would not affect the quality of

any surface water near the facility. The antidegradation provisions of the Surface Water Quality Standards are triggered when a facility seeks a new or expanded wastewater discharge permit. The Department's provisions on backsliding and anti-degradation apply to permitted discharges, not potential runoff from decommissioned sites. The Department and the Commission's intent to reference the surface water rules was to ensure that the surface water standards for radioactivity at N.J.A.C. 7:9B-1.14(c)6 were met in order to verify that health and safety of humans and the environment are sufficiently protected.

To ensure that licensees do not have to read the entire Surface Water Quality Standards rule (N.J.A.C. 7:9B), the Department and the Commission are modifying N.J.A.C. 7:28-12.8(c) on adoption to replace the reference to the entire surface water rule to the specific section that contains the standards for radioactivity.

The fact that there is only one facility in the State is now affected by the rule does not mean that other facilities will not be affected in the future. In fact, each facility at which there is a potential for radioactive materials to migrate to a stream could be affected. Creating an open class is not the equivalent of special legislation which is prohibited nor is it discriminatory.

11. COMMENT: The rules should allow calculation of dose based on realistic scenarios. Proposed N.J.A.C. 7:28-12.11(b) requires the use of default clean up criteria whose bases are specific exposure scenarios. Licensees may request consideration of alternate parameters for site-specific characteristics, but not for site-specific exposure scenarios. NRC guidance allows the use of realistic site-specific scenarios with

justification for the reasons stated in their License Termination Rule Analysis, and Consolidated Decommissioning Guidance, NUREG-1757, Vol. 2, Ch.5. Reevaluate the approach to exposure scenario selection, in light of the more recent NRC guidance. (6)

RESPONSE: The Department and the Commission do allow the use of some, but not all, alternate site-specific exposure scenarios. For example, adopted N.J.A.C. 7:28-12.11(c)4 (formerly N.J.A.C. 7:28-12.10(c)4) allows the Department to consider alternate indoor and outdoor occupancy times, if they are justified by land uses other than residential or commercial.

In proposing the current rules the Department and the Commission considered the updated NRC guidance, but the basis for Tables 6 and 7 at N.J.A.C. 7:28-12.11(b) is still justified as presented in the publication entitled, Development of Generic Standards for Remediation of Radioactively Contaminated Soils in New Jersey, which was made available to the public on the Department's website, and by hard copy if requested. . The Department and the Commission established sufficiently conservative bounds on the exposure scenarios in Tables 6 and 7 of N.J.A.C. 7:28-12.11(b) to ensure that the dose criteria would be met for the length of time the residual radionuclides would be present (thousands to billions of years).

12. COMMENT: Dose calculations based on realistic degradation of engineering controls over time should be allowed. The NRC approach reflects that engineered structures degrade by known physical processes. N.J.A.C. 7:28-12.11(e) assumes that engineered structures instantaneously fail at the precise moment when institutional

controls are presumed to end. The proposed rule does not and can not provide a reasoned basis for assuming engineered structures simply vanish, rather than degrading through processes consistent with the known physical world. (6)

RESPONSE: Adopted N.J.A.C. 7:28-12.11(e), which is identical to previous N.J.A.C. 7:28-10(e), does not assume that the engineered barriers fail instantaneously. Rather, the rules require the Department to consider the public health consequences in the event that the engineered barriers completely fail at some point in the future. This is a reasonable approach to ensure an adequate degree of protection to the public health and safety. The NRC approach of assuming that engineered structures degrade over time does not take into account intentional human intervention.

In the Department's experience, human intervention greatly increases radiation exposure at radiologically contaminated sites. At some sites, signs indicating that radioactive materials are present are missing, fences have holes cut into them, and there is evidence (including the presence of a mattress and warm coffee cup) of persons residing on sites that are restricted due to the presence of radioactive materials. This intentional degradation of engineering controls occurred after only ten years.

Whenever engineering controls fail, the licensee would have to show that the all control fails dose criterion (100 mrem/y) is met. This level is over six times the unrestricted dose criterion of 15 mrem per year for the all controls fail scenario.

