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DEPARTMENT OF ENVIRONMENTAL PROTECTION

ENVIRONMENTAL REGULATION

DIVISION OF ENVIRONMENTAL SAFETY AND HEALTH

COMMISSION ON RADIATION PROTECTION

Radiation Protection Programs

Proposed 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

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

Proposed 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.

Authorized By: Lisa P. Jackson,
Commissioner, Department of Environmental Protection
Julie K. Timins, M.D.,
Chair, Commission on Radiation Protection

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

DEP Docket Number: _____

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

Proposal Number:

Submit written comments no later than July 18, 2008 to:

Alice A. Previte, Esq.

Attn: DEP Docket Number _____

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New Jersey Department of Environmental Protection

Office of Legal Affairs

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The Department of Environmental Protection (Department) and the Commission on Radiation Protection (Commission) request that commenters submit comments on disk or CD as well as on paper. Submittals on disk or CD must not be access-restricted (locked or read-only) in order to facilitate use by the Department of the electronically submitted comments.

The agency proposal follows:

Summary

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

In 1958, the Radiation Protection Act (the Act), N.J.S.A. 26:2D-1 et seq., was enacted. The Act regulates the possession, handling, and use of sources of radiation within the State of New Jersey. The Act also created the New Jersey Commission on Radiation Protection (hereinafter, “Commission”) and vested in that body the power to promulgate rules and regulations as may be necessary to prohibit and prevent unnecessary radiation. Additionally the Act, at N.J.S.A. 26:2D-9, authorizes the Department to establish and charge fees for the services it performs under the Act.

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These fees have been established in previous rulemakings and reflect the actual or projected expenses incurred by the Department in performing the activities for which fees are charged.

Regulations implementing the Act were first promulgated in 1960 and the State began registering possessors of naturally occurring or accelerator produced radioactive materials (NARM). Accelerators use magnetic and electric fields to impart large kinetic energy to charged particles, such as electrons, protons, deuterons and helium ions. These particles bombard a “target” element, which transforms it into a radionuclide. These radionuclides are used primarily in nuclear medicine procedures, certain industries, and for research. Naturally occurring radioactive materials (NORM) include uranium, thorium, and radium and their progeny. These radionuclides are present in rocks, soil, and groundwater and are part of the earth’s natural environment. When any human activity increases the concentration of NORM or increases the potential for human exposure, they are then referred to as technologically enhanced radioactive materials (TENORM).

New Jersey has a comprehensive radiation protection program encompassing x-ray machines, 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 – radiologic technologists, nuclear medicine technologists, radon testers and mitigators, and qualified medical physicists.

Until the proposed new rules and amendments are implemented, New Jersey will continue to rely on the Federal government to license and regulate nuclear reactors and weapons grade material, and also sources of radiation, which are Atomic Energy Act (AEA) radioactive material. The United States Nuclear Regulatory Commission (NRC) regulates these AEA materials, which are source, special nuclear, and byproduct radioactive materials. Source material is defined by the NRC

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as uranium or thorium, or any combination thereof, in any physical or chemical form; or ores that contain by weight one-twentieth of one percent or more of uranium, thorium or any combination thereof. Special nuclear material is plutonium, uranium-233, or uranium enriched in the isotopes uranium-233 or uranium-235.

States have the option to assume responsibility for regulation of radioactive materials that are governed under the AEA through an agreement between the Governor of the state and the 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

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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 proposed 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.

In order to make the State's rules "adequate and compatible" with the Federal rules, as the Federal rules require an Agreement State's rules to be, the Department and the Commission propose to incorporate by reference substantial portions of the Federal rules. The Department and the Commission also propose to amend the existing rules to exclude State licensees from subchapters that will apply only to registrants of ionizing radiation-producing machines, to include those categories of materials that the NRC currently regulates, and to update the requirements regarding occupational exposures for both registrants and licensees, along with other changes described below. Throughout the proposed and amended rules, wherever the Department and the Commission incorporate the Federal rules by reference, or propose language that is based upon the Federal rules, the amendment is done in order that the rules are adequate and compatible with the Federal rules, which is necessary in order for New Jersey to become an Agreement State.

By becoming an Agreement State, New Jersey anticipates that its licensees will realize an economic benefit. Not only does the NRC regulate nuclear material, but it also develops guidance and information technology systems for the regulated community, and provides technical support, event follow-up, and an Integrated Materials Performance Evaluation Program. It also oversees the Agreement States, international activities, and undertakes activities with other Federal agencies, such as the Environmental Protection Agency (USEPA) and the Department of Energy. Ninety-six

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percent of the cost of running the NRC is paid by fees charged to licensees that are not in

Agreement States. The NRC does not have authority to impose fees on Agreement States and their licensees. Accordingly, as more states become Agreement States, the NRC's programs are supported by an increasingly smaller number of NRC licensees. Approximately 20 percent of existing licensees are not in Agreement States. Although the NRC is attempting to control the costs of processing licenses, it is still faced with escalating costs and fewer licensees to support the regulatory burden.

If New Jersey becomes an Agreement State, licensees in New Jersey that possess both NRC and State licenses under the existing system would no longer be subject to dual regulation. New Jersey would become the sole regulatory authority. Moreover, the proposed fees for licensees of AEA radioactive materials are less than the existing NRC fees, because the NRC is not able to pass its costs to licensees in Agreement States.

The Department and the Commission are proposing to amend the existing rules and add new subchapters so that existing licensees that have only an NRC license will find the transition to be practically seamless. Insofar as licensees with NRC licenses are concerned, the proposed rules will be almost identical to the existing Federal rules. Aside from decommissioning, there will be no major difference between what is now required by the NRC and what will be required by the State.

Registrants of ionizing radiation-producing machines will be affected by the proposed amendments on limiting and determining occupational dose and doses to members of the public. NRC licensees who administer radiopharmaceuticals will be required to use a dose calibrator each time a dose is administered, which the NRC does not now require.

The Department and the Commission intend that the proposed new rules and amendments will be operative when New Jersey becomes an Agreement State.

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A summary of the proposed new rules and amendments follows.

Subchapter 1: General Provisions

To become an Agreement State to regulate source, special nuclear, and byproduct material, which are currently regulated by the NRC, and to make the State's regulations compatible with the NRC's, the Department and the Commission propose to amend the purpose and scope of the rules at N.J.A.C. 7:28-1.1 to include the language used by the NRC at 10 CFR 20.1001 and 1002. The amended rule specifies that the regulations apply to people licensed or registered by the Department for activities involving radioactive materials, ionizing radiation-producing machines, or non-ionizing radiation producing sources, and establish regulations for the protection against radiation resulting from activities licensed or registered by the Department. The amended language indicates that the rules are applicable to licensees that possess or use source, by-product, and certain special nuclear materials. As in the existing rules, the rules also apply to licensees that possess or use diffuse NARM and ionizing radiation producing machines. Diffuse NARM is NARM that does not fall under the new NRC definition of byproduct material and would be regulated by the State, regardless of whether it becomes an Agreement State.

Definitions at N.J.A.C. 7:28-1.4 that have a corresponding definition used by the NRC at 10 CFR 20, are being deleted from Section 1.4 and incorporated by reference at N.J.A.C. 7:28-6, Standards for protection against radiation. "Background radiation," proposed to be deleted from N.J.A.C. 7:28-1.4(a), and "adult," "collective dose," "committed dose equivalent," "committed effective dose equivalent," "deep-dose equivalent," "dose or radiation dose," "effective dose equivalent," "member of the public," "minor," "reference man," "stochastic effects," "total effective dose equivalent," "unrefined and unprocessed ore," and "very high radiation area" at N.J.A.C. 7:28-

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1.4(b) are proposed to be deleted. The proposed definitions of the terms at N.J.A.C. 7:28-6, which are incorporated by reference from the Federal rules, are identical to the existing definitions at N.J.A.C. 7:28-1.4. The definition of "unrefined and unprocessed ore" is proposed to be deleted from N.J.A.C. 7:28-1.4(b) because there is a definition of the term in the Federal rules.

The definitions of "absorbed dose," "ALARA," "controlled area," "dose equivalent," "occupational dose," "person," "radiation area," and "survey," at N.J.A.C. 7:28-1.4(a) and "airborne radioactivity area," "byproduct material," "curie," "declared pregnant woman," "high radiation area," "license," "licensee," "monitoring," "public dose," "rad," "rem," "sealed source" (discussed in the summary for N.J.A.C. 7:28-51), "source material," "special nuclear material in quantities not sufficient to form a critical mass," and "weighting factor," at N.J.A.C. 7:28-1.4(b) are proposed to be deleted, and replaced at N.J.A.C. 7:28-6.1 with Federal definitions that are not identical to the existing definitions. None of the incorporated Federal definitions at proposed N.J.A.C. 7:28-6.1, except "byproduct material," "occupational dose," "high radiation area," "radiation area," and "weighting factor," expand or diminish the scope of the terms; they are being amended to include new International System (SI) units, to delete references to NRC regulated material, or are wording changes that clarify the meaning of the term.

The proposed incorporated definition of "byproduct material" at N.J.A.C. 7:28-6.1 incorporates discrete sources of NARM into the definition, as mandated by the Energy Policy Act of 2005. This definition includes discrete sources of NARM. Since the Department already regulated these radioactive materials, there will be no impact on the public or the regulated community.

The proposed incorporated definition of "occupational dose" at N.J.A.C. 7:28-6.1 allows the exclusion of doses received from voluntary participation in medical research programs. Under the

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existing definition, this type of exposure would be added to the occupational dose since it was not specifically excluded. This added exclusion is not expected to have a significant impact on the calculation of occupational doses.

An additional qualifier is included in the incorporated definition of "high radiation area" at N.J.A.C. 7:28-6.1. Whereas the existing definition at N.J.A.C. 7:28-1.4 defined a high radiation area as levels that a major portion of the body could receive in excess of 100 millirem per hour, the proposed incorporated definition defines it as 100 millirem in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates. This could have the effect of expanding posting requirements because dose rates decrease rapidly as one increases the distance from the source. Under the existing definition the surveyor could pick any distance from the source, presumably, where the worker would spend the most time, which may drop the dose rate to under 100 millirem per hour. Under the proposed incorporated definition, the surveyor would need to measure the dose rate 30 cm from the source, which may cause the previously measured dose rate to increase above 100 millirem per hour, thereby requiring posting. This is not expected to have a significant impact, since it is the practice of most health physicists to err on the side of caution, and measure the dose rate close to the source.

The proposed incorporated definition of "radiation area" at N.J.A.C. 7:28-6.1 does not contain an alternate condition for posting (100 millirem in any workweek) that the existing definition contains. Without the alternate condition, certain licensees or registrants could relax the posting of radiation areas required under Subchapter 6 (for licensees) or Subchapter 10 (for registrants). It is not expected that this will have a significant impact to workers or the public, since there is still a requirement to post based on 5 millirem per hour, and because there are no existing licensees or registrants that have dose rates consistently at this level. The proposed

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incorporated definition has no reference to nonionizing radiation. As such, a new definition of "radiation area," which definition applies only to nonionizing sources, is proposed to be added to Subchapter 48, Fees for the registration of nonionizing radiation producing sources.

The proposed definition of "registrant" is being amended to explicitly state that it applies to radiation-producing machine sources of radiation.

The proposed incorporated definition of "weighting factor" at N.J.A.C. 7:28-6.1 allows the use of other weighting factors for external exposure, which would be approved on a case-by-case basis until such time as specific guidance is issued. There is still some uncertainty in the field of radiation protection regarding weighting factors for certain types of radiation. The proposed definition would allow the use of other factors if international or national radiation organizations came out with recommendations before the Federal regulations are revised. The Department would not approve other weighting factors without a strong justification. It is unknown if the impact would be to allow more radiation dose or less, since there haven't been any such recommendations to date.

The Department is proposing to define the terms "semi-annually" and "annually" that appear in the chapter and to define specific time periods within which testing and or record keeping must be performed. The Department is proposing these definitions to clarify the intention of the regulatory requirements for record keeping and/or quality control testing. For example, in Subchapter 22, "Quality Assurance Programs for Medical Diagnostic X-ray Installations," various quality control tests are required to be performed at specified intervals to ensure that quality assurance is "continually implemented" by regulated facilities.

The existing definitions of "State license," and "State licensee" at 1.4(a) are proposed to be deleted because the proposed amended rules do away with the need to distinguish between NRC

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and State licensees. Wherever the terms appear in the rules, they will be replaced with “license” and “licensee.”

Proposed new definitions at N.J.A.C. 7:28-1.4(b) are "domestic sewage," "domestic treatment works," and "sewage sludge," which are the same as the definitions of the terms in the Department’s New Jersey Pollutant Discharge Elimination System regulations at N.J.A.C. 7:14A-1.2.

The term "medical radiographer" is proposed to be deleted. The term is not used in the existing or proposed amended rules.

The terms “sanitary sewer system” and “residuals” are being deleted. The Department and the Commission instead propose to substitute the terms "domestic treatment works" and "sewage sludge," respectively, throughout the chapter, in order that the terms are consistent with the Department’s Bureau of Pretreatment and Residuals’ regulations at N.J.A.C. 7:14A.

The definition of “radioactive materials registrant” refers to those persons who hold a general license and must also register their activities with the State, as referenced in 10 CFR 31, incorporated by reference in N.J.A.C. 7:28-52. These facilities will be licensed by the State once New Jersey becomes an Agreement State. The definitions of “radiographer” and “radiographer’s assistant” are proposed to be amended to reflect that they will only apply to those people conducting radiographic operations with radiation-producing machines. Definitions applicable to radiographic operations using radioactive materials are found in the Federal regulations proposed to be incorporated by reference at N.J.A.C. 7:28-63. The definition of "radiography" is proposed to be amended to provide that only ionizing radiation-producing machines are utilized in the described examination, eliminating "sealed sources" as being used in an examination.

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The Department and the Commission propose to amend N.J.A.C. 7:28-1.5(a) to include a general telephone number, fax number, website address, and to delete an emergency telephone number that is no longer operational.

Subchapter 2: Use of Sources of Ionizing Radiation and Special Exemptions

Proposed new N.J.A.C. 7:28-2.13 allows the Department to obtain an injunction or court order to prevent a violation of the Radiation Protection Act, N.J.S.A. 26:2D-1, et seq., or any regulation or order issued under the Radiation Protection Act. The proposed rule also authorizes the Department to impose civil penalties for violations of this chapter, or the terms of any license. This language is consistent with the Federal rule at 10 CFR 20.2401. The existing related language with similar provisions is located in N.J.A.C. 7:28-4.16 which, as proposed to be amended, would apply only to licensees of diffuse NARM. The authority to obtain an injunction or court order to prevent a violation of the Radiation Protection Act is given in N.J.S.A. 26:2D-13. A violation of the Radiation Protection Act is also subject to criminal sanctions. (See N.J.S.A. 26:2D-22.)

Subchapter 3: Registration of Ionizing Radiation-Producing Machines

The Department and the Commission propose to amend N.J.A.C. 7:28-3.1(a) and (b) to delete the requirement to register NRC-licensed material. The heading of the subchapter is also proposed to be amended to be consistent with the proposed amended rule. Once it becomes an Agreement State, New Jersey will have the authority to license material that the NRC currently licenses. As such, the registration of such materials will no longer be necessary. The requirement to register ionizing radiation-producing machines will be retained.

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The Department and the Commission are proposing to delete N.J.A.C. 7:28-3.2(d) through (f) because these subsections all deal with the registration of radioactive material currently license by the NRC. When New Jersey becomes an Agreement State, such registration will no longer exist. For the same reason, the Department and the Commission propose to repeal N.J.A.C. 7:28-3.5 and 3.8 and reserve these sections. Once New Jersey becomes an Agreement State, registration of radioactive byproduct material, source material, or certain special nuclear material will no longer be necessary.

References to the transfer of registrations of radioactive material are proposed to be deleted from N.J.A.C. 7:28-3.6, since such registrations will no longer exist. Regulations concerning the transfer of registrations for ionizing radiation-producing machines will remain.

The Department and the Commission are proposing to remove the references to radioactive materials at N.J.A.C. 7:28-3.10. The section addresses the denial of applications for registration, as well as the suspension, modification or revocation of such registrations. The section will apply only to radiation-producing machines, once Agreement State status is achieved. Registrations of other radioactive materials, and the denial, suspension, modification, and revocation of those registrations, will no longer be necessary.

The Department and the Commission are proposing to repeal N.J.A.C. 7:28-3.11, and reserve the section. This section contains the table of radioactive materials and quantities exempt from registration. There is no need for this table once registration of radioactive materials ceases to exist.

N.J.A.C. 7:28-3.13 is proposed for repeal. It contains the fees related to the registration of radioactive material. There will be no need for the table if registration of radioactive materials is no longer required, as proposed.

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Subchapter 4: Licensing of Diffuse Naturally Occurring or Diffuse Accelerator Produced

Radioactive Materials

The Department and the Commission propose to amend Subchapter 4, and its heading, so that it applies only to diffuse sources of NARM. Because Congress amended the Energy Policy Act to change the definition of byproduct material to include discrete sources of NARM, the State must have regulations that encompass diffuse sources of NARM, in order that these sources are regulated.

Diffuse NARM is a radionuclide that has become concentrated, but not for the purpose of use in commercial, medical, or research activities. An example of diffuse NARM is the concentrated naturally occurring radioactive materials in a waste pile from a mineral extraction facility. In the process of extracting one or more non-radioactive minerals from soil, the naturally occurring radioactive materials become concentrated above licensing criteria in the waste pile. Because the waste has no use in commercial, medical, or research activities, it is not discrete and, therefore, not regulated under Federal (or Agreement State) authority.

The existing subchapter applies to all sources of NARM. Once the Federal Energy Policy Act of 2005 goes into effect in August 2009, NARM materials that the NRC would otherwise regulate will be regulated by the Agreement States, including New Jersey. The appropriate Federal regulations are incorporated throughout the chapter for that purpose. However, diffuse NARM is not a NRC-regulated material, and is not included in the Agreement State rules. Therefore, the State must amend its regulations in order that they apply to diffuse NARM. Therefore, the Department and the Commission are proposing to amend N.J.A.C. 7:28-4.1 to insert the word "diffuse" before accelerator produced and naturally occurring radioactive materials.

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The Department and the Commission are proposing to delete the phrase "except from this provision are byproduct, source, and special nuclear material." This phrase is no longer necessary because this subchapter applies only to diffuse NARM. Regulation of byproduct, source, and special nuclear material are addressed in the Federal rules that are proposed to be incorporated by reference elsewhere in these proposed rules.

The Department and the Commission are proposing to amend N.J.A.C. 7:28-4.2 in order to be consistent with the Federal regulations incorporated by reference at Subchapter 62 regarding New Jersey's reciprocity policy for recognition of licenses from other jurisdictions for other than diffuse NARM. If a licensee has a license from the NRC or another state, New Jersey proposes to grant a general license, to last no more than 180 days in any 12 month period, to allow the licensee to transport, receive, possess, or use the radioactive materials specified in such license within this State. In order to receive this general license, the licensees must notify the Department three days in advance of the date the general license is to take effect. Also, the Department will review the license conditions of the issuing authority to ensure that they meet New Jersey requirements before the general license is issued.

The existing rule allowed licensees from other jurisdictions to work only 20 days in New Jersey, and required notice to the Department two days in advance. This issuance of a general license, the increased amount of time that a licensee is allowed to work in the State, and the three days advance notice are all being amended to match the Federal rule at 10 CFR 150.20.

The proposed amendments to N.J.A.C. 7:28-4.3 limit the exemption provision to diffuse NARM, consistent with the proposed amendments to N.J.A.C. 7:28-4.1, discussed above. The proposed amendments also delete paragraph (a)4 that addresses material that the NRC has

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categorized as byproduct material (radium dials and watches), which falls under the NRC rules that are being incorporated by reference elsewhere in the proposed rules. The remaining paragraphs are proposed to be renumbered, and cross-references corrected. The exempt concentration table in N.J.A.C. 7:28-4.3(b) had an error in the footnote indicator for Column 2. One of the asterisks is proposed to be removed in the table to match the corresponding footnote.

The Department and the Commission are proposing to amend N.J.A.C. 7:28-4.4 and 4.5 to limit the their applicability to diffuse NARM. Under the existing rules, the licenses available under the section were for all naturally occurring or accelerator produced radioactive materials, not limited to diffuse NARM. As discussed above, once amendments to the Energy Policy Act take effect, the State will regulate diffuse NARM (under Subchapter 4), and source, byproduct (which will include NARM), and certain special nuclear material under the Federal regulations incorporated by reference. Reference to the testing of devices containing tritium and krypton is being deleted. Since the proposed amendments to N.J.A.C. 7:28-4.5 will limit its applicability to diffuse sources of NARM, it will no longer be applicable to these devices. Any required testing of these devices would fall under the Federal regulations incorporated by reference. N.J.A.C. 7:28-4.5(g)7 is proposed to be amended to correct cross-references to the new Subchapter 6, which incorporates licensee requirements for recordkeeping and reporting.