13. COMMENT: The Department and the Commission should allow use of NRC remediation dose criteria when appropriate and when justified based on the As Low As Reasonably Achievable (ALARA) principle. Proposed N.J.A.C. 7:28-12.11(e) would not

allow consideration of alternate remediation standards if they would result in increasing in any manner the allowed incremental dose criterion of 15 mrem per year, and would not allow consideration of remediation standards if they would be supported by increasing in any manner the allowed 100 mrem per year all controls fail dose criterion.

The proposal contains no justification for requiring stricter remediation standards than those provided by the NRC, nor for not allowing licensees to apply the Federal standards in appropriate cases. The proposed rule would prohibit returning land to productive use when allowed by Federal regulations. (6)

RESPONSE: Neither the remediation criterion of 15 mrem per year at N.J.A.C. 7:28-12.8(a)1 nor the all controls fail dose criterion of 100 mrem per year is new, nor is either amended in the adopted rules. These dose criteria have been in the rules since August 2000 (31 N.J.R. 1723(a), 32 N.J.R. 2866(a)). At the time they proposed the criteria, the Department and the Commission justified the 15 mrem per year incremental dose limit in a publication entitled, Development of Generic Standards for Remediation of Radioactively Contaminated Soils in New Jersey, which was made available to the public on the Department's website, and by hard copy if requested. The 100 mrem per year all controls fail dose criterion was justified in the Summary to the proposed Soil Remediation Standards for Radioactive Materials (31 N.J.R. 1724-1725). The fact that these dose criteria do not have an associated ALARA requirement is also not new. ALARA determinations allow the use of cost as a factor for performing or not performing a remedial action. The Department and the Commission did not include a provision for ALARA in meeting these dose criteria because the Brownfield and Contaminated Site Remediation Act (N.J.S.A. 58:10B-1 et seq.) does not allow such a provision.

As explained in the Response to Comment 9, above, there is flexibility in complying with the remediation standards, including the availability of a petition for alternative remediation standards, N.J.A.C. 7:28-12.11.

14. COMMENT: The Department and the Commission improperly designated source material as "diffuse NARM" without a rational basis. The proposed deletion of the exception for source, special nuclear and byproduct material at N.J.A.C. 7:4.1(b), could be used to regulate source material as diffuse NARM. (6)

RESPONSE: The Department and the Commission can understand the confusion this may have caused for source material licensees. There are several facilities in the State that in the past extracted minerals either from native sand or imported material, concentrated naturally occurring radioactive materials (NORM) in the process and are now left with waste piles with technologically enhanced NORM (TENORM). This TENORM does not meet the definition of source material (the uranium and thorium are below 0.05 percent by weight), but the concentration of uranium and/or thorium is above the exemption for licensing NARM. Any facility that possesses uranium or thorium or any combination thereof above 0.05 percent by weight will be regulated as source material through N.J.A.C. 7:28-60 (which is 10 CFR Part 40 incorporated by reference). Since replacing the deleted text will not affect the original intent of the proposal, and will avoid confusion for licensees that possess source material and TENORM, the Department and the Commission are modifying the rule on adoption to reinsert the exception for source, special nuclear, and byproduct material at N.J.A.C. 7:28-4.1(b)

Broad Scope Licensing

15. COMMENT: Proposed N.J.A.C. 7:28-54 incorporates by reference the Federal rules at 10 CFR Part 33, which include a provision that licensees cannot add or cause the addition of byproduct material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation, or application to, a human being (10 CFR 33.17(a)(4)). Currently, pharmaceutical companies that discover new molecular entities and develop them into medicine will in some way formulate a radio-labeled version of the drug which is then transferred to a NRC Medical Use licensee (10 CFR Part 35 or equivalent Agreement State licensee) for clinical testing in humans. Therefore, all pharmaceutical companies that engage in this practice have a condition in their broad scope license that excludes them from the limitation of 10 CFR 33.17(a)(4). How will the Department and the Commission address this issue, with a similar license condition or new regulations? (3, 10)

RESPONSE: The Department and the Commission are incorporating the Federal regulations at 10 CFR Part 33 by reference. There is no proposed change to the Federal requirement at 10 CFR 33.17(a)(4). Accordingly, unless a licensee has an exemption, the prohibition in the Federal rules will apply.

N.J.A.C. 7:28-2.8, Special exemptions, allows the Department, with the approval of the Commission, to grant an exemption from any requirement of the rules, provided the conditions of N.J.A.C. 7:28-2.8 are met. The pharmaceutical companies may apply for an exemption from N.J.A.C. 7:28-54.1 (and the prohibition of the Federal rules) through N.J.A.C. 7:28-2.8.

Fees

16. COMMENT: The basis for calculating certain fees is inconsistent with the governing New Jersey Statute. N.J.S.A. 26.2D-9(*1*) requires that fees shall be annual or periodic, shall be based on criteria contained in the fee schedule, and shall reflect the actual or projected expense incurred by the Department in the performance of the service. Proposed N.J.A.C. 7:28-64.10, where the fees are adjusted annually based on the consumer price index, do not comply with the requirements of N.J.S.A. 26.2D-9(*1*). (6)

RESPONSE: The adopted fees are based directly on the Department's cost to provide the services for which the fees are charged. Subsequent adjustment by the Consumer Price Index, as the rules allow, is a reasonable projection of the anticipated increase in the Department's costs. In the event that the inflation adjusted fees do not keep pace with the Department's actual costs, the Department can propose amended fees in accordance with the requirements of the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq.

17. COMMENT: The term "full cost" is used in Tables 2 of N.J.A.C. 7:28-64.2, Schedule of Fees. No definition of full cost was provided in the proposal and it is unclear whether this fee will be annual or periodic. (6)

RESPONSE: As stated in the Summary at 40 N.J.R. 2359, and as provided in N.J.A.C. 7:28-64.4(d), the Department incorporates by reference the fee provisions of 10 CFR Parts 170 and 171 for the purpose of calculating fees. Since the NRC charges full cost for decommissioning, the Department also charges full cost which is consistent with the Legislative mandate in N.J.S.A. 26D-9(1). Full cost means that the Department will

assign unique job numbers to a licensee and staff will code their timesheets appropriately. The Department will then bill the licensee semi-annually for the cost incurred (based on the salary of the specific staff members that coded time, fringe and indirect costs, and support services such as laboratory costs).

18. COMMENT: The Department proposes to charge fees for non-routine inspections (at full cost) and license amendments, but the NRC incorporates the cost of these activities in its annual fee. It will be difficult for the regulated community to budget for unforeseen events. Including the costs of these items in the annual fee would reduce paperwork for the Department and the licensee. (3, 4, 7, 8)

RESPONSE: To ensure that the Department collects sufficient funds to administer and implement the Agreement State program, the Department investigated the fee structures of other Agreement States. The majority of the Agreement States charge full cost for non-routine inspections and a graduated cost for license amendments.

Under the adopted rules, there is no separate fee for license amendment requests that involve little staff time to complete, such as facility name changes, and removal of authorized users. The Department charges fees for amendments that require staff time to complete, for example a request to add isotopes, change procedures, add authorized users; or a request requiring a site visit, a facility move or addition of a process. By charging separate fees the Department is ensuring that the cost is passed on to only those licensees that use the service and not shared among all licensees. There would be only a slight reduction of paperwork for the Department if these fees were included in the annual fee because billing is performed automatically as part of the Department's Environmental Management database

19. COMMENT: Reconsider charging a fee to universities and non-profit institutions. The NRC does not currently charge a fee. (8)

RESPONSE: As stated in the Summary, 40 N.J.R. 2363, the NRC recovers the cost incurred for university and non-profit institutions from the Omnibus Budget Reconciliation Act of 1990, as amended. The NRC gets fee relief to offset the costs not recovered by these non-profit educational facilities. Unlike the NRC, the Department does not have a mechanism to receive fee relief for those activities for which is does not charge fees or charges reduced fees. The Department is required to recover 100 percent of the cost of services it provides. There is no statutory provision for such exemption of fees. Furthermore, if the Department were to continue the fee exemption for these facilities, it would have to spread the cost among all for profit and non-university licensees, who would incur a higher fee.

A fee for non-profit educational institutions is not new. The previous rules contained Department fees at N.J.A.C. 7:28-4.19 with no exemptions for non-profit educational institutuions.