The proposed amendments to N.J.A.C. 7:28-4.6 limit the application of the section to diffuse sources of NARM, for the reasons discussed above. The Department and Commission propose to delete existing (e), which applies to material that is proposed to fall under the NRC regulations that are incorporated by reference elsewhere in the proposed rules. The proposed amended rule extends the validity of a license from five years to 10 years, in order to be compatible with the Federal regulations incorporated by reference elsewhere in the proposed rules. Licenses are updated

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periodically by license amendments, and inspections are performed throughout the period of the license, so extending the length of time that a license is valid does not limit the Department's ability to oversee all aspects of the licensee operations. The remaining subsections are proposed to be renumbered. A cross reference is proposed to be corrected at amended N.J.A.C. 7:28-4.6(g) to the new fee schedule at proposed N.J.A.C. 7:28-64.

The proposed amendments to N.J.A.C. 7:28-4.7 also limit the application of this section to diffuse sources of NARM. Additionally, the Department and Commission propose to delete those subsections that address training requirements for use of NARM, which will be addressed at proposed new Subchapter 55.

Proposed amendments to N.J.A.C. 7:28-4.8 limit the application of the section to diffuse NARM, and delete subsections that deal with NARM. The proposed amendments to N.J.A.C. 7:28-4.9 correct cross-references and delete subsection (f), which relates to reports of transfers of devices containing material to licensed individuals. The Department and Commission propose new reporting requirements for source, byproduct (which will include discrete NARM), and special nuclear material at N.J.A.C. 7:28-51 and 52, which are proposed to conform to the Federal requirements.

The Department and Commission propose to amend N.J.A.C. 7:28-4.13 to correct the cross-reference to recordkeeping. Recordkeeping requirements for licensees are proposed to be located in new Subchapter 6.

The Department and the Commission propose to add financial assurance requirements for licensees of diffuse NARM at proposed new N.J.A.C. 7:28-4.16. These requirements will be incorporated by reference from the NRC regulations at 10 CFR 30.35, with proposed amendments to replace "byproduct material" with "diffuse NARM," and to replace the requirement to comply

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with Subpart E of 10 CFR Part 20 with Subchapter 12. The amount of the financial assurance for decommissioning varies, depending on the quantity of byproduct material to be decommissioned. The financial assurance amounts range from \$113,000 to \$1,125,000, which must be made by prepayment; insurance or other surety or guarantee; a sinking fund to which payments are made every year, combined with a surety method or insurance; a statement of intent, which contains a cost method (for Federal, State or local government licensees only); or, when a government entity is assuming custody and ownership of a site, a financial assurance arrangement that is deemed acceptable by the government entity.

A licensee must keep records of information important to the decommissioning of the facility. The records must be kept until the site is released for unrestricted use; therefore, the licensee must transfer the records to a new licensee if the facility is sold or another licensee becomes responsible for it. Among the necessary records are information on spills or other activity that involves the spread of contamination; drawings of structures and equipment in areas where radioactive materials are used and or stored; locations of buried pipes that may be subject to contamination; and a list of certain restricted areas, areas where waste has been buried, and the location of areas containing material such that that the licensee would be required to decontaminate the area or dispose of the material if the license were to expire.

The Department and the Commission propose to amend N.J.A.C. 7:28-4.17 and 4.18 to correct numbering.

The existing fee schedule for State licensees at N.J.A.C. 7:28-4.19 is proposed to be repealed. Fees will be addressed in proposed new Subchapter 64, discussed below.

Subchapter 5: Controlled Areas for Registrants

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The Department and Commission propose to amend the heading of the subchapter and its headings to specify that this subchapter applies only to registrants. N.J.A.C. 7:28-5.1 through 5.3 are proposed to be amended to remove all references to radioactive materials or licensees. The Department and the Commission propose to repeal N.J.A.C. 7:28-5.4 because it applies only to licensees. Requirements for controlled areas for licensees are included in proposed new Subchapter 6.

Subchapter 6: Standards for Protection Against Radiation

The Department and the Commission propose to repeal N.J.A.C. 7:28-6, Dose Limits, which contains occupational limits to individuals in controlled areas, dose limits for members of the public, allowed concentrations in effluents from controlled areas, exposure limits for workers in the event of radiation incidents or emergencies, and dose limits for an embryo/fetus. All of these requirements, except exposure limits for workers in the event of radiation incidents or emergencies, are proposed to be replaced by comparable provisions from the Federal rule at 10 CFR Part 20, Standards for Protection against Radiation, incorporated by reference at proposed new Subchapter 6 and are discussed below. The proposed heading of the new subchapter reflects the new content.

Existing N.J.A.C. 7:28-6.4, regulating exposures in the event of radiation incidents or emergencies, is proposed to be deleted even though there is no corresponding requirement at 10 CFR Part 20. Doses received during accidents and emergencies are addressed at 10 CFR 20.1201(d), in that they must be subtracted from the limits for planned special exposures that the individual may receive during the current year or during the individual's lifetime. "Table 1, Occupational Values" from 10 CFR Part 20, Appendix B, will apply instead of the table of average concentrations used for occupational dose calculations at existing N.J.A.C. 7:28-6.5(a).

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The permissible annual occupational exposure limit will remain at 50 millisievert (5000 millirem) per year, as in the existing rules. However, the incorporated Federal rules contain the current methodology used by the NRC. Accordingly, the State will no longer rely upon an outdated methodology to calculate exposure. The proposed new rule remains consistent with the National Council on Radiation Protection's (NCRP) recommendation that exposure of occupational workers be limited to an annual effective dose of 50 millisievert (5000 millirems).

In proposed new Subchapter 6 and every proposed new subchapter that incorporates NRC provisions, the Department and the Commission propose to substitute appropriate references to the New Jersey Administrative Code for the references to the Code of Federal Regulation (CFR) in the Federal rules. Also, the terms "NRC" and "Nuclear Regulatory Commission" shall mean the Department.

The Department and the Commission do not propose to incorporate 10 CFR 20.1001, Purpose, and 10 CFR 20.1002, Scope. Language from these Federal rules was included in proposed amended N.J.A.C. 7:28-1.1(b) and (c).

The Federal rule at 10 CFR 20.1003 sets forth the definitions of proposed new Subchapter 6. The Summary of Subchapter 1, above, discusses the definitions that were formerly contained at Subchapter 1, and are proposed to be incorporated into Subchapter 6 from 10 CFR 20.1003. In addition to those definitions discussed above, the Department and Commission propose to incorporate "accelerator-produced radioactive material," "activity," "air-purifying respirator," "annual limit on intake," "assigned protection factor," "atmosphere-supplying respirator," "bioassay," "class," "constraint," "critical group," "decommission," "demand respirator," "derived air concentration," "discrete source," "disposable respirator," "distinguishable from background," "dosimetry processor," "embryo/fetus," "entrance or access point," "exposure," "external dose,"

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"extremity," "filtering facepiece," "fit factor," "fit test," "generally applicable environmental radiation standards," "government agency," "gray," "helmet," "hood," "individual," "individual monitoring," "individual monitoring devices," "internal dose," "lens dose equivalent (LDE)," "limits (dose limits)," "loose-fitting facepiece," "lost or missing licensed material," "nationally tracked source," "negative pressure respirator (tight fitting)," "nonstochastic effect," "particle accelerator," "planned special exposure," "positive pressure respirator," "powered air-purifying respirator (PAPR)," "pressure demand respirator," "qualitative fit test (QLFT)," "quality factor (Q)," "quantitative fit test (QNFT)," "quarter," "radiation (ionizing radiation)," "respiratory protective device," "restricted area," "self-contained breathing apparatus (SCBA)," "shallow-dose equivalent," "sievert," "site boundary," "special nuclear material," "supplied-air respirator (SAR)," "tight-fitting facepiece," "uranium fuel cycle," "user seal check (fit check)," "waste," "week," "whole body," "working level (WL)," "working level month (WLM)," and "year."

The Federal rule at 10 CFR 20.1006 identifies the nonbinding nature of interpretations unless they are in signed and approved by the Commissioner of the Department. The Department deleted the reference to interpretations by the General Counsel, which is a Federal entity.

The Federal rule at 10 CFR 20.1007 has not been incorporated by reference since it applies to communications with the NRC. Amended N.J.A.C. 7:28-1.5 provides the methods of communicating with the Department.

The Federal rule at 10 CFR 20.1008 concerns the implementation of regulations pertaining to protection against radiation as they pertain to previously issued licenses and regulations. Under this rule, the New Jersey rules apply in lieu of any license condition that cites to the NRC rules in effect prior to January 1, 1994, unless the license condition is more restrictive or less restrictive than the New Jersey rule, or the condition specifically exempts a licensee from a requirement in the

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rules. Only NRC-issued licenses contain citations to NRC rules in effect prior to January 1, 1994.

Therefore, this section applies only to NRC-issued licenses, not to licenses that were issued by the State.

If the license has more stringent conditions than are required under the New Jersey rules, then the conditions remain in effect until the license is amended. If the license has less stringent conditions, then the more stringent conditions in the rules apply, unless they are specifically exempted. If the license specifically exempts a licensee from a requirement in the rules, then the exemption remains in effect. If the license contains a condition that was in the NRC rules prior to January 1, 1994, but is not in the New Jersey rules, then the condition remains in effect until the license is amended or renewed, or there is a technical specification change. A technical specification refers to binding operating parameters mostly applicable to nuclear reactors. The term is being retained for consistency with the Federal rules.

The Federal rule at 10 CFR 20.1009 is not being incorporated by reference because it refers to Federal information collection requirements, which are not binding on the State. The NRC rules contain similar provisions in several of the Parts that the Department and Commission propose to incorporate by reference into the proposed new subchapters, discussed below. In each proposed new subchapter, the Department and Commission propose to specifically exclude the Federal information collection requirements.

The Federal rule at 10 CFR 20.1101 applies to radiation protection programs that the Department will require licensees to develop. Radiation protection programs ensure compliance with occupational and individual dose limits. In addition, the programs must demonstrate that these doses are “as low as reasonably achievable” (ALARA). Although the ALARA requirement is not in the existing regulations, it is routinely included as a licensing condition in almost all radioactive

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materials licensees, and is modeled after the NRC program. Addition of this requirement in the regulations is not expected to have a significant impact to the existing State licensees. The Federal rule at 10 CFR 20.1101(d) also has a constraint on air emissions of 10 mrem (0.1 millisievert) per year. Existing State licensees do not have this constraint imposed on them by regulations; however, the only State facilities that have air emissions are production facilities for Positron Emission Tomography (PET) radionuclides, and some of them have voluntarily demonstrated compliance with the 10 mrem/y constraint. There are currently six such facilities that do not have NRC licenses. Based on the modeling performed by the facilities that have demonstrated compliance, no facility would exceed the 10 mrem/y constraint, because the nuclides involved have such short half-lives.

The Federal rule at 10 CFR 20.1201 provides occupational dose limits for adults. Existing N.J.A.C. 7:28-6.1 has an outdated method of determining doses and uses outdated limits. The rule proposed to be incorporated by reference has an occupational dose limit of 5000 millirem per year total effective dose equivalent. Total effective dose equivalent takes into account both internal and external irradiation of the body. Equal absorbed doses of radiation may not result in equal risks of a given biological effect due to the fact that there may be differences in the type of radiation, the part of the body that is irradiated, or the irradiation conditions. The proposed new occupational dose limits and the new method to calculate dose presented in the incorporated rule take these factors into account.

Whether the existing rule is more or less stringent than the proposed new rule depends on what nuclides are involved and how the body is irradiated; however, it is certain that the proposed method is a more accurate way of determining dose. The existing method of determining occupational dose is outdated by more than 30 years. The science of radiation protection has

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improved, so the Department is updating these outdated methodologies of determining dose. In order for the incorporated Federal rules to apply to the State's registrants of ionizing radiation-producing machines, the Department proposes to amend the Federal language to include licensees and registrants where indicated.

The Federal rule at 10 CFR 20.1202 describes the compliance requirements for the summation of external and internal doses. These requirements are not applicable to registrants because ionizing radiation-producing machines produce only external doses. Licensees are allowed several ways to determine internal dose including comparing individual concentrations of radionuclides with the annual limit on intake (ALI) and performing a sum of the fractions, dividing the derived air concentrations (DAC) by 2000 hours (40 hours per week times 350 days per year), or using actual bioassay data. The requirements also specify that licensees need to account for doses from oral ingestion greater than 10 percent of the applicable oral ALI, and intake through wounds or adsorption through skin.

The Federal rule at 10 CFR 20.1203 requires licensees to determine external dose from airborne radioactive materials based upon measurements using instruments or individual monitoring devices. The existing rule does not have a similar specific requirement, although it is implied that external doses from airborne radioactive materials should be taken into account when determining occupational dose. The proposed new section provides licensees with more direction, such as when to use monitoring devices and instruments to measure deep-dose equivalent in order to determine accurate doses to the worker.

The Federal rule at 10 CFR 20.1204 provides for ways to determine internal exposure for the purpose of assessing dose, which include determining the concentrations of radioactive materials in air in work areas, determining the quantities of radioactive material in the body or

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excreted from the body, or a combination of these measurements. In cases where there exists specific information on the physical and biochemical properties or the radionuclides taken into the body that are different than the assumptions used to determine the ALI and/or DAC, then the upon approval by the Department, the licensee may use that information to calculate the committed effective dose equivalent. This section also provides for methods to use to determine compliance when more than one radionuclide is involved and when concentrations of some of the radionuclides are unknown. Some ALIs and DACs were determined based on their nonstochastic organ dose. This section allows the use of the stochastic ALI or DAC (given in parenthesis in Appendix B Table 1, Column 2 for some nuclides) provided the sum of the deep-dose equivalent and the committed dose equivalent to any organ or tissue other than the lens of the eye must be less than or equal to 50 rems (0.5 Sv).

The existing rules contains air concentration limits, but the limits were derived using the old methodology and are outdated. The proposed new method of determining internal exposure is more accurate and uses the committed effective dose equivalent, which takes into account the effectiveness of biological damage from the type of radiation and the organ or organs that are being exposed. The proposed new method averages the doses throughout the tissue in the 50 years after intake of a radionuclide into the body. The existing rules do not have any provisions for this type of dose determination, and could result in an inaccurate recording of dose. The Department does not anticipate that this proposed new rule will have a significant effect on the current State licensees because none of them operate at levels near the current limits.

The Federal rule at 10 CFR 20.1206 addresses requirements to authorize a planned special exposure to a worker. In exceptional circumstances, in order to allow certain tasks to be performed, it may be necessary, on rare occasions, to permit a few workers to receive a planned special

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exposure. Exceptional circumstances may be related to preventing prolonged exposures to workers or members of the public by repairing damaged safety devices or systems. For example, a source may get stuck in a position in which no shielding is provided. A worker may have to get exposed beyond the occupational limit in order to determine the cause and rectify the situation. In a planned special exposure, a worker is authorized to receive doses in addition to, and accounted for separately from the doses received under the limits specified in 10 CFR 20.1201. The proposed new section requires the licensee to inform the individual of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task for which the planned special exposures are being imposed. In addition, prior occupational doses must be documented, and the special exposures cannot result in more than double the proposed occupational standards in one year or five times the proposed occupational standards during the individual's lifetime. The existing rules allow doses in excess of the occupational limits, but without specific informed consent, and no mention of exceptional circumstances.

The Federal rule at 10 CFR 20.1207 provides for the occupational dose limits for minors, which are 10 percent of the annual dose limits for adult workers specified in 10 CFR 20.1201. Because the determination of dose is calculated differently than under the existing rule, the proposed new provisions provide a more accurate account of doses allowed for minors. Because this section applies to registrants as well as licensees, the Federal language is proposed to be changed to include licensees and registrants.

The Federal rule at 10 CFR 20.1208 provides for dose limits to an embryo/fetus. These proposed new limits are the same as in existing N.J.A.C. 7:28-6.6. The Department and Commission propose to expand the incorporated Federal rule to include registrants.

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The existing rule at NJAC 7:28-6.2, governing dose limits for individual members of the public, is based upon the Federal rules at 10 CFR 20.1301. Accordingly, the proposed new rule, which incorporates the Federal rule by reference, imposes the identical requirements on the regulated community, with the exception of an additional requirement that references the USEPA's environmental radiation standards at 40 CFR Part 190. A licensee must comply with both the NRC and the USEPA standards, if the licensee is subject to 40 CFR Part 190. As in the existing rule, the total effective dose equivalent from licensed or registered operations may not exceed 100 mrem in a year, exclusive of dose contributions from background radiation, any medical administration the individual has received, from exposure from other individuals who have been administered radioactive material and released under 10 CFR 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into domestic treatment works in accordance with 10 CFR 20.2003. As in the existing rule, this section also provides for limits on dose rates for unrestricted areas, and an allowance to receive doses up to 500 mrem per year when visiting an individual who has been administered radioactive material, but cannot yet be released under 10 CFR 35.75, or by demonstrating the need for and expected duration of operations in excess of 100 mrem/y as well as the requirement to maintain doses ALARA.

The Federal rule at 10 CFR 20.1302 provides the methods by which a licensee can demonstrate compliance with the proposed dose limits for individual members of the public. These methods include surveys in unrestricted and controlled areas and/or measurements of radioactive effluents. The proposed rule does not prescribe the method of taking measurements. It allows calculations to be substituted for measurements, and allows licensees the flexibility of applying site specific conditions to ensure compliance with the effluent limits. For example, if the aerosol size of a specific airborne emission is significantly different than the size assumed to derive the effluent

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limits in Appendix B of 10 CFR Part 20, which is incorporated by reference, then the licensee is allowed to adjust the effluent limits upon approval by the Department. This may have the effect of raising the effluent limit; however, the allowed total effective dose would not change. Unlike the proposed incorporated Federal rule, the existing rule does not specify how to demonstrate compliance with the public dose limit, other than effluent concentration limits.

The Department is not incorporating the Federal rules at 10 CFR 20.1401 through 1405, which are the radiological criteria for license termination. The Department's rules on decommissioning are at N.J.A.C. 7:28-12 and are discussed in the Summary for Subchapter 12, below.

The Federal rule at 10 CFR 20.1406 provides for minimization of contamination. This section requires licensees to describe in their application how the design of the facility and procedures for operations will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, radioactive waste. The existing rules for State licensees do not have such a requirement, but minimizing contamination is a basic element of existing practices of radiation safety by all licensees.

The Federal rule at 10 CFR 20.1501 sets forth general requirements for radiation surveys and personnel monitoring. The existing rule does not have general requirements for licensees to perform surveys to ensure compliance with the regulations. The proposed incorporated section requires that instruments be calibrated periodically. Although this is routinely included as a license condition, there is no specific requirement in the existing rules that the instruments must be calibrated. Dosimeters are devices that monitor exposure to radiation. Some devices need to be sent to a processor for results, while others, such as self reading dosimeters, can be read instantly.

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When the dosimeter needs to be sent to a processor, the section proposed to be incorporated by reference requires that it be sent to a dosimetry processor that holds a current personnel dosimetry accreditation from the National Voluntary Accreditation Program (NVLAP) of the National Institute of Standards and Technology. The existing rules have no such requirement.

The Federal rule at 10 CFR 20.1502 identifies conditions under which a licensee must monitor exposures to external and internal radiation of workers. These conditions are different for different individuals. For example, a licensee must supply and require the use of monitors for adult workers expected to receive, in one year, from radiation sources external to the body, in excess of 10 percent of the limits in N.J.A.C. 7:28-6.1(a); and for minors likely to receive in one year, in excess of 0.1 rem external dose to the whole body, in excess of 0.15 rem to the lens of the eye, or in excess of 0.5 rem to the skin or an extremity. A declared pregnant worker must be monitored if she is likely to receive during the entire pregnancy in excess of 0.1 rem external dose to the whole body. All individuals entering a high or very high radiation area, and at least one visitor in a group of visitors entering a controlled area must also be issued a dosimeter.

The existing rule has requirements for issuing dosimeters, which are the same for individuals entering a high or very high radiation area and visitors entering a controlled area. However, the existing requirements are different than the proposed incorporated requirements for adults and minors, and are silent on requirements for pregnant workers. For example, the existing rule requires an adult worker to wear dosimetry if the individual enters a controlled area under such circumstances that he or she would receive or would be likely to receive a dose in excess of 25 millirems (mrem) in any period of seven consecutive days. It is difficult to predict whether the proposed new rule will result in more or fewer workers requiring dosimetry, because that is

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dependent on the work that is being performed, and the levels and types of radiation to which the workers are being exposed.

The Federal rule at 10 CFR 20.1601 sets forth requirements related to control of access to high radiation areas. Under the existing rule, high radiation areas must be under direct, constant surveillance, unless the area is equipped with specific control devices, or the area is locked and the owner or supervisor of the activity maintains direct personal control over access to the key. The proposed incorporated rule allows the area to be protected by an audible or visible alarm signal (as in the existing rules), or by a device that causes the level of radiation to be reduced when someone enters the area. The existing rules contained a similar provision, in which the level of radiation would be reduced below that at which an individual might receive a dose of 100 millirems in one hour upon entry to the area. Under the proposed incorporated rule, the reduction in dose would be to a level at which an individual might receive a deep-dose equivalent of 0.1 rem (100 millirem) in one hour at 30 centimeters from the radiation source, or from any surface that the radiation penetrates. The licensee could also keep the entryways locked, as in the existing rule.

Instead of locking the doors or providing specific control devices to restrict access, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry, as in the existing rule. The proposed rule allows a licensee to apply to the Department for approval of alternative methods for controlling access to high radiation areas. The existing rule does not contain such an option. Whatever method the licensee uses to secure the high radiation area, the proposed rule requires that the method not prevent individuals from leaving the high radiation area.

The proposed incorporated rule specifies that an area does not need controlled access if the sources of the high radiation are packages prepared for transportation that remain in an area for

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three days or less, and have a dose rate less than 10 millirem per hour. There is no similar provision in the existing rule.

The Federal rule at 10 CFR 20.1602 requires licensees to conspicuously post, and restrict access to very high radiation areas. Very high radiation areas are areas where the dose rate is 500 rads per hour or more. The existing regulations do not have separate provisions for very high radiation areas, but treat them in the same manner as high radiation areas.

The Federal rule at 10 CFR 20.1701 requires licensees to use process or engineering controls to control the concentration of radioactive materials in air, for example containment, decontamination, or ventilation. The regulation is flexible as to which process or engineering controls are used. There are no requirements for such controls in the existing regulations.

The Federal rule at 10 CFR 20.1702 requires licensees to use other control methods to limit intakes, if it is not possible for them to apply the controls at 10 CFR 20.1701, proposed to be incorporated by reference. Examples of other control methods are control of access, limitation of exposure times, or use of respiratory protection equipment. There are no such requirements in the existing rule.

The Federal rule at 10 CFR 20.1703 requires the use of individual respiratory protection equipment to limit the intake of radioactive material. In addition, it requires that the respirators be tested and certified and outlines a respiratory protection program that includes among other things, air samples, bioassays, testing, procedures for fit testing, and recordkeeping. The proposed incorporated rule also requires a determination from a physician that the individual is medically fit to use a respirator. It also describes how the respirator must fit the person wearing it, and mandates that there can be no interferences with proper operation of the respirator, such as facial hair. The

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proposed rule specifies how to estimate dose to individuals from intake when respirators are in use.

The existing rule does not have any provisions for respirator use.

The Federal rule at 10 CFR 20.1704 allows the Department to impose additional restrictions on the use of respiratory protection equipment to ensure worker safety, such as to ensure that the respiratory protection program meets the ALARA principle, and to limit the extent to which respiratory protection can be used instead of process or engineering controls to limit doses. The Department determines if such additional restrictions on the use of respirators is required by reviewing the respiratory protection program during the review of the initial application, amendments, or renewals. Inspections may also reveal an over reliance on respirators when other process or engineering controls are easily implemented. Since the ALARA principle takes cost into account, the Department would not be able to require controls that are not cost effective in reducing doses. The existing rules have no such provisions.

The Federal rule at 10 CFR 20.1705 requires licensees to obtain approval from the Department prior to using assigned protection factors higher than those specified in the proposed Appendix A to 10 CFR Part 20. The appendix provides protection factors based on the form of the contaminant (gas, aerosol, or particulate) and the different types of respirators. There may be circumstances where the proposed conditions of respirator use do not match those that were assumed when the protection factors were developed.

Although many new provisions regarding respirator use are proposed in this subchapter, respirator use among the existing State licensees rarely occurs. The use of respirators is more common in nuclear power plant operations, which remains under the jurisdiction of the NRC.

The Federal rule at 10 CFR 20.1801 requires licensees to prevent unauthorized access to licensed materials stored in controlled or unrestricted areas. The Federal rule at 10 CFR 20.1802

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requires licensees to control and maintain constant surveillance over licensed material that is in a controlled or unrestricted area and that is not in storage. The existing rules do not contain such provisions, but they are currently included as license conditions.

The Federal rule at 10 CFR 20.1901 specifies the requirements for the radiation symbol. Where the existing rule specified the cross-hatched area to be magenta or purple, the new proposed language allows licensees to use the color black as well, and provides an exception to the color requirements for the standard radiation symbol. The existing rule does not allow an exception to the color requirements. The proposed incorporated rule also allows licensees to provide additional information related to radiation exposures on or near any required signs and labels, which is the same as in the existing rule.

The Federal rule at 10 CFR 20.1902 provides requirements for posting radiation areas, high radiation areas, very high radiation areas, airborne radioactivity areas, and areas in rooms in which licensed material is used or stored. The existing rule at N.J.A.C. 7:28-10.1 has similar provisions, with the exception that the existing rule allows natural uranium and natural thorium to be used or stored in an area without being posted until it is 100 times the quantity listed in existing N.J.A.C. 7:28-10.9. For all other isotopes, the existing rule requires posting if the quantity reaches 10 times the amount identified at existing N.J.A.C. 7:28-10.9, which is similar to the Federal requirements. Under the Federal rule, proposed to be incorporated by reference, there must be a sign posted if radioactive material is stored in an amount greater than 10 times the amount in Appendix C to 10 CFR 20, which is similar to existing N.J.A.C. 7:28-10.9. There is no exception for natural uranium and natural thorium.

The Federal rule at 10 CFR 20.1903 provides for exceptions to posting requirements. Conditions in which a licensee is not required to post caution signs in rooms or areas are when the

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room or area contains radioactive materials for periods of less than 8 hours, provided the materials are constantly attended and the room or area is subject to the licensee's control; rooms or area occupied by patients that could be released pursuant to 10 CFR 30.75; because of the presence of a sealed source provided the radiation levels at 30 centimeters does not exceed 5 millirem per hour; or rooms in hospitals or clinics that are used for teletherapy, provided access to the room is controlled pursuant to 10 CFR 20.35.615 and necessary precautions are taken to prevent exposures in excess of worker and public limits. Requirements pertaining to patients that could be released and rooms used for teletherapy are not in the existing regulations, but the other requirements listed above are found at existing N.J.A.C. 7:28-10.8.

The Federal rule at 10 CFR 20.1904 requires the labeling of each container of licensed material. The label must say "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL," and must provide information such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment. Existing N.J.A.C. 7:28-10.5 has similar provisions, except it provides an exception to the labeling requirements for containers of natural uranium and natural thorium. The Federal rule at 10 CFR 20.1904(a) has no such exception. The proposed new labeling requirements require more information than the existing rule, insofar as the existing rule does not require the label to identify the mass enrichment or radiation levels of the contents of the container. The list of label requirements in the proposed new rule is provided as an example of what is required; however, if less or more information is required in order "to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures," then the items in the rule are to be a starting point. The proposed incorporated language also requires licensees to remove or deface the radioactive material label on

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empty uncontaminated containers before the containers are removed to unrestricted areas or disposed of. The existing rule does not have specific requirements pertaining to empty containers.

The Federal rule at 10 CFR 20.1905 lists exemptions to labeling requirements. In addition to the exemptions in existing N.J.A.C. 7:28-10.8(e) through (g), the proposed new rule allows exemptions for containers holding licensed materials in quantities less than those listed in Table 3 of Appendix B of 10 CFR Part 20; containers attended by someone responsible for preventing exposures of individuals in excess of the dose limits; containers that are labeled in accordance with the Federal Department of Transportation requirements; containers that are accessible only to individuals authorized to handle or use them, so long as there is readily available written record of the contents; and installed manufacturing or process equipment.

The Federal rule at 10 CFR 20.1906 lists procedures for receiving and opening packages. There is no similar provision in the existing rules. Under the proposed incorporated rule, a licensee must make arrangements to be notified of delivery and must take possession expeditiously. The licensee must also monitor the external surface of certain types of packages, and of each package that appears to be crushed, wet, or damaged, or otherwise not intact. The proposed rule also includes time frames for performing such monitoring.

If radiation levels on the surface or exterior of the package exceed certain levels, the proposed rule requires the licensee to notify the Department immediately. Licensees must maintain written procedures for safely opening packages, and ensure that the procedures are followed. Finally, the proposed rule contains an exemption from the contamination monitoring requirement if special form sources are being transferred in licensee-owned or licensee-operated vehicles to and from a work site.

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The Federal rule at 10 CFR 20.2001 contains requirements on how licensed material shall be disposed of. Existing N.J.A.C. 7:28-11.1 contains general language that prohibits the disposal of radioactive material, except to the extent that it is allowed by the remaining sections of the subchapter. The Department and the Commission propose to repeal N.J.A.C. 7:28-11, and replace the general language of the existing rule with the text of 10 CFR 20.2001, which is more specific regarding how a licensee can dispose of licensed material. Allowed methods are transfer, decay in storage, release in effluents within limits, or as authorized in other parts of the subchapter as discussed below. Further, only licensed persons may receive the waste for disposition.

The Federal rule at 10 CFR 20.2002 allows licensees to propose procedures, not otherwise authorized in the regulations, to dispose of licensed material generated in the licensee's activities. The proposed incorporated rule, like the existing rule, requires approval from the Department before disposal of licensed material. Both the proposed and existing rules require the licensee or applicant for a license to describe the waste and the manner of disposal, an evaluation of the environment, the nature and location of other potentially affected facilities, and assurances regarding the level of doses as a result of disposal.

The Federal rule at 10 CFR 20.2003 provides for requirements for release of radioactive materials to a sanitary sewer. The Department and the Commission propose to replace the words "sanitary sewerage" with "domestic treatment works" in order to be compatible with the New Jersey Pollutant Discharge Elimination System regulations at N.J.A.C. 7:14A-1.2. The proposed incorporated rule is the same as existing N.J.A.C. 7:28-11.2, which is proposed to be repealed, except the incorporated rule will refer to tritium and carbon-14 in the total quantity allowed to be released into the domestic treatment works. The existing rule excluded the substances because the Department did not have the authority to regulate them. As an Agreement State, New Jersey will be

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responsible to regulate them. The amount of hydrogen-3 and carbon-14 that a licensee can release into a domestic treatment works in a year is proposed to be limited to one curie. The existing rule had no specific limit for those substances. The total amount of combined radioactive materials that a licensee can release into a domestic treatment works remains the same under the proposed incorporated and existing rules.

The Federal rule at 10 CFR 20.2004 allows for the incineration of certain radioactive materials specified under 10 CFR 20.2005, or that the Department specifically approves. Existing N.J.A.C. 7: 28-11.6 also allows a licensee to incinerate by specific approval, but it has no similar provision regarding hydrogen-3 or carbon-14, inasmuch as the State does not regulate hydrogen-3 or carbon-14. A significant portion of 10 CFR 20.2004 applies to nuclear reactors, which the State will have no authority to regulate; therefore, this part of the Federal rule is not incorporated by reference. (See proposed N.J.A.C. 7:28-6.1(b).)

The Federal rule at 10 CFR 20.2005 allows the disposal of certain quantities of hydrogen-3 and carbon-14 as if they were not radioactive, so long as they are not used as food for humans or animals. There is no similar provision in the existing rules, inasmuch as the State does not regulate hydrogen-3 or carbon-14. When New Jersey becomes an Agreement State, it will assume responsibility from the NRC for these materials.

The Federal rule at 10 CFR 20.2006 sets forth the requirements related to the transfer of radioactive waste for disposal and related manifests. These requirements include controlling the transfer of low-level radioactive waste by any generator, waste collector, or waste processor who ships low-level waste either directly or indirectly to a licensed low-level radioactive waste disposal facility. The rule establishes a manifest tracking system (the NRC's Uniform Low-Level Radioactive Waste Manifest), and supplements existing requirements concerning transfers and

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recordkeeping for such wastes. It also specifies that any licensee disposing of byproduct material must document the information on the Uniform Low-Level Radioactive Waste Manifest. There is no similar provision in the existing State regulations; however, most of the State licensed material is short-lived, and the majority of licensees dispose of this material through decay in storage. For the few State licensees that have long-lived radioactive material, the additional requirement is not expected to have a significant impact because waste collectors and processors already abide by these requirements.

The Federal rule at 10 CFR 20.2007 requires licensees to comply with other Federal, State and local environmental and health regulations related to the disposal of material covered by this subpart. While there is no existing requirement in the State regulations, all licensees are already required to comply with other Federal, State and local environmental and health regulations. For example, licensees are required to comply with all Federal Department of Transportation regulations regarding shipment of radioactive materials.

The Federal rule at 10 CFR 20.2008 concerns the disposal of certain byproduct material. The Energy Policy Act of 2005 mandates that the newly added byproduct material, that is discrete NARM, is not considered to be low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act (42 USC 2021b) (LLWPAA). The intent of this provision of the Energy Policy Act is that the newly added byproduct material is not to be impacted by the compact process of the LLRWPA. The compact process was designed to allow regions of the country to form alliances or compacts for the disposal of low-level radioactive waste. A region would consist of several states, with one state hosting the low-level radioactive waste disposal facility. The compact could then exclude all low-level radioactive waste that is not generated in their region from being disposed at their facility. By mandating that the newly added byproduct

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material is not considered low-level radioactive waste, this material will still be allowed to be disposed of at any facility as is the current process, not just at a facility in the compact region where it was generated.

Although the newly added byproduct material is not considered low-level radioactive waste, it does pose a similar hazard, and it does need to be disposed of appropriately. This proposed rule requires that the newly added byproduct material is to be disposed of in a facility licensed by the NRC under 10 CFR Part 61 or the Agreement State requirements, which are compatible to 10 CFR Part 61. This provision also allows for the disposal of the newly added byproduct material in a facility licensed by the NRC under other parts of the NRC regulations, such as facilities licensed under 10 CFR Part 40 Appendix A. The proposed incorporated rule also specifies that such disposal shall be authorized in accordance with any Federal or State solid or hazardous waste law, including the Resource Conservation and Recovery Act of 1976 (Solid Waste Disposal Act) 42 U.S.C. §§ 6901-6992k, October 21, 1976, as amended.

The Federal rule at 10 CFR 20.2101 provides licensees with the general provisions for recordkeeping, such as the unit of measure, and how to record doses received (such as deep-dose equivalent and committed effective dose equivalent). As explained above, the existing rule does not use these new dose quantities.

The Federal rule at 10 CFR 20.2102 requires licensees to maintain records of the radiation protection programs and specifies that the records of radiation protection programs must be kept until the license is terminated. A licensee must retain a record of the audit for three years. While there is no requirement in the existing regulations for recordkeeping, these requirements are included in each individual license.

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The Federal rule at 10 CFR 20.2103 requires licensees to maintain records of required surveys and calibrations for three years rather than the existing 10 years. The proposed requirements also include maintaining records of surveys used to determine external dose, results of measurements or calculations to determine internal dose, results of air sampling and bioassays, and measurements and calculations used to evaluate the release of radioactivity to the environment. Licensees would maintain such records until they were no longer licensed. Under the existing rule, licensees are required to maintain records of surveys for at least 10 years.

The Federal rule at 10 CFR 20.2104 provides requirements for determining worker's prior occupational dose. Acceptable records of prior occupational exposure include a written signed statement from the individual or the individual's former employer that discloses the nature and amount of any occupational dose received during the current year; an up-to-date NRC Form 4 or equivalent as a record of cumulative radiation dose; or reports obtained by telephone, telegram, electronic media, or letter from the most recent employer with written verification of the dose data if the authenticity of the transmitted report cannot be established.

The proposed incorporated rule also includes requirements for recording dose histories, including a provision to reduce the allowable dose limit by 1.25 rems for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational dose. Such individuals are may not participate in planned special exposures. The licensee must retain NRC Form 4 until the license is terminated, but may discard records used in preparing NRC Form 4 after three years. Existing N.J.A.C. 7:28-8.1(c) addresses prior occupational dose and requires that the owner supply the former employee, upon request, with the dose records. The retention time in the existing regulation for employees is 10 years after termination of employment. Exposure records for others shall be preserved for at least 10 years.

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The Federal rule at 10 CFR 20.2105 identifies the records that must be maintained in relation to planned special exposures. These include documentation of the exceptional circumstances requiring the planned special exposure, how the doses were maintained ALARA, what dose was expected, and the doses actually received. The existing rules do not have such detailed requirements, but contain a general requirement at N.J.A.C. 7:28-8.1(a) to record all exposures. Proposed amended N.J.A.C. 7:28:8.1, as discussed below, is consistent with 10 CFR 20.2015, proposed to be incorporated by reference.

The Federal rule at 10 CFR 20.2106 identifies the recordkeeping requirements associated with individual monitoring results. The proposed incorporated requirements specify the types of doses (occupational, emergency, special exposures, accidents) and quantities (deep-dose equivalent, committed effective dose equivalent, total effective dose equivalent, and the total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose) for which records must be kept. In addition, the proposed new section specifies the format of the record, requires annual recording, and mandates privacy protection practices. Licensees must retain records until license termination. The existing rule, N.J.A.C. 7:28-8.1, requires personnel exposure records to be maintained for 10 years after the termination of employment, and records regarding exposure of other persons to be retained for 10 years. The proposed rules include record retention provisions relating to declared pregnant women and exposure of the embryo/fetus. There is no similar requirement in the existing rules.

The Federal rule at 10 CFR 20.2107 requires licensees and registrants to maintain records sufficient to demonstrate compliance with the dose limits to members of the public. Requirements for record retention are provided for licensees (until license termination). The existing rule has only a general requirement to maintain records showing the results of all required surveys.

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The Federal rule at 10 CFR 20.2108 requires licensees to maintain records of disposal of licensed material under 10 CFR 20.2002 through 20.2005, 10 CFR Part 61, and disposal by burial, including past burials allowed under outdated NRC rules. A previous version of 10 CFR 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific NRC authorization. (See 10 CFR 20.2109, note 6.) Under the incorporated rule, licensees must notify the Department of NRC approved burial in soil. In this way, the Department can investigate the burial site before the license is terminated. There are no similar provisions in the existing rule.

The Federal rule at 10 CFR 20.2110 requires records to be stored in a manner that ensures that the record is legible throughout the retention period. Electronic media or microfilm storage is allowed, provided the legibility requirements are met. The existing rule at N.J.A.C. 7:27-8.1 requires that there be a record, or a true copy, but does not specify the manner of storage.

The Federal rule at 10 CFR 20.2201 provides licensees with the procedures to follow in the event of a theft or loss of radioactive materials. The existing rule requires lost or stolen sources of radiation to be reported immediately by telephone, telefax, or telegraph. The proposed incorporated rule requires reporting only by telephone, and only for certain quantities of licensed material. Written reports within 30 days of the occurrence are acceptable for lost or stolen licensed material in a lesser quantity.

The proposed incorporated rule also requires follow-up written reports, which must include a description of the material, a description of circumstances under which the loss or theft occurred, a statement of disposition, or probable disposition of the material involved, any exposures of individuals and dose incurred by persons in unrestricted areas, actions that will be taken, or were taken to recover the sources, and procedures or measures that will be taken to ensure against a

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recurrence of the loss or theft. The licensees will prepare such reports so that the names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report. The incorporated language replaces NRC contact information with the contact information for the Department provided in N.J.A.C. 7:28-1.5. The existing rule does not require identification of individuals who may have received exposure to radiation.

The Federal rule at 10 CFR 20.2202 governs notification of incidents. The proposed incorporated rule provides licensees and registrants with the timelines that must be met and the manner to be used when notifying the Department of incidents involving radioactive materials. In some instances, such as an individual incurring a total effective dose equivalent of 25 rems or more, the proposed incorporated rule requires notice to be given immediately. In other instances, such as an individual incurring a total effective dose equivalent of 5 rems or more, notice may be provided within 24 hours. Incident reports must include the names of any exposed individuals. The proposed notification requirements do not apply to planned special exposure, as long as the exposure is within the established limits and is reported in accordance with 10 CFR 20.2204. The existing rule at N.J.A.C.7:28-13.2 has similar requirements, but the dose levels for reporting are generally higher. It is difficult to compare the dose quantities under the existing rules with the proposed quantities, unless the specific circumstances of the exposures are known. Proposed amendments to N.J.A.C. 7:28-13.2 are discussed below.

The Federal rule at 10 CFR 20.2203 provides licensees with the timelines within which reports on incidents are to be submitted to the Department. Reports of certain types of exposure must be submitted within 30 days, and must include a description of the exposure estimates of the individual doses, the levels of radiation and concentrations of radioactive materials involved, the cause of the elevated exposures, and corrective steps taken or planned to ensure against a

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recurrence. The existing rule at N.J.A.C. 7:28-13.2 has similar provisions; however, it does not include the provision for a written report if the ALARA constraints for air emissions are exceeded.