20. COMMENT: There should not be a fee to non-profit educational institutions and private medical practices for non-contiguous additional use sites. Facilities with additional use sites within four miles of each other are now administered under a single Department license. Some universities have various sites across New Jersey, but all operate under the same NRC license. (4, 8)

RESPONSE: As stated in the Summary, 40 N.J.R. 2363, the Department considered the added costs to non-profit educational institutions and proposed relief by charging a reduced fee, or no fee, for certain additional use sites. Some colleges and universities have many buildings that are not adjacent or contiguous; that is, a campus may have buildings where radioactive materials are used that are more than five miles from the main facility that holds the radioactive materials license. In such cases, instead of charging the full fee, the Department is charging only 25 percent of the annual fee. In the case of the facility with an additional use site within four miles of the main facility, no additional use fee will be charged because there will be minimal additional cost to the Department to license and inspect facilities within five miles of each other.

In the case of a university with sites across the State, the additional use fee would be charged, and is appropriate, because the Department incurs additional expense by traveling throughout the State to perform inspections.

A comparison to the NRC license is not appropriate, since the NRC does not charge a fee to non-profit educational institutions.

Summary of Agency Initiated Changes

N.J.A.C. 7:28-1.1(b) is modified on adoption to add "install, handle, transport, store" to the list of activities that are governed by these rules. These terms were present in the previous rule and inadvertently deleted in the proposal.

N.J.A.C. 7:28-1.1(b) is also modified on adoption to make the rules applicable to all persons, rather than just those who are licensed or registered by the Department. Previous N.J.A.C. 7:28-1.1(b) has applied to "all persons installing, using, handling,

transporting or storing sources of radiation." Some of the categories of individuals who routinely install, use, handle, transport or store are not required to be registered or licensed by N.J.A.C. 7:28, yet are required to comply with the regulations. It is the intent of the Department and the Commission that the regulations apply to all individuals who come into contact with radiation sources. The proposed rules inadvertently limited the rules to registered or licensed individuals.

N.J.A.C. 7:28-6.1(d)6 is modified on adoption to delete redundant text.

N.J.A.C. 7:28-12.12(c)1ii is modified on adoption to clarify that there is determined to be substantial public interest in public outreach events related to restricted release license termination of contaminated sites if the Department receives a petition containing the signatures of 25 or more people. The proposal stated that the petition must contain the signatures of 25 people.

The Department and the Commission are modifying N.J.A.C. 7:28-12.15 on adoption to delete the requirement that no owner or licensee shall bury or construct an engineered barrier (cap) over radioactive material onsite unless the requirements of N.J.A.C. 7:28-12.8 and 12.11 are met. Proposed amended N.J.A.C. 7:28-12.15(a) could be interpreted as conflicting with the Technical Requirements for Site Remediation, N.J.A.C. 7:26E-5, Remedial Action Selection, and N.J.A.C. 7:26E-6, Remedial Action. Since the Site Remediation regulations regarding remedial actions are referenced in N.J.A.C. 7:28-12.6, Remedial action selection, and N.J.A.C. 7:28-12.7, Remedial action requirements, this modification will not destroy the intent of the original proposal, which was to prohibit capping or burial of radioactive material unless it met the dose requirements of N.J.A.C. 7:28-12.8 and 12.11 after remedial actions take place.

N.J.A.C. 7:28-17.4(k) is modified on adoption by replacement of the reference to a license with reference to a registration. This subchapter will regulate machine source radiography. Machine sources of radiation are registered with the State, not issued licenses.

N.J.A.C. 7:28-53.1(c) is modified on adoption to correct a cross reference.

N.J.A.C. 7:28-58.1(c)3 is modified on adoption to correct the punctuation. The beginning quotation marks are missing from the word "No," which will replace the wording to be deleted from the incorporated 10 CFR 40.6. The proposal did not clearly state that "No" will replace the deleted wording.

N.J.A.C. 7:28-59.1(c)18 is modified on adoption to correct the citation that will replace the CFR references being deleted. The correct citation should refer to N.J.A.C. 7:28-51 and N.J.A.C. 7:28-58.