The Federal rule at 10 CFR 20.2204 requires licensees to submit to the Department reports of planned special exposures within 30 days. The contact information provided in N.J.A.C. 7:28-1.5 replaces the NRC contact information in Appendix D to 10 CFR Part 20, in accordance with proposed N.J.A.C. 7:28-6.1(d)25. Reports of planned special exposures are not required in the existing rules.

The Federal rule at 10 CFR 20.2205 requires a licensee to provide a copy of a report required under 10 CFR 20.2203, 20.2204, or 20.2206 to the individual that was exposed at the same time the report is sent to the Department. The existing rule has a similar provision at N.J.A.C. 7:28-13.2(g). The requirement in the existing rule to include an advisory statement on the report, is no longer required.

The Federal rule at 10 CFR 20.2206 requires licensees who possess or use byproduct material for radiography pursuant to proposed N.J.A.C. 7:28-51 (incorporating 10 CFR Part 30 by reference), receive radioactive waste from other persons for disposal under 10 CFR Part 61, or who possess or use at any one time byproduct material in quantities that exceed any of the quantities listed in the table at 10 CFR 20.2206(a)(7), to file an annual report with the Department. The report will provide the results of individual exposure monitoring for each individual for whom monitoring was required under 10 CFR 20.1502, as well as for any person for whom monitoring was provided but not required. The existing rule has no such provisions.

The Federal rule at 10 CFR 20.2207 outlines requirements pertaining to nationally tracked sources. A nationally tracked source is defined as a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of 10

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CFR Part 20. Appendix E lists the radionuclides and the activity thresholds that constitute Category 1 and 2 nationally tracked sources. Licensees who manufacture, transfer, receive, disassembles, or disposes of a nationally tracked source must complete and submit a National Source Tracking Transaction report. Unlike other reports required under this proposed subchapter, reports required under this subsection must be sent to the NRC by using the on-line National Source Tracking System, electronically using a computer readable format, by facsimile, by mail, or by telephone with follow up by facsimile or mail. Also included in this part are timelines for correcting mistakes (reconciliation), and requirements for reporting initial inventories of nationally tracked sealed sources. Because this is a new requirement for NRC licensees, there is no existing Department regulation.

The Federal rule at 10 CFR 20.2302 allows the Department to impose additional requirements on a licensee or registrant, with the approval of the Commission, if the Department determines that such requirements are necessary to protect human health or minimize danger to human life or property. The Commission has broad authority under the Radiation Protection Act to prevent unnecessary radiation (N.J.S.A. 26:2D-10). Unnecessary radiation means the use or presence of any radiation in such manner as to be or tend to be injurious or dangerous to the health of the people or the industrial or agriculture potential of the State, or to the ecology of the State and its wildlife (N.J.S.A. 26:2D-2). The Commission also has the authority to formulate, adopt, promulgate, amend, and repeal regulations (N.J.S.A. 26:2D-6). Additional requirements could consist of provisions for new uses of radiation or additional security requirements as necessary to protect the public from terrorist attacks.

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Appendix A to the Federal rule at 10 CFR Part 20 lists assigned protection factors for respirators. As stated above, this is a new provision for those with only State licenses under the existing regulatory program; however, use of respirators is rare for these licensees.

Appendix B to the Federal rule at 10 CFR Part 20 provides annual limits on intake and derived air concentrations for occupational exposure, and effluent concentrations to air and water, and releases to sewerage. As part of the proposed repeal of Subchapter 11, the Appendix to the subchapter will also be repealed. The existing Appendix contains Concentrations for Effluent and Sanitary Sewer Releases. The limits for releases to sewerage at Appendix B to 10 CFR Part 20, proposed to be incorporated, are the same as in existing Appendix to Subchapter 11. The annual limits on intake and derived air concentrations for occupational exposure are new to the State rules, and are based on the updated dose quantities and methods for determining internal doses.

Appendix C to the Federal rule at 10 CFR Part 20 provides the quantities of radioactive material subject to the labeling and posting requirements. This table is the same as in existing N.J.A.C. 7:28-10.9, except for the elements Lanthanum-142, Cerium-141, and Europium-157, which contained typographical errors in the existing rule. The Department proposes to delete the table at NJAC 7:28-10.9. The first explanatory note in the existing table, designating quantities of certain nuclides as not applying to source material as defined by the NRC, is no longer needed because the State will be assuming regulatory control of this material. The second note to existing N.J.A.C. 7:28-10.9, regarding Rhenium-183, is no longer needed because there are no existing licensees who are licensed solely for this nuclide, and none are expected. Labeling and posting would be driven by other radionuclides on the license.

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Appendix D to the Federal rule at 10 CFR Part 20 lists the contact information for the NRC Headquarters and Regional Offices. This is necessary because information on nationally tracked sources is still sent to the NRC.

Appendix E to the Federal rule at 10 CFR Part 20 provides the thresholds for nationally tracked sources and was discussed at the proposed incorporation of 10 CFR 20.2207, above.

Appendix G to 10 CFR Part 20 establishes a manifest tracking system and controls transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility. General information requirements include the name, facility address, and telephone number of the shipper, an explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or combination of these identifiers, and the name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste. Shipment information requirements include the date of waste shipment, total number of packages/disposal containers, total disposal volume and weight, total radionuclide activity in the shipment, and information regarding certain specific radioisotopes. In addition to disposal container information, the appendix identifies uncontainerized waste information requirements, and multi-generator disposal container information requirements.

Certification is required by the authorized representative of the waste generator, processor, or collector by signing and dating the manifests, signifying that the transported materials are properly classified, described, packaged, marked, and labeled and comply with the applicable US Department of Transportation requirements.

Separate requirements are listed for licensees that transfer waste to waste collectors, waste collector licensees that handle only prepackaged waste, licensed waste processors who treat or

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repackage waste, and land disposal facility operators. Requirements are provided to ensure that the classification and identity of radioactive materials are known, and that tracking of the waste is performed so that if the radioactive waste is not received by the intended recipient, the shipper would receive notification. Requirements on follow up by the shipper are also provided such as investigating and reporting to the NRC.

At this time the State does not have a low-level waste land disposal facility pursuant to 10 CFR Part 61, so any incorporated requirements pertaining to such a disposal facility would have no applicability. Nevertheless, the Department and Commission propose to incorporate the requirements, in the event that there is such a facility in the State in the future. Proposed new N.J.A.C. 7:28-6.1(e) provides direction on where to find information concerning requests for adjudicatory hearings and requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested.

Subchapter 7: Radiation Surveys and Personnel Monitoring for Registrants

The Department and Commission propose to amend the subchapter heading to specify that this subchapter applies only to registrants. N.J.A.C. 7:28-7.1 and 7.4 are proposed to be amended to remove all references to radioactive materials or licensees. The Department and the Commission propose to repeal N.J.A.C. 7:28-7.5 because it applies only to licensees. Requirements for surveys and personnel monitoring for licensees are included in proposed new Subchapter 6.

Subchapter 8: Records

The Department and Commission propose to amend the subchapter heading to specify that this subchapter applies only to registrants. N.J.A.C. 7:28-8.1 and 8.2 are proposed to be amended to

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remove all references to radioactive materials or licensees. The Department and the Commission propose to repeal N.J.A.C. 7:28-8.3 and 8.4 because they apply only to licensees. N.J.A.C. 7:28-8.5 will be renumbered as 8.3. Requirements for records for licensees are included in proposed new Subchapter 6.

Subchapter 9: Radioactive Contamination Control

The Department and the Commission propose to repeal and reserve Subchapter 9, because it is applicable only to licensees, and requirements for contamination control are included in proposed new Subchapter 6.

Subchapter 10: Labeling, Posting and Controls

The Department and Commission propose to amend the subchapter heading to indicate that this subchapter applies only to registrants. N.J.A.C. 7:28-10.1 is proposed to be amended to remove the reference to radioactive materials. The Department and the Commission propose to repeal N.J.A.C. 7:28-10.4 and 10.5 because they apply only to licensees. N.J.A.C. 7:28-10.6 will be renumbered to 10.4 and is proposed to be amended to remove references to containers containing radioactive materials. The Department and the Commission propose to renumber N.J.A.C. 7:28-10.8 to 10.6 and amend them to delete references to radioactive materials. The Department and the Commission propose to repeal N.J.A.C. 7:28-10.9. Requirements for labeling, posting and controls are included in proposed new Subchapter 6, including the quantities of radioactive material that require labeling and posting.

Subchapter 11: Disposal of Radioactive Materials

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The Department and the Commission propose to repeal and reserve Subchapter 11 because it is applicable only to licensees. Requirements for disposal of radioactive materials, formerly in Subchapter 11, are included in proposed new Subchapter 6.

Subchapter 12: Remediation Standards for Radioactive Materials

Under the existing regulatory system, when a cleanup involves both NRC regulated material and State regulated material, the licensee must provide duplicate documentation and ensure that both Federal and State regulatory requirements are met. Both regulatory agencies provide comments to the licensee. Such comments are potentially incompatible. As a result, remediation could be delayed. By becoming an Agreement State, New Jersey will replace the dual system with a single system. There will be only one regulatory framework and one dose criterion. Under the existing Federal and State rules, the NRC requires remediation to a dose of 25 mrem per year (mrem/y) with an As Low As Reasonably Achievable (ALARA) requirement. The Department's and the Commission's existing rules require remediation to a dose of 15 mrem/y. (See N.J.A.C. 7:28-12.8.)

The NRC does not require a state to adopt the NRC's remediation dose criterion in order to become an Agreement State; consequently, the Department is continuing its remediation dose criterion of 15 mrem/y. As a practical matter, because of the ALARA requirement, the decommissioning of NRC licensees has usually resulted in a remaining dose less than 15 mrem/y.

The Department and the Commission propose to amend N.J.A.C. 7:28-12.2(a) and (c) to use the terms "standards" and "dose criteria," because both terms are used in the rules. (See N.J.A.C. 7:28-4.3(a)10 (dose criteria) and N.J.A.C. 7:28-12.9 (standards).) N.J.A.C. 7:28-12.2(a)1 is proposed to be amended to include source, byproduct, certain special nuclear material and diffuse

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NARM. The addition of these materials is necessary in order for the State's rules to be compatible with the Federal rules at 10 CFR Part 20 Subpart E-Radiological Criteria for Decommissioning.

Because accelerator-produced material is included in the revised definition of byproduct material, N.J.A.C. 7:28-12.2(a)2 is no longer necessary, and is proposed to be deleted.

The Department and the Commission propose to renumber existing N.J.A.C. 7:28-12.2(a)3 as (a)2, and to specifically include licensees among those persons that the State may compel to perform remediation activities. "Licensee" is proposed to be added to clarify that the remediation standards and dose criteria apply at license termination. Although a "licensee" is a "person," the Department and Commission propose to add the term in order to make it clear that the State may compel all persons, including licensees at the termination of a license to comply.

At N.J.A.C. 7:28-12.2(c), the reference to soil remediation standards is proposed to be deleted. The remediation standards apply not only to soil, but also to ground and surface water. (See proposed amended N.J.A.C. 7:28-12.8.)

The Department and the Commission propose to amend N.J.A.C. 7:28-12.3 to add a new definition of "contaminated site." Because Subchapter 12 applies to both licensees and owners of contaminated sites, the Department and Commission felt that a definition of contaminated site was appropriate. Since there is already a definition in the Department's Technical Requirements for Site Remediation that accurately describes contaminated sites, that definition is in the proposed rules.

The definition of "engineering control" is proposed to be amended to include ground water monitoring systems and ground water containment systems, including slurry walls and ground water pumping systems as examples of engineering controls. These systems were already included by the language in the definition "include, without limitation," but now they are express examples.

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The definition of “remediation standards” is proposed to be amended to reference not only the Brownfield and Contaminated Site Remediation Act, but also the remediation standards established in this chapter.

The definition of “uncontaminated surface soil” is proposed to be amended to make it clear that the background radionuclide concentration must be less than the remediation standards, rather than less than the limits for residual remediation standards. The phrase “limits for residual” was not necessary in the existing rule and is not appropriate now that the definition of “residual radionuclides” has been replaced with “residual radioactivity.”

The definition of "radioactive contamination or radioactive contaminant" is proposed to be amended to add building materials, and/or equipment at concentrations above natural background levels because the Department will have the authority to regulate more than soil when New Jersey becomes an Agreement State. The term "residual radionuclides" is being changed to "residual radioactivity" to be consistent with the NRC definition at 10 CFR 20.1003.

The Department and the Commission are proposing to amend the definition of "appropriate period of time" to change the criteria under which the appropriate period is calculated. Under the existing rule, the appropriate period was measured by the half-life of a radionuclide. Under the proposed amended rule, the Department would determine what is an appropriate period of time, taking into consideration not only the half-life, but also other conditions. The amended definition will have the effect at proposed amended N.J.A.C. 7:28-12.11 and 12 of allowing the restricted release of sites contaminated with long-lived radionuclides, which is consistent with the Brownfield and Contaminated Site Remediation Act, N.J.S.A.58:10B, and the Industrial Site Recovery Act, N.J.S.A. 13:1K-6. The amended definition allows the Department to make a determination whether or not engineering or institutional controls would be expected to last, based on the proposed

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restricted release remediation and/or decommissioning plans in order to meet the 15 millirem per year dose criterion. For example, if a licensee or person responsible for remediation of the site were to propose an alternate standard for naturally occurring radioactive materials (with half-lives in the billions of years) that relied on the existence of an engineered barrier to meet the 15 millirem per year restricted release criteria, the Department would consider such a proposal, so long as the 100 millirem per year all controls fail dose criterion is also met. All controls fail assumes that all institutional and engineering controls fail. Engineering controls are anything that mitigates dose, including, but not limited to backfill, fences, or other covers.

The Department and the Commission are proposing to amend N.J.A.C. 7:28-12.4(a) and (c) to include "licensee" for the reasons described above with regard to proposed amended NJAC 7:28-12.2(a). Although a licensee is, technically, a "person," the Department and Commission are adding the word "licensee" in order to make it clear that a licensee may petition the Department.

The Department and the Commission propose new N.J.A.C. 7:28-12.4(b) to specify that certain licensees must submit a decommissioning plan, depending on the types, quantities, and half-lives of the licensed materials. Existing N.J.A.C. 7:28-12.4(b) is proposed to be moved to N.J.A.C. 7:28-12.4(c).

The Department and the Commission propose to add language from the Brownfield and Contaminated Site Remediation Act, N.J.S.A. 58:10-23.11(g), to proposed N.J.A.C. 7:28-12.4(d). The proposed amended rule would prohibit the Department from requiring a more stringent remediation standard upon approval of a work plan or similar plan, unless the new remediation standard is an order of magnitude lower than the formerly approved standard. This proposed language is being added to be compatible with the Federal rule at 10 CFR 20.1401(c), which

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requires additional cleanup only if the activity remaining on the site could result in a significant threat to public health and safety.

The Department and the Commission are proposing to amend N.J.A.C. 12.5(a) and (b) to include "licensee." Although a licensee is, technically, a "person," the Department and Commission are adding the word "licensee" in order to make it clear that a licensee may petition the Department. The Department and the Commission are proposing to delete N.J.A.C. 7:28-12.5(c), which requires certain analytical procedures to be used for radionuclide soil analysis. Subsequent to the existing rules being promulgated, the Department amended N.J.A.C. 7:18 to include laboratory certification of radionuclides in soils; therefore, the existing subsection is no longer needed. The remaining subsections are proposed to be renumbered.

The Department and the Commission propose to amend N.J.A.C. 7:28-12.5(c) to add "or water," and delete reference to participation in the International Atomic Energy Commission or US Department of Energy intercomparison analyses. Since Subchapter 12 was last amended, the Department's Office of Quality Assurance (OQA) now certifies laboratories for radiological analysis of soil and water. Previously, only analyses of radionuclides in water was regulated. This amendment will eliminate the need for separate intercomparison studies, since full certification is now available. Because the remediation standards include compliance with groundwater and surface water standards, as well as soil standards, a remediation may involve both analyses. The laboratory performing the analysis would need to be certified for each analysis.

The Department and the Commission are proposing to relocate existing N.J.A.C. 7:28-12.8(a)3 to N.J.A.C. 7:28-12.8(b), so that it is not under the requirements of N.J.A.C. 7:28-12.8(a). The requirement for groundwater to be remediated to comply with the New Jersey Groundwater

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Quality Standards (N.J.A.C. 7:9C) should not be interpreted as an increment above background.

The rule text was improperly located in the existing rules.

The Department and the Commission are proposing new N.J.A.C. 7:28-12.8(c) to require a person responsible for remediating a site to comply with surface water quality criteria, in order for the site to be considered remediated or the license to be terminated. The Department's surface water criteria are at N.J.A.C. 7:9B. This requirement is being added to ensure that sites are fully remediated before the Department issues a No Further Action letter or terminates a license.

The Department and the Commission are proposing to amend N.J.A.C. 7:28-12.9 to specify that the contamination limits in the section's tables apply to Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) and source material. The specific nuclides that constitute source material are the same as those in the existing tables; it is just the initial concentrations that determine whether a material is classified as TENORM or source material. As an Agreement State, New Jersey would have jurisdiction over building contamination, as well as soil contamination. Accordingly, the words "in soils" are proposed to be deleted from N.J.A.C. 7:28-12.9 because the concentration limits in the section would no longer be limited to soil, but would also apply to volumetrically contaminated building materials. The Commission and the Department are proposing to amend Tables 3A and 3B, "Allowed Incremental Derived Concentration Guideline Level of Individual Radionuclides in Soils; Restricted Use Standards for Radioactive Contamination" to correct errors. The standards in Table 3A are presented in picocuries per gram and in Table 3B in becquerels per gram. While the existing concentrations for Actinium-227 and Thorium-232 meet the restricted use dose criterion of 15 millirem per year for a vertical extent of one foot, they do not meet the "all controls fail" dose criterion of 100 millirem per year when the uncontaminated surface soil (an engineering control) is set to zero. The remediation

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standards for all other nuclides and vertical extents listed in the Tables meet the "all controls fail"

dose criterion of 100 millirem per year. There was also an error discovered in Table 3B. The units of Table 3B should be becquerels per gram (Bq/g), not picocuries per gram (pCi/g) as in the existing rule.

The Department and the Commission are proposing new N.J.A.C. 7:28-12.10, which sets forth the remediation standards for accelerator-produced, byproduct, and certain nuclear materials, all of which will be regulated by New Jersey when it becomes an Agreement State. Because the Department is not providing generic remediation standards for these radionuclides, acceptable methods for determining compliance are outlined, such as which models to use and what parameters are acceptable. Acceptable models are those that have parameters equivalent to the NJDEP's model, RaSoRS, which is available at <http://www.state.nj.us/dep/rpp/index.htm>. The proposed new rule also requires dose calculations to be performed to the longer of peak dose, or 1000 years. This requirement is consistent with and for the same reason as the amendment to N.J.A.C. 7:28-12.10(g)2iii, discussed below.

The Department and the Commission are proposing to renumber existing N.J.A.C. 7:28-12.10 as N.J.A.C. 7:28-11 and amend (a) through (d), (f), and (h) to remove the word "soil" and "soil cleanup" for the same reason as described above with regard to N.J.A.C. 7:28-12.9. Proposed amendments to (a), (e), (f), and (h) add licensees to the persons who may petition the Department for alternative remediation standards. Although a licensee is, technically, a "person," the Department and Commission are adding the word "licensee" in order to make it clear that a licensee may petition the Department. Proposed new N.J.A.C. 7:28-12.11(a)4 requires an alternative remediation standard to meet the requirements of the Surface Water Quality Standards. This amendment is consistent with proposed amended N.J.A.C. 7:28-12.8(a)4.

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At N.J.A.C. 7:28-12.11(b), the Department and the Commission propose to delete the word "background." As written, the rule would allow remediation to a background standard of 15 millirem per year (15 mrem/y). The dose should be the incremental dose, rather than the incremental background dose, as set forth in existing N.J.A.C. 7:28-12.10(a)1.

The Department and the Commission propose amended N.J.A.C. 7:28-12.11(g)2iii to change the time period that dose calculations should be extended. The existing rule requires the calculations to be extended for 1,000 years; whereas, the proposed amended rule requires calculations be extended until the time of peak dose or 1000 years, whichever is longer. The extension to the time of peak dose is necessary because some of the radionuclides regulated by the Department have half-lives of millions and billions of years. Extending calculations for 1000 years is inadequate, in some cases. The reason for this change relates to the 1992 Energy Policy Act, 42 USC §13317, which directs the USEPA to promulgate site-specific standards for Yucca Mountain (the proposed high level nuclear waste repository), "based upon and consistent with the findings and recommendations" of a National Research Council review (NAS report) "Technical Bases for Yucca Mountain Standards," National Research Council, National Academy Press, 1995. The NAS report concluded that there is "no scientific basis for limiting the time period of the individual risk standard to 10,000 years or any other value," and recommended that assessment be performed out to the time of peak risk, which may be several hundred thousand years in the future. Since dose can be converted to risk, it can be concluded that the dose assessment should also be performed out to the time of peak dose.

Existing N.J.A.C. 7:28-12.11 is proposed to be renumbered as 12.12. The Department and the Commission are proposing to amend the rule to include the NRC provisions for financial assurance at 10 CFR 20.1403. This will require a licensee to establish acceptable financial

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assurance mechanisms, such as funds placed in an account separate from the licensee's administrative control, surety method, insurance, or other guarantee method. This is being proposed to ensure that sufficient funds are available to implement and maintain any active engineered or institutional controls. The existing regulations require that the responsible party provide for the costs of implementing and maintaining the requisite active engineered or institutional controls, but do not specify any approved methods to accomplish this.

Proposed amended N.J.A.C. 7:28-12-11(c) includes public outreach provisions in order to be compatible with the Department's Technical Requirements for Site Remediation rules at N.J.A.C. 7:26E-1.4(o) and to be compatible with the NRC regulations at 10 CFR 20.1403(d)(2).

The Department and the Commission are proposing to renumber N.J.A.C. 7:28-12.12 and 12.13 as N.J.A.C. 7:28-12.13 and 12.14, and to add the word "licensee" to both rules, for the reasons described above.

The Department and the Commission propose new N.J.A.C. 7:28-12.15, which is taken from existing N.J.A.C. 7:28-11.4, proposed to be repealed, and amended to change the name from "Disposal by burial in the soil" to "Requirements pertaining to onsite burial or capping." This is intended to make it clear that onsite burial (whether it is called disposal or not) and capping is prohibited without prior written approval from the Department. The existing rule applies to disposal by burial in the soil. Proposed new N.J.A.C. 7:28-12.15(b) prohibits the conversion of burial sites to other uses without written permission from the Department. Proposed new N.J.A.C. 7:28-12.15(c) requires notice to the Department before a property on which radioactive material has been buried in the soil, or capped, is converted to other use, or title is transferred. Additionally, the Department and the Commission propose to extend the application of the rule to owners, as well as licensees, in the event that these are separate entities.

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The Department and the Commission are proposing to correct errors in the two tables for restricted use in Appendix A. While the existing concentrations for Radium-226 for a vertical extent of one foot meet the restricted use dose criterion of 15 millirem per year, they do not meet the "all controls fail" dose criterion of 100 millirem per year when the uncontaminated surface soil (an engineering control) is set to zero. The remediation standards for all other vertical extents listed in the Tables meet the "all controls fail" dose criterion of 100 millirem per year. There was an error discovered in the third caption to Appendix A. The units should be becquerels per gram (Bq/g), not picocuries per gram (pCi/g), as in the existing rule.

Subchapter 13: Reports of Thefts and Radiation Incidents

The Department and the Commission propose to amend the subchapter heading to specify that this subchapter applies only to registrants. N.J.A.C. 7:28-13.1 and 13.2 are proposed to be amended to remove the reference to radioactive materials.

Subchapter 17: Industrial and Nonmedical Radiography

Existing Subchapter 17 regulates industrial and nonmedical radiography. The existing regulations cover both ionizing radiation-producing machines and radioactive materials used in such radiographic procedures. The Department and the Commission propose to limit the applicability of Subchapter 17 to industrial and nonmedical radiography using ionizing radiation-producing machines, such as x-ray machines. Because only references to radioactive materials are proposed to be deleted, the rule remains unchanged for ionizing radiation-producing machine radiography. Proposed new Subchapter 63 will incorporate by reference the Federal rules for industrial and nonmedical radiography using radioactive materials, and is discussed below.

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Subchapter 18: Major Nuclear Facilities

The Department and the Commission propose to amend Subchapter 18, "Major nuclear facilities," to amend cross references. The Department and Commission intend that individuals receive no radiation exposures from environmental or direct radiation that are in excess of the limits throughout proposed new Subchapter 6. Because existing N.J.A.C. 7:28-6.1 and 6.2 are proposed to be repealed, the references to them are no longer correct.

Subchapter 48: Fees for the Registration of Nonionizing Radiation Producing Sources

The Department and the Commission propose to amend N.J.A.C. 7:28-48.2 to include a definition of "radiation area," which applies only to nonionizing radiation producing sources. The existing definition of "radiation area" is proposed to be deleted from Subchapter 1. The NRC definition is proposed to be incorporated by reference into Subchapter 6. The proposed definition at Subchapter 28 includes the language of the definition of existing Subchapter 1, which relates to nonionizing radiation.

Subchapter 49 (Reserved.)

The Department and the Commission propose a reserved Subchapter 49. In future, the Department and the Commission anticipate locating rules regarding non-ionizing radiation in this subchapter. Accordingly, it proposes a placeholder.

Subchapter 50: Notices, Instructions and Reports to Workers: Inspection and Investigations

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Proposed new Subchapter 50 incorporates by reference the Federal regulations at 10 CFR Part 19. In this and every new subchapter that incorporates NRC provisions, the Department and the Commission propose to substitute appropriate references to the New Jersey Administrative Code for the references to the Code of Federal Regulation (CFR) in the Federal rules. Also, unless specifically noted, the terms “NRC” and “Nuclear Regulatory Commission” shall mean the Department, and the terms “General Counsel” and “Office of the General Counsel” shall mean the “Office of the Attorney General of New Jersey.” Similarly, throughout the Federal rules proposed to be incorporated by reference in Subchapters 50 through 63, where a report or communication is to be made to the NRC, unless otherwise specified, the report or communication shall be made to the Department, at the address at N.J.A.C. 7:28-1.5.

The Federal rule at 10 CFR 19.1 sets forth the scope of proposed new Subchapter 50. The subchapter establishes requirements for notices, instructions, and reports by licensees to individuals participating in licensed activities. It also provides the options available to these individuals in connection with Department inspections of licensees to ascertain compliance with requirements regarding radiological working conditions. Additionally, the proposed new subchapter establishes the rights and responsibilities of the Department and individuals during interviews compelled by subpoena as part of agency inspections or investigations pursuant to section 161c of the Atomic Energy Act of 1954, as amended, on any matter within the Department's jurisdiction.

The Federal rule at 10 CFR 19.2 identifies the scope of the proposed new subchapter. The subchapter applies to all persons who receive, possess, use, or transfer material licensed by the Department under N.J.A.C. 7:28-51 through 64. Although 10 CFR 19.2 states that it also applies to persons who receive, possess, use or transfer materials pursuant to 10 CFR Parts 50, 60, 63, 72 and 76, the State is not assuming responsibility for those materials. Accordingly, provisions relating to

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10 CFR Parts 50, 60, 63, 72 and 76 are not part of the incorporation by reference and are not included in any of the proposed new subchapters.

The Federal definitions at 10 CFR 19.3 proposed to be incorporated by reference are “exclusion,” “restricted area,” “sequestration,” and “worker.” These are terms that are not otherwise defined in Chapter 28. The remaining definitions in the Federal rule are the same as the definitions of the terms that the Department and the Commission propose to incorporate by reference at N.J.A.C. 7:28-6. Because the definitions at N.J.A.C. 7:28-6 apply throughout Chapter 28, the Department and the Commission do not propose to repeat them.

Throughout the Federal rules proposed to be incorporated by reference in Subchapters 50 through 64, no oral interpretations of rules will be binding on the Department. Only written interpretations by the New Jersey Attorney General are binding, unless the Department authorizes otherwise in writing. As discussed above, the Department and Commission propose to replace "written interpretations by the General Counsel" at 10 CFR 19.4 and elsewhere in the incorporated rules with "written interpretations, signed and approved by the Commissioner of the Department."

The Federal rules at 10 CFR 19.11 require licensees to post notices to workers. Licensees must post copies of the applicable regulations, their license, violations and any response to violations. In lieu of these postings, if posting is not practicable, the licensee may post a notice describing where these items may be reviewed. Licensees are also required to post a copy of NRC's Form 3, "Notice to Employees," if they have an NRC license. In accordance with proposed new N.J.A.C. 7:28-50.1(d), a facility that is licensed solely by the Department must post only the Department's form RPP-14, "Notice to Employees, Standards for Protection Against Radiation." No NRC form is necessary for such facilities. The Department proposes throughout proposed new Subchapters 50 through 64 to require the Department's form RPP-14, rather than NRC's Form 3,

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from facilities that are licensed solely by the Department. The Department's form will be available on the Department's website, <http://www.nj.gov/dep/rpp/index.htm>.

In accordance with 10 CFR 19.12, those employees who are likely to receive an annual occupational dose greater than 1 mSv (100 mrem), in normal or abnormal situations, must be kept informed of the storage, transfer or use of radiation and radioactive material. They must also be given appropriate radiation safety training. Employers are required to advise workers of the radiation reports that workers can request.

The various reports available to workers are identified in 10 CFR 19.13. Workers are to be provided with a report of their internal and external exposure to radiation on an annual basis. At the request of a worker formerly engaged in licensed activities controlled by the licensee, the licensee is also required to provide such a worker with a report of that worker's exposure to radiation or radioactive materials. If a licensee is required to report to the Department any exposure of an individual to radiation, the licensee is required to provide the individual with a report of the exposure data contained in the report. At the request of a worker who is terminating employment, the licensee shall provide to the worker, or to the worker's designee, a report on the radiation dose received by that worker during the current year.

The Federal rule at 10 CFR 19.14 requires licensees to permit an inspection by the Department at all reasonable times. During such inspections, Department representatives may consult privately with workers. Aside from these instances, the licensee or their representative may accompany the Department representative during the inspection. A worker's representative may also accompany the Department representative during an inspection. Although these representatives are usually individuals who are routinely engaged in the licensed activities under the control of the licensee, the regulations will allow the licensee or the workers to designate a

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consultant for this purpose. Department representatives may refuse to permit the accompaniment of anyone who interferes with an inspection or does not possess any necessary authorizations.

The manner in which employees, and employee representatives, may communicate with Department inspectors during an inspection is set forth at 10 CFR 19.15. Inspectors may consult privately with workers, and the workers may bring conditions to the attention of inspectors. The communications, while allowed, must not violate the safety instructions that workers were given under 10 CFR 19.12.

Workers, themselves, may request that the Department inspect a facility, if he or she believes that there has been a violation of the Act, the regulations, or license conditions, as discussed in 10 CFR 19.16. Such a request must be in writing, and set forth the grounds for the notice, and must be signed. If the worker's notice is well founded, the Department will inspect the facility. The Department will provide a copy to the licensee at the time of the inspection, but the worker can request that his or her name be withheld.

If the Department determines that an employee's report does not warrant an inspection, the Department will notify the employee in writing, in accordance with 10 CFR 19.17. Any appeals to such a decision will be made to the Department. The Department shall be the contact for all correspondence related to such issues, rather than the NRC. The employee may contact the Department at the address provided in the rule text.

The Federal rule at 10 CFR 19.18 describes the means by which interviews compelled by subpoena are to be conducted. The rule includes provisions regarding sequestration and representation by counsel. If the Department determines that the witness's counsel is to be excluded, the rule also provides the mechanism for appeal.

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“Whistleblower” protection is provided at 10 CFR 19.20. A licensee, or contractor or subcontractor of the licensee cannot discriminate against an employee for engaging in protected activities, such as communicating with the Department about possible violations. The Department and the Commission propose that protected activities, and other such whistleblower actions, be enforced through New Jersey’s Conscientious Employee Protection Act at N.J.S.A. 34:19-1 et seq., without prejudicing any other remedies available. The protected activities reference in 10 CFR Parts 50, 60, 63, 72 and 76 are not incorporated by reference because authority for these regulations is retained exclusively by the NRC.

In order to prevent a violation of the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, as amended, or regulations or order issued pursuant to those Acts, including the proposed new and amended rules, 10 CFR 19.30 allows the Department to obtain an injunction or other court order. In addition, a court order may be obtained for the payment of civil penalties.

Upon application by a licensee or upon the Department’s own initiative, 10 CFR 19.31 allows the Department, with the approval of the Commission on Radiation Protection, to grant an exemption from the requirements of the regulations, if the exemption is determined to be authorized in compliance with N.J.A.C. 7:28-2.8. While the NRC may grant exemption requests on its own, the Department, in accordance with N.J.A.C. 7:28-2.8, may grant exemptions only with the approval of the Commission on Radiation Protection. The Radiation Protection Act (N.J.S.A 26:2D) gives the Commission on Radiation Protection the power to formulate, adopt, promulgate, amend and repeal codes, rules and regulations as may be necessary to prohibit and prevent unnecessary radiation. This applies throughout the Federal rules proposed to be incorporated by reference in Subchapters 50 through 63, where the Department and Commission propose to add the requirement

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for Commission approval to any exemption provision proposed to be incorporated from the Federal rules.

Discrimination on the grounds of sex is prohibited under 10 CFR 19.32. Although the Federal rule bases the prohibition on Title VI of the Civil Rights Act of 1964, the Department and the Commission propose that this provision will be enforced through the New Jersey law against discrimination subject to N.J.S.A. 10:5-1 et seq. and applicable sections of Title VI of the Civil Rights Act of 1964, without prejudicing any other remedies available. Allegations of discrimination are to be reported to the Division on Civil Rights at the address specified in the rule language.

Lastly, as described in 10 CFR 19.40, criminal sanctions are authorized for violations of certain portions of Subchapter 50. Violations of 10 CFR 19.1 through 4, 19.16 through 18, 19.30, 19.31, and 19.40 are not subject to criminal sanction.

The Department does not propose to incorporate by reference those provisions of sections of 10 CFR Part 19 that involve communications with the NRC (10 CFR 19.5) because the contacts and addresses are inapplicable. When New Jersey becomes an Agreement State, communications regarding this proposed subchapter will be with the Department, not with NRC. The Department also does not propose to incorporate by reference the provisions relating to information collection requirements of the Federal government (10 CFR 19.8). Section 19.8 of the Federal rules relates solely to the NRC's interaction with the Federal Office of Management and Budget. Throughout proposed new Subchapters 50 through 64, the Department proposes not to incorporate provisions of the Federal rules regarding communications with the NRC and information collection, for the same reasons.

Subchapter 51: Rules of General Applicability to Domestic Licensing of Byproduct Material

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Proposed new Subchapter 51 incorporates by reference provisions of 10 CFR Part 30, which contains rules generally applicable to domestic licensing of byproduct material. The rules apply to all persons in New Jersey, and govern domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended, and under title II of the Energy Reorganization Act of 1974, and exemptions from the domestic licensing requirements permitted by Section 81 of the Act. This subchapter also gives notice that any person, who is involved in deliberate misconduct, as described under the subchapter, is subject to an enforcement action.

If there is a conflict between any portion of the general rules proposed to be incorporated from 10 CFR Part 30 and a specific requirement in any other NRC rule that the Department is incorporating by reference, the specific provision will govern, in accordance with the “resolution of conflict” provision that the Department proposes to incorporate from 10 CFR 30.2.

Under the NRC rules, 10 CFR 30.3, unless a person is specifically exempted, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material, except as authorized in a specific or general license issued by the Department or the NRC. The NRC will continue to issue licenses to Federal facilities located in the State, even after New Jersey becomes an Agreement State.

The Department proposes to incorporate from 10 CFR 30.4 the definitions of “agreement state,” “alert,” “commencement of construction,” “dentist” for the purposes of this subchapter, “microcurie,” “millicurie,” “person,” “physician” for the purposes of this subchapter, “podiatrist” for the purposes of this subchapter, “principal activities,” “production facility,” “research and development,” “sealed source,” “site area emergency,” “United States” and “utilization facility.” The remaining definitions in the Federal rule are the same as the definitions of the terms that the Department and the Commission propose to incorporate by reference at N.J.A.C. 7:28-6. Because

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the definitions at N.J.A.C. 7:28-6 apply throughout Chapter 28, the Department and the Commission do not propose to repeat them.

Discrimination against an employee for whistleblower activities, refusing to participate in an unlawful practice, or testifying in a matter involving the Department, is prohibited under 10 CFR 30.7. The Federal rule, proposed to be incorporated by reference, provides sanctions against persons that do discriminate. The Department and the Commission propose that protected activities, and other such whistleblower actions, be enforced through New Jersey's Conscientious Employee Protection Act at N.J.S.A. 34:19-1 et seq., without prejudicing any other remedies available.

The Federal regulations at 10 CFR 30.9 require all information submitted to the Department to be complete and accurate. If there is specific information that the applicant or licensee provides that has a significant implication for public health and safety or common defense and security, the applicant or licensee must notify the Department.

Deliberate misconduct is described in 10 CFR 30.10. The rule prohibits deliberate misconduct that causes, or would cause if not detected, a violation of a Department requirement. The rule also prohibits deliberate submission of false or inaccurate information. A violation is subject to enforcement action. This description of deliberate misconduct applies throughout the Federal rules proposed to be incorporated by reference in Subchapters 50 through 63.

The Federal rules at 10 CFR 31.11 through 31.21 provide exemptions from the licensing requirements of 10 CFR Part 30 (proposed Subchapter 51). Further, if a licensee's activities are licensed under 10 CFR Part 72 (governing licensing requirements for the independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than class c waste), the activities are exempt from this proposed subchapter. Similarly, except as provided in 10 CFR Part

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61 (licensing requirements for land disposal of radioactive waste), if a licensee is exempt under 10 CFR Part 61, its activities are not subject to this proposed subchapter. The Department of Energy is also exempt from this subchapter, to the extent its activities are subject to 10 CFR Parts 60 and 62 (disposal of high-level radioactive wastes in geologic repositories, and criteria and procedures for emergency access to non-Federal and regional low-level waste disposal facilities, respectively).

Further exemption is provided at 10 CFR 30.12, for persons using byproduct material under certain contracts with the Department of Energy and NRC contracts. If such a contractor, under his or her prime contract with the Department of Energy, manufactures, produces, transfers, receives, acquire, owns, possesses or uses byproduct material for work for the Department of Energy at a Federal site; or for certain activities related to atomic weapons; or for nuclear reactors or nuclear devices in a Federally-owned vehicle or vessel, then he or she is exempt from the proposed subchapter. Under certain situations, a prime contractor or subcontractor of the Department of Energy or the NRC is exempt from this subchapter, if the Department (with the approval of the Commission on Radiation Protection) determines that the exemption is authorized by law, and there is adequate assurance that the work can be accomplished without undue risk to the public health and safety.

The United States Postal Service and other carriers and warehousemen are exempt from proposed Subchapters 51 through 56, to the extent that they transport or store byproduct material in the regular course of carriage (or incidental storage) for someone else. This exemption is included in the Federal rules at 10 CFR 30.13.

The Federal rule at 10 CFR 30.14 exempts small quantities of byproduct material from the licensing requirements. Provided the amount is not in excess of the amounts at 10 CFR 30.70 (proposed to be incorporated by reference at N.J.A.C. 7:28-60), no license is required. The rule

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precludes the import of byproduct material, or products containing byproduct material. A manufacturer, processor, or producer of a product in an Agreement State other than New Jersey is exempt from the requirements for a license, to the extent that he or she transfers byproduct material in a product or material in concentrations not in excess of those, at 10 CFR 30.70. The material must have been introduced into the product by a licensee holding a specific license issued by an Agreement State, the NRC, or the Atomic Energy Commission. The Federal rule prohibits anyone from introducing byproduct material into a product or material if he or she knows or has reason to believe that it will be transferred to someone who is exempt from the licensing requirements, unless the transferring person has a license for the transfer.

The Federal rule at 10 CFR 30.15 provides an exemption for byproduct material in timepieces, lock illuminators, and other products, provided the amount of material is under specified amounts, and the radiation dose is within specified limits. The exemption does not apply to people who apply byproduct material to the products, or those who incorporate the byproduct materials into the products, or those who initially transfer the products for sale or distribution.

Other than for the manufacturer and initial transferor for sale or distribution, no license is required for the receipt, possession, use, transfer ownership or acquisition of resins containing scandium-46, designed for sand consolidation in oil wells, according to 10 CFR 30.16. Similarly, 10 CFR 30.19 exempts from the licensing requirements all but the persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147. The exemption does not apply if any of the three materials is used in toys or adornments, or products primarily for a frivolous purpose.

Under 10 CFR 30.18, a person who receives, possesses, uses, transfers, owns or acquires byproduct material in individual quantities less than the amounts specified at 10 CFR 30.71

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(proposed to be incorporated by reference at N.J.A.C. 7:28-61) is exempt from the licensing requirements of proposed Subchapters 51 through 57. Also, persons who acquired byproduct material under an NRC general license prior to September 25, 1971 are exempt. The rule does not authorize incorporation of the byproduct into products intended for commercial distribution. Nor can a person transfer individual quantities of the material, except in accordance with a proper license.

Manufacturers and those who process, produce or initially transfer gas and aerosol detectors containing byproduct material for sale or distribution do need appropriate licenses. However, those who acquire or possess the products after that time are exempt from licensing, in accordance with proposed amended N.J.A.C. 7:28-1 through 13 and proposed new subchapters N.J.A.C. 7:28-51 through 57 and 63. The exemption applies to gas and aerosol detectors that are designed to protect life or property from fires and airborne hazards.