N.J.A.C. 7:28-61.1(c)10 is modified on adoption to delete duplicative words.

N.J.A.C. 7:28-64, Table 1, Fee Category 7.C is modified on adoption to correct the punctuation by adding a period to the end of the sentence that concludes "...when authorized on the same license." The proposal had omitted the period.

N.J.A.C. 7:28-64.8 is modified on adoption by replacement of the word "application" with the word "letter." The proposal refers to applications for license amendments. There are no such applications. Requests for an amendment to a license will be in the form of a letter to the Department.

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 Department and the Commission are adopting new rules and amendments in order that the State's rules are compatible with the NRC regulations, so that New Jersey can become an Agreement State. Except as discussed below, the adopted rules and amendments do not exceed Federal standards.

The NRC regulations at 10 CFR 20.1401(d) require modeling to 1000 years; whereas, the adopted amendment at N.J.A.C. 7:28-12.10(d) requires modeling to the time of peak dose. The adopted amendment appears to be more stringent than the NRC regulations at 10 CFR 20.1401(d). However, in the NRC's response to comment on their proposed decommissioning regulations, 62 Fed. Reg. at 39083 (Response F.7.3), the NRC explains that the 1000 year provision is intended to apply only to short-lived nuclides. Short-lived nuclides are defined as having half-lives between 5.3 and 30 years and which would decay to unrestricted dose levels in about 10-60 years. (62 Fed. Reg. at 39069.) For long-lived nuclides, future calculations beyond 1000 years would be valuable. (62 Fed. Reg. at 39083.) Thus, the intent of 10 CFR 20.1401(d) is to require additional longer dose assessments, depending on the duration of the nuclides. Therefore, based on the regulatory intent of 10 CFR 20.1401(d), the adopted amendment to increase the time period of interest is not more stringent than the Federal regulation at 10 CFR 20.1401(d). The short-lived nuclides to which the 1000 years was intended to apply would have decayed to unrestricted levels by 1000 years. Accordingly, the

proposed rule is not more stringent than the Federal rule, and no further analysis is required.

Although the NRC rules do not require compliance with specific water quality standards, the adopted amendments to N.J.A.C. 7:28-12.8, which include adherence to the Surface Water Quality standards, can be compared to the NRC's requirement of an all pathways dose criterion. The "all pathways" requirement, as applied to surface water, means that surface water contamination that results in human exposure must be assessed as part of the 25 mrem/year dose criterion. Surface water that is contaminated with radiation could result in contaminated fish, contamination of irrigation water used for crops, and human exposure to radiation through recreational bathing. The Department does not require consideration of these pathways in dose assessments to demonstrate compliance with the Department's dose decommissioning criterion. By requiring adherence to the Surface Water Quality Standards, the Department and the Commission are both taking into account the potential dose that could result from contamination of surface water, resulting in no significant difference between the two approaches. Therefore, the adoption is consistent with the Federal rule and no further analysis is required.

Adopted Subchapter 55, medical use of radioactive materials, incorporates by reference the Federal rules at 10 CFR Part 35; however, the Department and the Commission are requiring licensees to use a dose calibrator before administering radiopharmaceuticals. NRC currently requires the use of this instrument 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 the

Commission 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.

The cost of a new dose calibrator is about $7,000. The cost of personnel time to use the calibrator is estimated to be about 40 hours per year, at a pay rate of about $33.00/hour (2006 pay rate obtained from the NJ Nuclear Medicine Technologist Board). The cost of personnel time to ensure that the calibrator is properly calibrated (a linearity check) may require a consultant, and is estimated to take about five hours per year at a pay rate of $50.00 per hour, for a total cost of $8,570.

The benefit from using a dose calibrator is the avoidance of administering an improper dose. The Department and Commission are aware of a reported incident in which 4 mCi of Thallium-201 were administered to a patient, instead of the prescribed dose of Tc-99m pertechnate. The administration resulted in a whole body dose of 5.2 rem, which could have been avoided had a dose calibrator been used. The NRC uses $2,000 per person-rem in its ALARA analyses. (Appendix N of NUREG-1757, Consolidated Decommissioning Guidance, Vol. 2, Rev.2.) Thus, the cost of the improperly administered dose was $2,000 times 5.2 rem, or $10,400. Even if only one misadministration happens per year, the benefit of the averted dose ($10,400) outweighs the cost of buying and using a new dose calibrator ($8,570).