The Federal rule at 10 CFR 30.21 exempts receipt, possession, use, transfer, ownership, or acquisition of capsules containing carbon-14 urea for “in vivo” diagnostic use for humans from the licensing requirements of 10 CFR Part 30, proposed to be incorporated by reference. Research use of the capsules on humans is not exempt, however. The Department is not proposing to incorporate 10 CFR 30.21(c) by reference into proposed Subchapter 51 because the rule relates to manufacturing of capsules containing carbon-14 urea. The NRC is retaining control over the manufacture, packaging, and transfer of capsules containing carbon-14 urea for commercial distribution.

The Federal rule at 10 CFR 30.31 identifies two types of licenses: general, and specific. A specific license is issued under 10 CFR Parts 32 through 36, and 29, which are incorporated by

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reference at proposed Subchapters 53 through 57. A general license is effective without the filing of an application, although registration might be required under the particular general license.

In order to apply for a specific license, an applicant must comply with the requirements of 10 CFR 30.32, which includes timing, completeness, what is to be included in the application, and the payment of a fee for a new permit. At proposed N.J.A.C. 7:28-51.1(c)13, the Department and Commission propose to require an applicant to submit a form that is available from the Department at the address listed in N.J.A.C. 7:28-1.5(a) or at the Department's web site at www.nj.gov/dep/rpp/rms/rmsdown.htm. Because New Jersey will become an Agreement State, the State's form replaces the NRC's form, and the applicant will file with the Department, rather than with the NRC.

Those licensees who have filed applications, statements or reports with the NRC will not be required to resubmit reports and information to the Department. As part of becoming an Agreement State, New Jersey will receive from the NRC copies of all submittals from NRC licensees.

The Federal rule also requires payment of a fee for a new license. The Federal rule refers to the fee schedule at 10 CFR 170.31; however, the Department proposes at new N.J.A.C. 7:28-64 its own schedule of fees, discussed below. Accordingly, the Department proposes at new N.J.A.C. 7:28-51.1(c)14 to refer instead to proposed new Subchapter 64.

Among the application requirements is the need for a proposed decommissioning funding plan or a certification of financial assurance for decommissioning, and an emergency plan for responding to a release of radioactive material. The applicant must provide the emergency plan to offsite response organizations prior to submitting the plan to the Department.

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The conditions under which an application for a specific license will be approved are at 10 CFR 30.33.

Each license that the Department issues is subject to the terms and conditions of 10 CFR 30.34 that are proposed to be incorporated by reference. The license cannot be transferred, without the Department's consent. Each license identifies locations and purposes to which the byproduct material is limited. A licensee is prohibited from using the byproduct material in any location or for any purpose other than as specified in the license. The rule gives the Department the authority to incorporate into any license issued under proposed Subchapters 51 through 57 the requirement that the licensee submit reports and keep records, and allow inspections as may be necessary to effectuate the purposes of the Act and regulations. It may also add conditions to the license in order to protect health, or minimize danger to life or property. The Department does not propose to incorporate by reference 10 CFR 30.34(e)(1) and (3), which allow the NRC to add requirements to a license in order to promote the common defense and security, or protect restricted data.

Licensees who must submit emergency plans (as required in proposed Subchapter 50), must follow the plan that the Department approves. The licensee may change the emergency plan without approval only if the changes do not decrease the effectiveness of the plan, and report any changes to the Department and emergency responders.

The rule also requires licensees who prepare certain radiopharmaceuticals must make certain tests of the products, record the results, and retain the records for three years. A licensee with a license for a portable gauge must secure the gauges from unauthorized removal when the gauge is not under the control and constant surveillance of the licensee. A licensee must notify the Department if the licensee files for bankruptcy.

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As set forth in proposed N.J.A.C. 7:28-51.1(b)4, the Department does not propose to incorporate 10 CFR 30.21(c). This provision would have incorporated sections 183 b through d of the Act (42 USC §§ 2011) into each license issued under proposed Subchapters 52 through 57, whether or not the provisions are expressly stated in the license.

The Federal rule at 10 CFR 30.35 discusses in detail the decommissioning plans and financial assurance that were discussed above with regard to 10 CFR 30.32. The amount of the financial assurance for decommissioning varies, depending on the quantity of byproduct material to be decommissioned. The financial assurance amounts range from \$113,000 to \$1,125,000. The financial assurance must be made by prepayment; insurance or other surety or guarantee; a sinking fund to which payments are made every year, combined with a surety method or insurance; a statement of intent, which contains a cost method (for Federal, State or local government licensees only); or, when a government entity is assuming custody and ownership of a site, a financial assurance arrangement that is deemed acceptable by the government entity.

A licensee must keep records of information important to the decommissioning of the facility. The records must be kept until the site is released for unrestricted use; therefore, the licensee must transfer the records to a new licensee if the facility is sold or another licensee becomes responsible for it. Among the necessary records are information on spills or other activity that involves the spread of contamination; drawings of structures and equipment in areas where radioactive materials are used and or stored; locations of buried pipes that may be subject to contamination; and a list of certain restricted areas, areas where waste has been buried, and the location of areas containing material such that that the licensee would be required to decontaminate the area or dispose of the material if the license were to expire.

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Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas are addressed at 10 CFR 30.36. The rule discusses when specific licenses expire, which varies depending on the licensee, whether an application for renewal has been filed, and other circumstances. If the Department revokes a specific license, it expires at the end of the day on which the final determination to revoke is made, or the expiration date that the Department specifies in the determination or other order.

Each specific license continues in effect, even beyond the expiration date if necessary, with respect to possession of byproduct material until the Department notifies the licensee in writing that the license is terminated. During this period, the licensee must control access to restricted areas and continue with decommissioning.

The licensee must provide notice to the Department, and begin decommissioning the site and regulated areas, or submit a decommissioning plan and begin decommissioning (if appropriate) if the license has expired; the licensee is ceasing activities; or the licensee has not conducted any of the principal activities under the license for 24 months. During this time, all financial assurances must be kept in place, and may need to be increased, if the cost estimate for decommissioning is greater than previously estimated. With the approval of the Department, after the decommissioning plan is approved, the licensee may reduce the amount of financial assurance as the amount of material at the site is reduced.

A licensee must submit a decommissioning plan if the license requires it, or if the Department has not previously approved the activities necessary to carry out decommissioning, and the activities could increase potential health and safety impacts to workers or to the public.

Decommissioning must take place within 24 months following the initiation of decommissioning, unless the Department has approved a request for an alternative schedule.

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Circumstances that the Department will consider in approving an alternative schedule include technical feasibility; waste disposal capacity; whether allowing short-lived radionuclides to decay will result in a significant volume reduction in wastes requiring disposal, or a significant reduction in radiation exposure to workers; and other site-specific factors.

As last step of decommissioning, the licensee must certify the disposition of all licensed material. The licensee must also conduct a radiation survey of the premises and report the results to the Department, or otherwise demonstrate the premises are suitable for restricted or unrestricted use, in accordance with proposed N.J.A.C. 7:28-12.

Specific licenses will be terminated by written notice to the licensee if the Department determines that the licensee has taken appropriate measures to decommission the site and meet the requirements of the rules.

If a licensee wishes to renew his or her license, he or she must comply with 10 CFR 30.38, which contains application requirements. The Department does not require that the applicant use the NRC form, but, at N.J.A.C. 7:28-1.1(c)17, requires an applicant to use the Department's form, which is available from the Department via the website or address provided at N.J.A.C. 7:28-1.5(a). Similarly, if a licensee wishes to amend his or her license, 10 CFR 30.38 requires a licensee to obtain Department approval. The Department does not require that the applicant use the NRC form, but, at N.J.A.C. 7:28-1.1(c)18, requires an applicant to send a letter to the Department describing the request.

The Federal regulations at 10 CFR 30.39 inform those applicants who want to renew or amend their license that their request will be evaluated against the requirements stipulated in 10 CFR 30.33, proposed to be incorporated by reference at N.J.A.C. 7:28-51, as well as against the

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applicable requirements of 10 CFR 32 through 36 and 39, proposed to be incorporated by reference at N.J.A.C. 7:28-53 through 57 and 63.

Transfers of byproduct material are discussed in 10 CFR 30.41. Licensees are not permitted to transfer byproduct material except to the U.S. Department of Energy, the licensing agency of an Agreement State, exempt persons to the extent permitted by such exemption, persons authorized to receive byproduct material under a general or specific license issued by the Department, the NRC or another Agreement State, or as otherwise authorized in writing by the Department.

Prior to the transfer of material, the person making the transfer is required to verify that the party to whom the material is being transferred is authorized to receive the material under a general or specific license. This verification can be made by the transferor reviewing a copy of the transferee's specific license or registration or by written certification from the transferee that they are authorized by license or registration to receive the material. For emergency shipments, an oral certification from the transferee can be accepted, as long as it is followed-up in writing within ten days. Confirmation can also be obtained from other official records of the Department, the NRC or the licensing agency of another Agreement State. Confirmation through a reporting service, which has based their information on records compiled from official sources, is also acceptable.

Reporting requirements are discussed in the Federal regulation at 10 CFR 30.50. Licensees are required to immediately report to the Department any event that prevents protective actions to avoid radiation exposure or events involving the release of licensed material that could exceed regulatory limits. Notification made no later than four hours after the occurrence of the event will be considered "immediate."

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Slightly later notice, within 24 hours, is required upon discovery of certain unplanned contamination events, an event in which necessary equipment is disabled or fails to function, or requires unplanned medical treatment of a person who has spreadable contamination on their clothing or body. Notice within twenty-four hours is also required for any unplanned fire or explosion involving licensed material when the quantity of material is greater than five times the lowest annual limit on intake specified in appendix B of 10 CFR 20, as proposed to be incorporated by reference at N.J.A.C. 7:28-6 and the damage affects the licensed material or its container.

Reports by the licensee are to be made by phone during office hours to (609) 984-5462 or during off-hours, weekends and holidays to the Department's hotline at 1-877-927-6337 (1-877 WARN DEP). Licensees are required to follow-up the initial phone call with a written report within 30 days. The report is to be sent to the Department at the address specified in N.J.A.C. 7:28-1.5(a).

Under the Federal regulations at 10 CFR 30.51, licensees are required to keep records of the receipt, transfer and disposal of byproduct material. Records of receipt are required to be kept for the length of time the licensee possess the material, and for three years after transfer or disposal. Records of transfer are to be retained for three years after the transfer. Disposal records are to be retained by the licensee who disposed of the material until the termination of their license. Any additional recordkeeping requirements specified in 10 CFR 30 through 36, as proposed to be incorporated by reference at N.J.A.C. 7:28-51 through 56 and 63, are to be followed, as well as any such requirement specified in a license condition. If a retention period is not specified, the records in question are to be maintained until the Department terminates the licensed activity for which the records are required.

Required records may be originals, copies, microform copies or stored electronically. Records are to be maintained with safeguards that protect against loss or tampering. In the event of

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any conflicts between the recordkeeping requirements specified in the regulations and those that may appear in a license condition or other Department approval or authorization, the requirements of the regulation are to be followed, unless the Department had granted a specific exemption from the specified requirement in question.

Prior to license termination, licensees authorized to possess radioactive material with half-lives greater than 120 days, in unsealed form, are required to forward to the Department records of disposal, including burials authorized prior to January 28, 1981, as well as records of surveys required by 10 CFR 20.2103(b)(4), as proposed to be incorporated by reference at N.J.A.C. 7:28-6. If material has been transferred, the transferor shall send the transferee the records that are required to be maintained. The new licensee shall maintain the records of any disposal of licensed material, including burials authorized before January 28, 1981, until the license is terminated. Records of surveys required by 10 CFR 20.2103(b)(4), as incorporated by reference at N.J.A.C. 7:28-6, and explained earlier in this summary, are also to be maintained by the new licensee until the license is terminated.

Prior to license termination, licensees are required to forward records related to financial assurance and decommissioning, as specified in 10 CFR 30.35(g), as incorporated by reference in N.J.A.C. 7:28-51, and discussed earlier in this summary, to the Department at the address specified in N.J.A.C. 7:28-1.5(a).

Licensees are to allow the Department to conduct inspections of their radioactive material, their premises and their facilities where the material is used or stored at all reasonable times and shall make all required records available for inspection under 10 CFR 30.52.

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Licenses are required to allow the Department, under 10 CFR 30.53, to conduct tests of the licensed material, the facilities where the material is used or stored, its radiation detection and monitoring instruments and other equipment connected with the use or storage of licensed material.

The Federal regulations at 10 CFR 30.61, inform licensees that the terms and conditions of each license are subject to amendment, revision or modification in accordance with changes to applicable statutes and the regulations derived from those statutes. Additionally, any license can be revoked, suspended or modified for any false statement made by an applicant or licensee, for any condition discovered that would have initially caused the denial of a license or for failure to observe the terms and conditions of any applicable laws or regulations. Except for cases of willfulness or those in which the public health and well-being require otherwise, a license will not be modified, suspended or revoked unless the actions which may result in the modification, suspension or revocation have been brought to the attention of the licensee in writing and the licensee has had the opportunity to demonstrate compliance with the law or regulation in question.

The Department has the authority to withhold or recall material from any licensee who is not equipped to observe or fails to protect health as determined by the Department or who uses the materials in violation of applicable laws or regulations or in a manner other than that disclosed in their application for a license under 10 CFR 30.62.

A table of exempt concentrations of radioactive materials is presented in Schedule A 10 CFR 30.70, while a table of exempt quantities of radioactive materials is provided in Schedule B at 10 CFR 30.71. The regulations at 10 CFR 30.72, Schedule C, provide the quantities of radioactive material that require consideration of the need for an emergency plan for responding to a release of material.

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Appendix A to the Federal regulations at 10 CFR Part 30 presents the “Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning.” The appendix discusses the financial criteria that must be met in order for an applicant or a licensee to demonstrate that their parent company guarantees funding will be available to cover decommissioning costs. The parent company must meet one of the two listed criteria. The first criterion includes certain financial ratios, net working capital, tangible net worth and parent company assets. The second criterion includes current bond ratings, tangible net worth and parent company assets.

The parent company’s independent certified public accountant shall have reviewed the data used in the financial test. The company is required to report to the Department if the auditor has identified any areas that need to be adjusted such that the company would no longer pass the financial test. The parent company is required to repeat the financial test annually within 90 days of the close of each fiscal year. Notification must be sent to the Department by certified mail within 90 days after the end of the fiscal year if the annual review shows the parent company no longer meets the financial test. The licensee has 120 days after the end of the fiscal year to provide an alternate means of financial assurance.

Additionally, the appendix also stipulates the terms that must be included in any parent company guarantee. The terms of the guarantee must provide that the guarantee will remain in force unless the notice of cancellation is provided by certified mail to the licensee and the Department, alternative financial assurance will be provided in the name of the licensee if the parent company no longer passes the financial test, parent company guarantees and financial test provisions remain in effect until the Department has terminated the license and in the event a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department.

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Appendix B to 10 CFR 30, as incorporated by reference at N.J.A.C. 7:28-51, lists the quantities of radioactive material that require labeling.

Appendix C provides the “Criteria Relating to Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning” at 10 CFR Part 30. The appendix provides the criteria that must be met in order for an applicant or licensee to provide its own guarantee that funding will be available for decommissioning. The appendix provides the financial tests that must be passed, as well as the terms of the self-guarantee.

To pass the financial test, a company must meet all of the listed criteria related to tangible net worth, assets, bond rating and class of equity securities. The company’s independent certified public accountant shall have reviewed the data used in the financial test. The company is required to report to the Department if the auditor has identified any areas that need to be adjusted such that the company would no longer pass the financial test. The annual requirement to repeat the financial test, and the steps to be taken if the company fails the test, are the same as in Appendix A.

Additionally, the appendix also stipulates the terms that must be included in any company self-guarantee. The terms of the guarantee must provide that the guarantee will remain in force unless the notice of cancellation is provided by certified mail to the licensee and the Department, alternative financial assurance will be provided in the name of the licensee if the parent company no longer passes the financial test, company guarantees and financial test provisions remain in effect until the Department has terminated the license. Additionally, licensees must send the Department and to their independent auditor copies of reports from the latest fiscal year that they have filed with the Securities and Exchange Commission. Licensees must also inform the Department in writing if their bond rating ceases to be rated at any category of “A” or above within 20 days after publication of the change. Lastly, a written guarantee to the Department from the applicant or licensee must be

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provided stating they will fund and carry out required decommissioning or will set up and fund a trust for this purpose, if so directed by the Department.

Appendix D to 10 CFR Part 30 describe the “Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies that have No Outstanding Rated Bonds.” The appendix discusses the financial criteria that must be met in order for an applicant or a licensee to demonstrate its ability to self-guarantee funding will be available to cover decommissioning costs.

To pass the financial test, a company must meet all of the listed criteria related to tangible net worth, assets and cash flow. The company’s independent certified public accountant shall have reviewed the data used in the financial test. The company is required to report to the Department if the auditor has identified any areas that need to be adjusted such that the company would no longer pass the financial test. The annual requirement to repeat the financial test, and the steps to be taken if the company fails the test, are the same as in Appendix A.

Additionally, the appendix also stipulates the terms that must be included in any company self-guarantee. The terms of the guarantee must provide that the guarantee will remain in force unless the notice of cancellation is provided by certified mail to the licensee and the Department, alternative financial assurance will be provided within 90 days of the Department’s receipt of a notice of cancellation of the guarantee, the company guarantees and financial test provisions remain in effect until the Department has terminated the license. Lastly, a written guarantee to the Department from the applicant or licensee must be provided stating they will fund and carry out required decommissioning or will set up and fund a trust for this purpose, if so directed by the Department.

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The “Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals” is discussed at Appendix E to 10 CFR Part 30. The appendix discusses the financial criteria that must be met in order for an applicant or a licensee to demonstrate their ability to self-guarantee funding will be available to cover decommissioning costs.

To pass the financial test, a college or university must pass one of two listed criteria. One applies to applicants or licensees that issue bonds and how to decide if the bond rating is acceptable. The other criteria applies to applicants or licensees that do not issue bonds and relates to their assets and whether the assets are sufficient.

To pass the financial test, hospitals must pass one of two listed criteria. One applies to applicants or licensees that issue bonds and discusses how to decide if the bond rating is acceptable. The other criteria applies to applicants or licensees that do not issue bonds, and relates to their revenue, ratio of long-term debt to assets, ratio of assets to liabilities and operating revenues.

Additionally, the licensee’s independent certified public accountant shall have reviewed the data used in the financial test. The company is required to report to the Department if the auditor has identified any areas that need to be adjusted such that the company would no longer pass the financial test. The company is required to repeat the financial test annually within 90 days of the close of each fiscal year. Notification must be sent to the Department by certified mail within 90 days after the end of the fiscal year if the annual review shows the company no longer meets the financial test. The licensee has 120 days after the end of the fiscal year to provide an alternate means of financial assurance.

Appendix E also stipulates the terms that must be included in any self-guarantee. The terms of the guarantee must provide that the guarantee will remain in force unless the notice of

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cancellation is provided by certified mail to the licensee and the Department, alternative financial assurance will be provided within 90 days of the Department's receipt of a notice of cancellation of the guarantee and the company guarantees and financial test provisions remain in effect until the Department has terminated the license. Lastly, a written guarantee to the Department from the applicant or licensee must be provided stating they will fund and carry out required decommissioning or will set up and fund a trust for this purpose, if so directed by the Department. Licensees must also inform the Department in writing if their bond rating ceases to be rated at any category of "A" or above within 20 days after publication of the change.

Discussions in 10 CFR 30.63 and 30.64 related to interpretations, violations and criminal penalties are the same as was discussed in the summary to subchapter 50.

Subchapter 52: General Domestic Licenses for Byproduct Material

Proposed new Subchapter 52 incorporates by reference 10 CFR Part 31, which contains rules establishing general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material.

Some of the rules of general applicability to domestic licensing of byproduct material, contained in 10 CFR Part 30 (incorporated by reference at proposed N.J.A.C. 7:28-51), are also applicable to general licenses established by this subchapter. The specific portions of 10 CFR Part 30 are identified at 10 CFR 31.2. General licensees are also subject to 10 CFR Parts 19 and 20, as proposed to be incorporated by reference at Subchapters 50 and 6. Additional terms are contained in the general license, itself.

Although 10 CFR 30.2 specifies that a general license is also subject to 10 CFR Part 21, Reporting of Defects and Noncompliance, the Department and Commission do not propose to

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incorporate those rules. Accordingly, general licensees are required to report defects and issues of noncompliance related to facilities, activities or basic components that could cause substantial safety hazards or that such supplied items contain defects to the NRC.

Proposed new Subchapter 52 issues a general license to transfer, receive, acquire, own, possess and use byproduct material contained in certain devices and equipment that have been manufactured by a specific licensee under the terms of their specific license, as discussed in 10 CFR 31.3. These devices include static elimination devices, which are used to eliminate static and contain no more than 500 micro curies of polonium-210 per device, and ion generating tubes, which ionize the air and contain not more than 500 micro curies of polonium-210 or not more than 50 millicuries of hydrogen-3 per device. A general license does not authorize the manufacture or import of such devices.

The proposed new subchapter also issues a general license for measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere, as set forth at 10 CFR 31.5. These licenses are issued to firms and government agencies to acquire, possess, use or transfer byproduct material contained in devices used for detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere in accord with the specifications described below.

Such general licenses apply only to byproduct material contained in devices that have been manufactured or initially transferred and labeled according to the specifications contained in a specific license issued under 10 CFR 32.51, as proposed to be incorporated by reference in N.J.A.C. 7:28-53, or an equivalent license issued by the NRC or another Agreement State. Such devices must be received from a specific licensee or through an appropriate transfer.

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The Federal rule sets forth requirements for labeling, testing, and recordkeeping related to devices containing byproduct material, and instruction in the event the device is damaged or fails. It also contains requirements for appropriate transfer and disposal of devices containing byproduct material, which include notification to the Department.

In order for a device to be included under the general license, the device must be annually registered with the Department. Registration includes payment of the appropriate fee (set forth in proposed Subchapter 64), as well as providing the Department contact information for the general licensee, information about the device, and certification that a representative of the general licensee is aware of the general license requirements. Each address for a location of use of such a device will be considered a separate general license requiring a separate registration and fee.

Such persons operating in areas subject to NRC jurisdiction need not register with the NRC if the device is used for less than 180 days in any calendar year. Reports of changes in the location of use, or location of primary storage for portable devices, shall be made to the Department within 30 days of the effective date of the change.

Devices subject to a general license may not be held if they are not in use for longer than two years, unless they are being kept for future use and are included in the licensee's physical quarterly inventory. Periodic testing of the devices is not required during storage; however, the devices must be tested before use or transfer.

The Federal regulations at 10 CFR 31.6 allow any person who holds a specific license (described in 10 CFR 31.5) from an Agreement State to install and service such a device in any non-agreement state and in off-shore waters as defined in 10 CFR 150.3(f), as incorporated by reference in proposed N.J.A.C. 7:28-62. The device has to have been manufactured, labeled, installed and serviced in accordance with the provisions of a specific license, and the person holding the specific

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license must assure that any required labels affixed to the device state that removal of the label is prohibited.

Proposed Subchapter 52, at 10 CFR 31.7, issues a general license to own, receive acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147. The safety device must have been manufactured or assembled under the provisions of a specific license. Persons owning, receiving, acquiring, possessing or using such devices are exempt from the regulatory requirements of 10 CFR Parts 19 and 20, as incorporated by reference, and 10 CFR Part 21. They are, however, subject to N.J.A.C. 7:28-6 (reports of theft of loss and reportable radiation incidents).

The general license does not permit the manufacture, assembly, repair or import of devices containing tritium or promethium-147, or the export of luminous safety products that contain these nuclides. The general license does not allow the ownership, receipt, acquisition, possession or use of promethium-147 in instrument dials.

Americium-241, in the form of calibration or reference sources, is covered by the general license issued at 10 CFR Part 31.8. A general licensee may own, receive, acquire, possess, use and transfer americium-241 in the form of such sources. The general licensee is not authorized to manufacture, export or import these sources. These sources must have been manufactured or initially transferred according to a specific license issued pursuant to proposed N.J.A.C. 7:28-53, or by the specific license issued by another Agreement State or by the NRC. These general licensees are subject to the applicable sections of 10 CFR Parts 30.14(d), 30.34(a) through (e), and 30.50 through 30.63, related to transfer of material to exempt persons, applicability of other Department regulations and other regulations related to records, inspections, tests and reports as described above

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in the Summary of Subchapter 51. Also applicable are the requirements of 10 CFR Parts 19 and 20, as incorporated by reference at proposed N.J.A.C. 7:28-50 and 6, and 10 CFR Part 21. The Federal rule limits the amount that a licensee can possess at one location to five microcuries, and requires specific labeling of sources. The rule also limits the transfer and disposal of the sources, contains specific storage requirements, and limitations on the use of the sources.

A general licensee may own byproduct material without regard to quantity under 10 CFR Part 31.9. However, the licensee may not manufacture, produce, transfer, receive, possess, use, import or export byproduct material, unless the licensee is subject to a specific license to do so. These regulations authorize the ownership of byproduct or source material, but do not authorize the possession or use of the material. The purpose of this provision, according to the NRC, is to allow investment groups or individuals (materials brokers) to purchase radioactive material or devices. The purchaser can then lease or sell the material or device to the ultimate user. The purchaser can have the material or device shipped directly from the manufacturer to the end user. The explanation is from an e-mail to the Department from the NRC received January 18, 2008.

Under the Federal regulations at 10 CFR Part 31.10, a general license is issued to own, receive, acquire, possess, use and transfer strontium-90 in ice detection devices, provided the devices are manufactured or initially transferred under a specific license issued by an Agreement State or the NRC. Persons generally licensed for these devices are required to stop using these devices if they are damaged, and either have them repaired by a specific licensee or dispose of them as described in proposed N.J.A.C. 7:28-6. General licensees must ensure that any labels affixed to these devices, which contain statements prohibiting the removal of the label, remain affixed on the device. Aside from the disposal and notification requirements of proposed N.J.A.C. 7:28-6, general licensees for these devices are exempt from the other requirements of N.J.A.C. 7:28-6 and 50, and

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the Federal reporting requirements of 10 CFR Part 21. Lastly, general licensees of these devices are prohibited from manufacturing, assembling, disassembling, repairing or importing these devices.

A general license is issued under 10 CFR 31.11 to physicians, veterinarians, clinical laboratories or hospitals, allowing them to receive, acquire, possess, transfer or use iodine-125, iodine-131, carbon-14, hydrogen-3, iron-59, selenium-75, or mock iodine-125. The general license allows the material to be used for certain in vitro clinical or laboratory tests that do not involve the internal or external administration of byproduct material to people or animals. The general licensees are not authorized to receive, acquire, possess, use or transfer byproduct material, unless they have filed NRC Form 483 or the equivalent Department form, available via the Department's website at www.nj.gov/dep/rpp/rms/rmsdown.htm or by requesting a copy by telephone during business hours at (609) 984-5462. The Department must have approved the form and provided an assigned registration number to the licensee, or the licensee must have a specific license for medical use of byproduct material under proposed N.J.A.C. 7:28-55.

Licensees under 10 CFR 31.11 are not authorized to possess at any one time a combined total of more than 200 microcuries of iodine-125, iodine-131, selenium-75, and/or iron-59. The general license restricts the storage, use, transfer and disposal of the material. Labeling of material is also specified at 10 CFR 31.11.

If there is a change to any information that the general licensee provided to the Department when it registered material under the general license, then the general licensee must report the change in writing to the Department within 30 days after the effective date of the change. Aside from the disposal and notification requirements of the proposed amended N.J.A.C. 7:28-6, general licensees for these devices are exempt from the other requirements of proposed N.J.A.C. 7:28:1 through 13 and 50, and the Federal reporting requirements of 10 CFR Part 21.

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As described in 10 CFR 31.12, records are to remain legible throughout the retention period, typically three years unless otherwise specified in the regulations. Records may be kept as originals, copies or electronically. Licensees are to have safeguards in place to guard against record tampering or loss.

The Federal rules at 10 CFR 31.13 and 14 discuss violations and criminal penalties. These provisions are the same as in 10 CFR Part 50, discussed above.

The Department and the Commission propose N.J.A.C. 7:28-52.1(d) through (g), in addition to the incorporation provisions of 10 CFR Part 31. The proposed subsections identify the Department's form that is comparable to the NRC Form 3, and specify which form must be posted by which general licensees. The proposed subsections also instruct licensees that reports are to be submitted to the Department (contact information is at proposed amended N.J.A.C. 7:28-1.5(a), and that any fees that the Federal rules require are to be in an amount identified at proposed N.J.A.C. 7:28-63.

Subchapter 53: Specific Domestic Licenses to Manufacture or Transfer Certain Items

Containing Byproduct Material

Proposed new Subchapter 53 incorporates by reference 10 CFR Part 32, which prescribes requirements for the issuance of specific licenses to manufacture or transfer certain items containing byproduct material. In particular, the subchapter applies to specific licenses for persons who manufacture or initially transfer items containing byproduct material for sale or distribution to persons exempted from the licensing requirements of 10 CFR Part 30, incorporated by reference at proposed N.J.A.C. 7:28-51, or persons generally licensed under 10 CFR Part 31 or 10 CFR Part 35,

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incorporated by reference at proposed N.J.A.C. 7:28-52 and 55, respectively. This subchapter also prescribes certain regulations governing holders of these licenses.

The Department proposes to incorporate from 10 CFR 32.2 the definition of “lot tolerance percent defective.” The remaining definitions in the Federal rule are the same as the definitions of the terms that the Department and Commission propose to incorporate by reference at N.J.A.C. 7:28-6. Because the definitions at N.J.A.C. 7:28-6 apply throughout Chapter 28, the Department and Commission do not propose to repeat them.

The Federal rule at 10 CFR 32.3 requires that records be maintained. This is the same requirement as discussed above, with regard to 10 CFR 31.12, incorporated by reference into proposed N.J.A.C. 7:28-52.

The Federal rule at 10 CFR 32.11 provides the requirements that need to be met before the Department will approve an application for a specific license under the proposed new subchapter. The applicant for a specific license must satisfy the general requirements at 10 CFR 30.33, as incorporated by reference at proposed N.J.A.C. 7:28-51, discussed above. Additionally, the application must describe the product or material into which the byproduct material will be introduced, the intended use of the byproduct material and the product or material into which it is being introduced, the method of introduction, the initial concentration of the byproduct material when introduced, methods to be used to ensure that only the intended amount of material is introduced, an estimate of the time between the introduction of the material and the transfer of the product or material and an estimate of the concentration of the radioactive material at the time of transfer.

The application must also provide assurance that the concentration of radioactive material in the product at the time the product is transferred will not exceed the concentrations at 10 CFR

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Part 30.70, as incorporated by reference at proposed N.J.A.C. 7:28-51; reconcentration of the material to levels greater than those specified in 10 CFR Part 30.70 will not occur; use of lower concentrations is not an option; and the product is not likely to be incorporated into any food, beverage, cosmetic, drug or other commodity that can be ingested, inhaled or applied to a person.

The Federal regulations at 10 CFR Part 32.12 specify the records that must be maintained, and what is to be contained in the material transfer report that the licensee must file with the Department. Information in the reports include the type and quantity of each product into which radioactive material was introduced during the reporting period, the name and address of the owner or possessor of the product at the time the radioactive material was introduced, the type and quantity of radioactive material introduced in to each product, and the initial concentrations of the radioactive material at the time it was introduced into the product.

A licensee must file a material transfer report with the Department within 30 days following the five year anniversary of the filing of the licensee's last report, or the filing of a license renewal application, or the licensee's notifying the Department of its intention to permanently discontinue activities authorized by its license. If no transfers of radioactive material have been made during the reporting period, the filed report should state this fact. A licensee must maintain records of these transfers for one year after the transfer is reported to the Department.

A licensee is prohibited by 10 CFR Part 32.13 from incorporating radioactive material into a product if the licensee knows or has reason to believe that the product will be transferred to someone exempt under 10 CFR Part 30.14, as incorporated by reference at proposed N.J.A.C. 7:28-51, or the equivalent regulations of another Agreement State or the NRC.

The Federal regulations at 10 CFR 32.17 identifies the requirements for an application for a specific license to manufacture, or initially transfer, synthetic plastic resins containing scandium-

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46 for use in sand consolidation in oil wells. The Department will approve an application for a specific license if the application satisfies the general requirements at 10 CFR 30.33, as incorporated by reference at proposed N.J.A.C. 7:28-51. The applicant must describe the product and control procedures to assure that the permissible concentration of scandium-46 in the final product is not exceeded. The Federal rule also contains labeling requirements.

The Federal regulations at 10 CFR 32.51 concern the manufacture or initial transfer of devices containing byproduct material to generally licensed persons. The Department will approve a specific license for such activities if the application satisfies the general requirements of 10 CFR 30.33 related to the issuance of a license. An applicant must also submit information on the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing operating and safety instructions and potential hazards of the device, as well as information on the labeling of the device and source housing. The applicant must show that, under accident conditions, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the amount specified at 10 CFR 32.24, proposed to be incorporated by reference. An applicant must also provide information related to potential radiation exposures if the applicant wishes to allow a general licensee to engage in certain activities, such as source installation or collecting leak test samples.

The Federal regulations at 10 CFR 32.51a provide certain license conditions applicable to the licensees described in the preceding paragraph. These regulations discuss the information that is to be provided to people to whom a device containing generally licensed radioactive material is to be transferred. The regulations include the timing of when such information is to be related to a transferee. The regulations also allow that alternative means of conveying this information to customers may be proposed and discuss the steps to take in the event of bankruptcy.

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The initial transfer of a device to a general licensee is governed by 10 CFR 32.52. Persons licensed under 10 CFR 32.51 need to submit reports to the Department on a quarterly basis, on NRC Form 653 or an equivalent Department form. The report details the transfer of devices that contain radioactive material. Any intermediaries prior to possession by the end user must also be reported. The report must also discuss any devices received from general licensees, changes to devices possessed by general licensees, the period of time covered by the report and the identity of the licensee submitting the report, including the specific license number. If no transfers have occurred, this also needs to be reported. Transfers of such devices to general licensees in other Agreement States or to general licensees in an NRC State must be reported to the responsible Agreement State agency or to the NRC. The reports are to include the information as discussed previously in this paragraph. Records of such transfers and receipts will need retained for three years following the transfer or receipt.

The requirements for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices for use in aircraft are governed by 10 CFR 32.53. In order for an application for these activities to be approved, the applicant must satisfy the general requirements of 10 CFR 30.33 related to the issuance of a license, and provide enough information on each device to evaluate any potential radiation exposure. A device may contain no more than 10 curies of tritium and no more than 300 millicuries of promethium-147 and cannot exceed the maximum exposure limit of 0.5 millirad per hour. The Department will approve an application if it meets the above requirements, and the Department determines that there is little likelihood that the material will be released. The device must also pass the prototype testing prescribed at 10 CFR 32.101, Schedule B, as incorporated by reference in this proposed subchapter.

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The Federal regulations at 10 CFR 32.54 concern the labeling of luminous safety devices for use in aircraft. The device must have a detailed label; or it can have an abbreviated label, provided that a detailed leaflet accompanies the device in the shipping container.

Quality assurance and prohibitions on transfer of these devices are addressed at 10 CFR 32.55. Licensees must visually inspect each device and reject those with obvious physical defects that could affect the containment of the radioactive material, and take random samples of the size determined by the “Lot Tolerance Percent Defective of 5.0 percent” as described in 10 CFR 32.110. Each device in the sample must be tested for leakage, radiation exposure levels emitted from the device or alternate testing methodology that will meet the prescribed objectives of the tests detailed in the regulations. Licensees may not transfer devices found to be defective, unless the defective units have been repaired and passed the prescribed tests. Licensees may also not transfer sample lots unless the individual devices found to be defective have been removed or repaired and re-tested, with the devices subsequently passing the prescribed tests.

The Federal regulations at 10 CFR 32.56 require each licensee to annually submit a report to the Supervisor of the Radioactive Materials Section, at the address provided in N.J.A.C. 7:28-1.5(a), on the total quantity of radioactive material transferred to general licensees, identifying the general licensee by name and providing the types and numbers of devices transferred. The reports are to cover the year ending June 30 and be submitted within 30 calendar days after that date.

Requirements for a license to manufacture or initially transfer calibration or reference sources containing americium-241 are described at 10 CFR 32.57. The Department will approve an application for a specific license if the applicant satisfies the general requirements of 10 CFR 30.33. Additionally, the applicant must provide enough information on each device to evaluate any potential radiation exposure. This information needs to include the quantity of radioactive material

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in each device, along with the chemical and physical form of the material, information on the construction and design, information on how the radioactive material is bound within the device, information on the types and results of prototype testing that demonstrate that the radioactive material will not be released under normal conditions of use, quality control procedures, a description of the labeling that will be affixed to the device or its storage container, as well as any additional information the Department feels is necessary to adequately determine the safety of the device.

A source can contain no more than 5 microcuries of americium-241. An application for a special license for a source that contains more than 0.005 microcuries of americium-241 will be approved if the Department determines that the material will not be released or removed under normal conditions of use, and the source has been subjected to and passed the prototype tests prescribed by 10 CFR 32.102, Schedule C.

The licensee is required to label each source or source storage container with information related to the safe use and storage of the device and the provided or substantially similar warning statement, in accordance with 10 CFR 32.58.

The requirements related to the leak testing of these sources are provided in 10 CFR 32.59. Licensees must dry wipe test each source containing greater than 0.1 microcuries of americium-241 prior to transferring the source to general licensees. If any leak test detects more than 0.005 microcuries of activity, the source will be considered to be leaking and cannot be transferred to a general licensee.

The Federal regulations at 10 CFR 32.61 cover the requirements for the manufacture or initial transfer of ice detection devices containing strontium-90. In order for an application for these activities to be approved, the applicant must satisfy the general requirements of 10 CFR 30.33

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related to the issuance of a license, and provide enough information on each device to evaluate any potential radiation exposure. This information must include the quantity of radioactive material in each device, along with the chemical and physical form of the material, information on the construction, design and shielding of the source, a radiation profile of the device, information on the types and results of prototype testing that demonstrate that the radioactive material will not be released or removed under the most severe conditions likely to be encountered in normal conditions of handling and use, quality control procedures employed during device manufacture, a description of the labeling that will be affixed to the device, instructions to be provided to the general licensee on the handling and installation of the device, as well as any additional information the Department feels is necessary to adequately determine the safety of the device.

Each label is required to contain the radiation caution symbol as prescribed in the Federal Regulations at 10 CFR 20.1901(a), incorporated by reference at proposed new N.J.A.C. 7:28-6, a statement that the device contains strontium-90, the quantity of radioactive material, instructions on proper disposal, a statement that the manufacturer or civil authorities are to be notified if the device is found, removal of the labeling is prohibited and that disassembly or repair of the device is only to be conducted by such people specifically licensed for such activities.

In order for a specific license to be granted, the Department, based upon the provided information, must conclude that the radioactive material will not be released under the most severe conditions likely to be encountered during normal handling and use, the device is designed so that direct contact with the radioactive material is precluded and the source is shielded to prevent an exposure greater than 0.5 rem in a year under ordinary circumstances, the device is designed so it cannot be easily disassembled, and the device has passed all required prototype testing, as well as the quality assurance testing as prescribed at 10 CFR 32.62, as described below.

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The licensee must visually inspect each ice detection device and reject any device with an observable physical defect that could affect the containment of the radioactive material. The licensee must also conduct additional specified quality assurance tests including, but not limited to, an immersion test. Alternatives to the specified procedures may be submitted to the Department for review, as long as they meet the described standards.

The licensee is prohibited from transferring to general licensees any device that was tested and found to be defective, as described above, unless the units have been repaired, retested and passed the described tests. Additionally, licensees are prohibited from transferring to general licensees any inspection lot which has been rejected, unless individual defective units have been sorted and removed or the defective units repaired, retested and passed the described tests.

Application requirements for a specific licenses to manufacture and distribute byproduct material in certain in vitro clinical or laboratory testing under a general license is discussed in the Federal regulations at 10 CFR 32.71. In order for an application for these activities to be approved, the applicant must satisfy the general requirements of 10 CFR 30.33 related to the issuance of a license, the radioactive material is manufactured in prepackaged units that meet the specified quantities per listed nuclide and each unit has a durable, clearly visible label indicating the identity of the nuclide, the quantity of material contained and displays the radiation caution symbol accompanied by a written warning. An additional informational statement must be part of the affixed label or be included in a leaflet or brochure that accompanies the package. This informational statement concerns the precautions on the handling and storage of the radioactive material. Waste disposal requirements must also be included if the package contains mock iodine-125.

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The Federal regulations under 10 CFR 32.72 concern the manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under 10 CFR Part 35, incorporated by reference at proposed N.J.A.C. 7:28-55. In order for an application for these activities to be approved, the applicant must satisfy the general requirements of 10 CFR 30.33 related to the issuance of a license, submit evidence of being registered or licensed as a drug manufacturer or licensed as a pharmacy or operating as a nuclear pharmacy within a Federal medical institution, submit information on the radionuclide and its packaging to show the packaging is adequate for safe handling and storing and satisfies the specified requirements related to the labeling of each transport radiation shield, syringe, vial or other container used to hold a radioactive drug. The radiation symbol and certain cautionary wording must be on each label.