In practice, the costs associated with this analysis are overestimated. The majority of medical facilities already possess dose calibrators and use them.

Full text of the adoption follows. Deletions from the proposed rule are shown by square brackets with asterisks *[thus]*. Additions to the proposed rule are shown by underline with asterisks *thus*.

SUBCHAPTER 1 GENERAL PROVISIONS

7:28-1.1 Purpose and Scope

(a) (No change.)

(b) This chapter applies to*all persons and* persons licensed or registered by the Department to receive, possess, use, transfer, *install, handle, transport, store,* or dispose of ionizing radiation producing machines, non-ionizing radiation producing sources, diffuse technologically enhanced naturally occurring radioactive materials, diffuse accelerator-produced radioactive materials, by-product, source, or certain special nuclear material or to operate a production or utilization facility under N.J.A.C. 7:28-51 through 60. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under N.J.A.C. 7:28-55.1, or to exposure from voluntary participation in medical research programs.

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

SUBCHAPTER 4 LICENSING OF DIFFUSE NATURALLY OCCURRING OR DIFFUSE ACCELERATOR PRODUCED RADIOACTIVE MATERIALS

7:28-4.1 Scope and general provisions

(a) (No change from proposal.)

(b) No person shall manufacture, produce, transfer, distribute or arrange for the distribution, sell, lease, receive, acquire, own, possess or use any diffuse naturally occurring or diffuse accelerator produced radioactive materials, including TENORM, in this State unless authorized by a specific license issued by the Department as provided by N.J.A.C. 7:28-4.7 and 4.8, a general license as provided in N.J.A.C. 7:28-4.5, or an exemption as provided in N.J.A.C. 7:28-4.3. *Excepted from this provision are by-product, source and special nuclear materials*.

(c) (No change from proposal.)

SUBCHAPTER 6. STANDARDS FOR PROTECTION AGAINST RADIATION

7:28-6.1 Incorporation by reference

(a) – (c) (No change from proposal.)

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

1. – 5. (No change from proposal.)

6. 10 CFR 20.1003, in the definition of "license," replace "parts 30 through 36,39, 40, 50, 60, 61, 63, 70, or 72," with "N.J.A.C. 7:28-4, 51 through *[56 through]* 60, or 63";

7. – 27. (No change from proposal.)

(e) (No change from proposal.)

SUBCHAPTER 12. REMEDIATION STANDARDS FOR RADIOACTIVE MATERIALS

7:28-12.8 Radiation dose standards applicable to remediation of radioactive contamination of all real property

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

(c) Radioactively contaminated surface water shall be remediated to comply with the New Jersey Surface Water Quality Standards, N.J.A.C. 7:9B*-1.14(c)6*.

7:28-12.11 Petition for alternative remediation standards for radioactive contamination

(a) In lieu of using the minimum remediation standards for radioactive contamination found at N.J.A.C. 7:28-12.9 or developed under N.J.A.C. 7:28-12.10, a person or licensee may petition the Department for an alternative remediation standard for radioactive contamination. Such an alternate remediation standard:

1. – 3. (No change from proposal.)

4. Shall not result in radionuclide in surface water levels exceeding those in the New Jersey Surface Quality Standards in N.J.A.C. 7:9B*-1.14(c)6.*

(b) – (h) (No change from proposal.)

7:28-12.12 Requirements pertaining to engineering or institutional controls

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

(c) A person responsible for conducting the remediation, or the licensee, shall conduct public outreach if the Department determines that outreach is needed, or when the Department determines that there is substantial public interest in activities concerning restricted release license termination.

1. The Department may determine that there is substantial public interest when it receives:

i. (No change from proposal.)

ii. A petition containing the signatures of 25 *or more* people that live or work within 200 feet of the extent of contamination, if contamination has migrated from the site boundary; or

iii. (No change from proposal.)

2. – 4. (No change from proposal.)

7:28-12.15 Requirements pertaining to onsite burial or capping

[(a) No owner or licensee shall bury or construct an engineered barrier (cap) over radioactive material onsite unless the requirements of N.J.A.C. 7:28-12.8 and 12.11 are met.]

[(b)] *(a)* (No change in text.)

[(c)] *(b)* (No change in text.)

SUBCHAPTER 17. INDUSTRIAL AND NON-MEDICAL X-RAY RADIOGRAPHY

7:28-17.4 Equipment control

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

(k) Each owner shall maintain current logs, which shall be kept available for inspection by the Department at the address specified in the *[license]* *registration*, showing for each radiation source the following information.

1. - 3. (No change from proposal.)

SUBCHAPTER 53. SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

7:28-53.1 Incorporation by reference

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

(c) The following provisions of 10 CFR Part *[30]* *32* are incorporated by reference with the specified changes:

1. - 16. (No change from proposal.)

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

SUBCHAPTER 58. DOMESTIC LICENSING OF SOURCE MATERIAL

7:28-58.1 Incorporation by reference

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

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

1. - 2. (No change from proposal.)

3. 10 CFR 40.6, delete "Except as specifically authorized by the Commission in writing, no" with *"*No," and replace "by the General Counsel" with "signed and approved by the Commissioner of the Department,";

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

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

SUBCHAPTER 59. LICENSING REQUIREMENTS FOR LAND DISPOSAL OF RADIOACTIVE WASTE

7:28-59.1 Incorporation by reference

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

(c) The following provisions of 10 CFR Part 61 are incorporated by reference with the specified changes:

1. - 17. (No change from proposal.)

18. 10 CFR 61.80(g), replace "§§30.55, 40.64" with "N.J.A.C. 7:28-51, *and* N.J.A.C. 7:28-58 *[and §§]*";

19. - 21. (No change from proposal.)

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

SUBCHAPTER 61. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

7:28-61.1 Incorporation by reference

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

(c) The following provisions of 10 CFR Part 71 are incorporated by reference with the specified changes:

1. - 9. (No change from proposal.)

10. 10 CFR 71.12, replace "Commission" with "Department, with approval of the Commission on Radiation Protection," and replace "by law and will not endanger life or property nor the common defense and security *[and security]*" with "in accordance with the provisions of N.J.A.C. 7:28-2.8";

(d) - (e) (No change to proposal.)

SUBCHAPTER 64. RADIOACTIVE MATERIALS LICENSE FEES

7:28-64.2 Schedule of fees

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

Table 1

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

FEE CATEGORY	LICENSE TYPE	ANNUAL FEE ($)
...		
7.	Medical	
A.	Licenses issued under subchapters 51, 55, 58, and 60 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.	10,125
B.	Licenses of broad scope issued to medical	21,615

institutions or two or more physicians under subchapters 51, 55, 58, and 60 of this chapter authorizing research and development, including human use of byproduct material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Separate fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Category 7.B. or 7.C.

C.	Other licenses issued under subchapters 51, 55, 58, and 60 of this chapter for human use of byproduct material, source material, and/or special nuclear material except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license*. * Separate fees will not be assessed for pacemaker licenses issued to medical institutions who also hold nuclear medicine licenses under Category 7.B. or 7.C.	3,600

...

7:28-64.8 Fees for license amendments

[An application for] *A letter requesting* an amendment to a specific license shall be accompanied by payment in full of the fee specified in Table 2 at N.J.A.C. 7:28-64.2.

Based on consultation with staff, I hereby certify that the above statements, including the Comparison with Federal Law Statement addressing the requirements of Executive Order 27(1994), and N.J.S.A. 52:14B-1 et.seq., permit the public to understand accurately and plainly the purpose and consequences of these adopted rules. I hereby authorize this adoption.

Date: _____

_____
Julie K. Timins, M.D., Chairperson
Commission on Radiation Protection

Based on consultation with staff, I hereby certify that the above statements, including the Comparison with Federal Law Statement addressing the requirements of Executive Order 27(1994), and N.J.S.A. 52:14B-1 et.seq., permit the public to understand accurately and plainly the purpose and consequences of these adopted rules. I hereby authorize this adoption.

Date: _____

_____
Lisa P. Jackson, Commissioner
Department of Environmental Protection