Licensed pharmacies or nuclear pharmacies operating within Federal medical institutions may prepare radioactive drugs for medical use provided the drug is prepared by an authorized nuclear pharmacist or an individual under the supervision of an authorized nuclear pharmacist. Drug manufacturers, pharmacies and nuclear pharmacies must submit copies of each individual's certification, permit, licensure or registration to the Department, at the address provided in N.J.A.A. 7:28-1.5(a), no later than 30 days after the licensee allows the person to work as an authorized nuclear pharmacist.

A licensee is required to possess and use instrumentation to measure the radioactivity of drugs, such as a dose calibrator, and is required to measure the amount of radioactivity in the drugs prior to transfer. Prior to initial use of each such instrument, periodically and following repair, a licensee shall perform accuracy, geometry and linearity testing as appropriate, making any necessary adjustments. Licensees shall also check each such instrument for constancy and proper operation at the beginning of each day of use. A licensee is also required to comply with any

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applicable Federal Food and Drug Administration requirements concerning radioactive drugs, as well as any other Federal or State requirements.

The manufacture and distribution of sources or devices containing byproduct material for medical use is covered by the Federal regulations in 10 CFR 32.74. In order for an application for these activities to be approved, the applicant must satisfy the general requirements of 10 CFR 30.33 related to the issuance of a license, submit sufficient information to evaluate the radiation safety of the source or device and ensure the label that will be affixed to the source, device or the storage container for the source or device contains the required information such as, but not limited to, the radionuclide and the date of assay. If the applicant requests a leak testing interval of greater than six months, the applicant must supply sufficient justification to support the request. Those applications filed with the NRC prior to or on October 15, 1974, for a license to manufacture or distribute sources or devices that had been distributed prior to or on August 16, 1974, allow the applicant to continue the distribution of such sources or devices until the Department issues the license or otherwise notifies the applicant.

The Federal regulations at 10 CFR 32.101 provide a schedule for prototype tests for luminous safety devices for use in aircraft. Applicants for a license for these devices must conduct prototype tests on each of five prototype devices. Prototype testing shall include temperature-altitude tests, vibration tests, accelerated weathering tests, shock tests and hermetic seal tests. Observations shall be made of each device after each test to check for evidence of physical damage or leakage. Any evidence of damage or leakage is cause for rejection of the design, if the damage or leakage can be attributed to a design defect. The detection of more than 2200 disintegrations per minute of tritium or promethium-147 per 100 square centimeters of surface wipe tested or more

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than 0.1 percent of the original amount of tritium or promethium-147 in the water will be cause for the rejection of a device.

The Federal regulations at 10 CFR 32.102 provide a schedule for prototype tests for calibration or reference sources containing americium-241. Applicants for a license for devices designed to contain more than 0.005 microcuries of americium-241 must conduct prototype tests, in the order listed, on each of five prototype devices. Prototype testing shall include an initial measurement of the quantity of radioactive material deposited on the source, dry wipe testing, wet wipe testing, water soak testing and a second dry wipe test. The discovery of more than 0.005 microcuries of radioactivity during any test is cause for rejection of the source design. Results of the prototype testing provided to the Department must be reported in units of microcuries and percent removal from the total amount of activity deposited on the source.

The Federal regulations at 10 CFR 32.103 provide a schedule for prototype tests for ice detection devices containing strontium-90. Applicants for a license for these devices must conduct prototype tests on each of five prototype devices. Prototype testing shall include temperature-altitude tests, vibration tests, shock tests and hermetic seal and waterproof tests. After each test, each device will be examined for any physical damage or loss of strontium-90. Any evidence of physical damage or loss of strontium-90 will be cause for rejection of the design, if the damage or failure can be attributed to a design defect. If the leak test detects more than 2200 disintegrations per minute of strontium-90 per 100 square centimeters of surface wiped or more than 0.1 percent of the original amount of strontium-90, it will be cause for rejection of the device.

The Federal regulations at 10 CFR 32.110 provide the requirements for acceptance sampling procedures under certain specific licenses. Devices licensed under 10 CFR 32.14, 32.53 or 32.61, as incorporated by reference at N.J.A.C. 7:28-53 and previously described in this

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summary, for which testing is required as stipulated in 10 CFR 32.15, 32.55 or 32.62, as previously discussed, are required to have a random sample taken from each inspection lot in accord with the appropriately listed "Sampling Table" as determined by the designated "Lot Tolerance Percent Defective." A lot will be considered acceptable if the number of defective devices does not exceed the acceptance number listed in the appropriate table. The entire inspection lot is rejected if the number of defective devices exceeds the acceptance number.

The Federal rules at 10 CFR 32.301 and 303 discuss violations and criminal penalties. These provisions are the same as at 10 CFR Part 50, discussed above.

The Department does not propose to incorporate by reference 10 CFR 32.14 through 16, 18 through 23, 25 through 29, 40, and 210, which refer to programs that the NRC is not transferring to Agreement States.

Subchapter 54: Specific Domestic Licenses of Broad Scope for Byproduct Material

Proposed new Subchapter 54 incorporates by reference 10 CFR Part 33. The proposed new subchapter prescribes requirements for the issuance of specific licenses of broad scope for byproduct material ("broad licenses") and regulates holders of such licenses. The requirements of this proposed subchapter are in addition to, other requirements, such as 10 CFR Part 30, as proposed to be incorporated by reference at N.J.A.C. 7:28-51. Proposed Subchapter 51 applies to applications and licenses subject to this proposed subchapter.

The Federal regulations at 10 CFR 33.11 describe the different types of specific licenses of broad scope, specifically Types A, B and C. Type A licenses authorize the receipt, acquisition, ownership, possession, use and transfer of radioactive material in quantities that do not exceed the amounts specified in the specific license, usually in the multicurie range.

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Type B licenses authorize the receipt, acquisition, ownership, possession, use and transfer of radioactive material specified in Schedule A of 10 CFR 33.100, as proposed to be incorporated by reference at N.J.A.C. 7:28-54. If only one nuclide is possessed, the possession limit is as specified in Schedule A, Column I. If two or more nuclides are possessed, the possession limit is determined by taking the ratio of the amount possessed to the quantity specified in Column I of Schedule A for each nuclide. The sum of the ratios cannot exceed unity.

Lastly, Type C licenses authorize the receipt, acquisition, ownership, possession, use and transfer of radioactive material specified in Schedule A of 10 CFR 33.100. If only one nuclide is possessed, the possession limit is as specified in Schedule A, Column II. If two or more nuclides are possessed, the possession limit is determined by taking the ratio of the amount possessed to the quantity specified in Column II of Schedule A for each nuclide. The sum of the ratios cannot exceed unity.

The Federal regulations at 10 CFR 33.12 direct those people who wish to obtain a broad scope license to file an application with the Department.

The Federal regulations at 10 CFR 33.13 provide the requirements that must be met to obtain a Type A license of broad scope. An applicant must demonstrate that he or she meets the requirements of 10 CFR 30.33, as proposed to be incorporated by reference at N.J.A.C. 7:28-51 and discussed earlier in this Summary; has had experience in a reasonable number of activities involving radioactive material; has established administrative controls and procedures, including recordkeeping, necessary to assure safe operations; has established a Radiation Safety Committee; has appointed a radiation safety officer; and has established procedures to ensure control of procurement and use of radioactive material, the evaluation of safety considerations of proposed

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uses of material and the review, approval and recording by the Radiation Safety Committee of the evaluation of the proposed uses.

The Federal regulations at 10 CFR 33.14 provide the requirements that must be met to obtain a Type B license of broad scope. An applicant must demonstrate that he or she meets the requirements of 10 CFR 30.33, as proposed to be incorporated by reference at N.J.A.C. 7:28-51 and discussed earlier in this Summary; has established administrative controls and procedures, including recordkeeping, necessary to assure safe operations; has appointed a radiation safety officer; and has established procedures to ensure control of procurement and use of radioactive material, the evaluation of safety considerations of proposed uses of material and the review, approval and recording by the Radiation Safety Officer of the evaluation of the proposed uses.

The Federal regulations at 10 CFR 33.15 provide the requirements that must be met to obtain a Type C license of broad scope. An applicant must demonstrate that he or she meets the requirements of 10 CFR 30.33, as proposed to be incorporated by reference at N.J.A.C. 7:28-51 and discussed earlier in this summary; and has submitted a statement that the material will be used only by or under the direct supervision of people who have received a college degree at least at the bachelor's level, or equivalent training and experience, in the physical or biological sciences or engineering. This person must have had at least 40 hours of training and experience in the safe handling of radioactive material, as well as in the characteristics of ionizing radiation, units of radiation dose and quantity, radiation detection instrumentation and the biological hazards of exposure to radiation. Lastly, the applicant must have established administrative controls and procedures to ensure control of procurement and use of radioactive material, including recordkeeping, necessary to assure safe operations. An application for a specific license other than a broad scope license will be considered an application for a broad scope license, if the applicable

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criteria of a broad scope license as discussed in this Subchapter is satisfied, as per the Federal regulations at 10 CFR 33.16.

The Federal regulations at 10 CFR 33.17 provide the conditions of a broad scope license. Licensees are not authorized to conduct tracer studies involving the direct release of radioactive material into the environment, receive, acquire, possess, use, transfer or import devices containing more than 100,000 Curies or more of radioactive material in sealed sources used for irradiation purposes, conduct activities that require a specific license under 10 CFR Part 32, 34 or 35, as proposed to be incorporated by reference at N.J.A.C. 7:28-53, 55 or 63, or add radioactive material to any food, beverage, cosmetic, drug or other product that can be ingested, inhaled or applied to a human being.

Type A licensees are also alerted that material under their license may only be used by, or under the direct supervision of individuals approved by their Radiation Safety Committee. Type B licensees are informed that material under their license may only be used by, or under the direct supervision of individuals approved by their Radiation safety Officer. Lastly, Type C licensees are informed that material under their license may only be used by, or under the direct supervision of individuals who meet the requirements of 10 CFR 33.15, as proposed to be incorporated by reference in N.J.A.C. 7:28-54, and previously discussed in this Summary.

The Federal regulations at 10 CFR 33.100, Schedule A, provide the columns of quantities of material to be referenced by applicants and licensees for specific licenses of broad scope.

In order to prevent a violation of the Atomic Energy Act of 1954, Title II of the Energy Reorganization Act of 1974, or regulations or order issued pursuant to those Acts, including the proposed new and amended rules, 10 CFR 33.21 allows the Department to obtain an injunction or other court order. In addition, a court order may be obtained for the payment of civil penalties.

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Lastly, as described in 10 CFR 33.23, criminal sanctions are authorized for violations of certain portions of proposed Subchapter 54. Violations of 10 CFR 33.1, 19.21, and 19.23 are not subject to criminal sanction.

Subchapter 55: Medical Use of Byproduct Material

Proposed new Subchapter 55 contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this subchapter are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of 10 CFR 19, 20, 30, and 71, proposed to be incorporated by reference at N.J.A.C. 7:28-50, 6, 51 and 61, respectively, apply to applicants and licensees subject to this subchapter unless specifically exempted.

This subchapter proposes to require the use of a dose calibrator prior to the administration of radiopharmaceuticals to humans. The NRC requires the use of this device only for certain administrations. This proposed difference between the proposed rules and the Federal rules is discussed in more detail in the Federal Standards Analysis, below. Aside from this expansion of the use of a dose calibrator, this proposed subchapter incorporates by reference the Federal regulations found at 10 CFR Part 35.

The Department proposes to incorporate from 10 CFR 35.2, for purposes of this subchapter only, the definitions of “address of use,” “agreement state,” “area of use,” “authorized medical physicist,” “authorized nuclear pharmacist,” “authorized user,” “brachytherapy,” “brachytherapy source,” “client’s address,” “dedicated check source,” “dentist,” “high dose-rate

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remote afterloader,” “low dose-rate remote afterloader,” “management,” “manual brachytherapy,” “medical event,” “medical institution,” “medical use,” “medium dose-rate remote afterloader,” “mobile medical service,” “output,” “patient intervention,” “pharmacist,” “physician,” “podiatrist,” “preceptor,” “prescribed dosage,” “prescribed dose,” “pulsed dose-rate remote afterloader,” “radiation safety officer,” “sealed source and device registry,” “stereotactic radiosurgery,” “structured educational program,” “teletherapy,” “temporary job site,” “therapeutic dosage,” “therapeutic dose,” “treatment site,” “type of use,” “unit dosage” and “written directive.” The definitions of the medical professionals, for example, may differ in 10 CFR Part 35 from the definitions in other portions of Chapter 28. The remaining definitions in the Federal rule are the same as the definitions of the terms that the Department and the Commission propose to incorporate by reference at N.J.A.C. 7:28-6. Because the definitions at N.J.A.C. 7:28-6 apply throughout Chapter 28, the Department and the Commission do not propose to repeat them.

The Federal regulations in 10 CFR 35.5, as proposed to be incorporated by reference, require the maintenance of records in legible form throughout specified retention periods. Records may be originals, copies, microform copies or stored electronically. Records are to be maintained with safeguards that protect against loss or tampering.

The Federal regulations at 10 CFR 35.6 provide provisions for the protection of human research subjects. Licensees may only use material for the uses specified in their licenses. If the research is conducted, funded, supported or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Research Subjects, prior to conducting the research, that licensee must have the research reviewed and approved by an Institutional Review Board and obtain “informed consent” from the research subject. If this does not apply, the licensee must apply for and receive an amendment to their medical use license. The amendment request must include

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commitments to obtaining review and approval from an Institutional Review Board and “informed consent” from the research subject prior to conducting the research.

A licensee must comply with other applicable Food and Drug Administration, Federal or State requirements that govern radioactive drugs or devices, as per 10 CFR 35.7.

The Federal regulations at 10 CFR 35.10 concern the implementation of the regulations. License conditions that exempted licensees from a provision of 10 CFR Part 35 on October 24, 2002, will continue in effect. In those instances where a license condition is different from the requirements in 10 CFR Part 35, the requirements of 10 CFR Part 35 are to be followed. Licensees are to continue to abide by license conditions concerning the implementation of procedures concerning safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units, as well as spot-checks of teletherapy units, remote afterloader units and gamma stereotactic radiosurgery units until there is a modification of the applicable condition.

A specific license is required to manufacture, produce, acquire, receive, possess, prepare use or transfer radioactive material for medical use, as per the Federal regulations of 10 CFR 35.11. Exceptions are made for those persons who are receiving, possessing, using or transferring radioactive material under the supervision of an authorized user or preparing such material for medical use under the direct supervision of an authorized nuclear pharmacist, as discussed in 10 CFR 35.27, proposed to be incorporated by reference at N.J.A.C. 7:28-55 and discussed below in this Summary. These exceptions do not apply if prohibited by a license condition.

The regulations at 10 CFR 35.12 stipulate that all license applications be signed by the applicant’s or licensee’s management. Applications are to include facility diagrams, equipment, training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized

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medical physicist(s), and authorized nuclear pharmacist(s) and safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units, as well as spot-checks of teletherapy units, remote afterloader units and gamma stereotactic radiosurgery units. Requests for amendments to licenses may be made to the Department in the form of a letter. License renewals are to be made on forms available from the Department.

Additionally, applicants for medical uses of radioactive material not explicitly discussed elsewhere in 10 CFR Part 35 are to include any other safety aspects that are not addressed in the general administrative or technical requirements specified elsewhere, specific information on radiation safety precautions and instructions, methods used to measure administered doses and dosages and the calibration, maintenance and repair of instruments and equipment with their application. Applicants that satisfy the requirements of 10 CFR 33.13, as previously discussed in this Summary, may apply for a Type A license of broad scope.

As per the Federal regulation at 10 CFR 35.13, licensees are required to apply for and receive a license amendment prior to the receipt, preparation or use of radioactive material for which they are not authorized by their current license and prior to allowing anyone to function as an authorized user, authorized nuclear pharmacist, or authorized medical physicist. Exceptions are made for authorized users, authorized nuclear pharmacists and authorized medical physicist for those people who satisfy the training requirements applicable to those titles. Exceptions are also made for authorized users, authorized nuclear pharmacists and authorized medical physicists who are listed on an NRC license or license from another Agreement State, on a permit issued by the NRC or on a specific broad scope license issued by another Agreement State, on an NRC master material license or by a commercial nuclear pharmacy.

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An amendment must also be approved before a licensee changes the Radiation Safety Officer, unless the person is functioning as a temporary Radiation Safety Officer, as per 10 CFR 35.24(c) and discussed later in this Summary, prior to receiving material for which they are not currently licensed, different forms of that material or amounts in excess of their licensed amount of material. Amendments must also be approved prior to changing areas of use, except for those materials for which a written directive is not required, address of use or revises safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units, as well as spot-checks of teletherapy units, remote afterloader units and gamma stereotactic radiosurgery units.

Under the Federal regulations at 10 CFR 35.14, licensees shall provide the Department with a copy of the board certification, signed preceptorship, NRC or Agreement State license, NRC master material license, permit from an NRC or Agreement State license of broad scope, or permit from an NRC master material license broad scope permittee no later than 30 days after the licensee allows the individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist. For those people working in a nuclear pharmacy, verification of additional case experience must be provided in the same timeframe for authorized users using unsealed radioactive material that requires a written directive. Any additional training also needs to be submitted within 30 days for authorized users of sealed sources in remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units and for authorized medical physicists.

Licensees have 30 days to inform the Department when an authorized user, authorized nuclear pharmacist, authorized medical physicist or Radiation Safety Officer has discontinued service or has a change of name. The licensee must also inform the Department in this same timeframe if they are allowing someone qualified to be a Radiation Safety Officer to function as a

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temporary Radiation Safety Officer, if the licensee's mailing address changes, if the licensee's name changes without a transfer of control, or if the licensee has changed the areas of use. Any additional information required to be submitted shall be forwarded to the Department at the address listed in N.J.A.C. 7:28-1.5(a).

The exemptions related to Type A licenses of broad scope are covered in 10 CFR 35.15. These licensees are exempt from the requirement to file an amendment request for the medical use of byproduct material not explicitly discussed in other areas of 10 CFR Part 35, the provisions concerning license amendments as discussed above, the provisions concerning required notifications, as discussed above, and the provisions concerning sealed sources as discussed below in this Summary.

The regulations at 10 CFR 35.18 describe the circumstances under which a license can be issued. Licenses can be issued if an appropriate application has been filed, if the appropriate fee has been paid, a review of the application has found that the applicant is equipped and committed to observe applicable safety standards that will protect the public and has satisfied the general requirements stipulated in 10 CFR Part 30, as proposed to be incorporated by reference at N.J.A.C. 7:28-51 and discussed above in this Summary. Applicants for mobile medical services can be approved if they meet the requirements previously discussed in this paragraph and assure that people to whom radioactive materials, or radiation from implants, have been administered can be released from the licensee's control.

The Department, with approval of the Commission on Radiation Protection, may issue special exemptions upon application of an interested party, or based on its own initiative, from the regulations of 10 CFR Part 35, as long as the exemption is authorized in compliance N.J.A.C. 7:28-2.8. The Federal regulations at 10 CFR 35.24 discuss the authority and responsibility for the

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radiation safety program. The licensee's management is required to approve in writing any license application, license renewal or license amendment request, any person prior to allowing that person to function as an authorized user, authorized nuclear pharmacist or authorized medical physicist and certain changes to the radiation safety program, as discussed later in this summary.

The management will also appoint a Radiation Safety Officer, who will accept the appointment in writing. Through the Radiation Safety Officer, the management will ensure that activities are being conducted with approved procedures and applicable requirements. For up to 60 days each year, licensees are permitted to allow someone qualified to be a Radiation Safety Officer to act as a temporary Radiation Safety Officer. More than one temporary Radiation Safety Officer may be appointed if needed to adequately oversee all the uses of material permitted by the license. Licensees are required to establish the authority, duties and responsibilities of the Radiation Safety Officer in writing. Licensees are to provide the Radiation Safety Officer with the authority, resources and power to identify radiation safety problems, the ability to take actions to correct the problems, stop unsafe operations and verify that corrective actions have been employed.

Licensees authorized to conduct two or more different types of uses of radioactive material involving unsealed material for which a written directive is required, manual brachytherapy or the use of remote afterloader units, teletherapy units, gamma stereotactic radiosurgery units or two or more types of the aforementioned units are required to establish a Radiation Safety Committee. The Committee must include an authorized user for each type of use authorized by the license, the Radiation Safety Officer, a representative of the nursing service and a representative of management who cannot be an authorized user or the Radiation Safety Officer. Others members can be included as considered appropriate by the licensee. Appropriate records shall be maintained as discussed later in this summary.

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Under the Federal rule at 10 CFR 35.26, licensees can revise their radiation safety program without prior approval from the Department if the revision does not require an amendment, as reviewed in the discussion of 10 CFR 35.13 above, the revision complies with the regulations and the license in question, the revision has been reviewed and approved by the licensee's Radiation Safety Officer and their management and any people impacted by the revision are instructed on changes prior to their implementation. Records of these changes are to be retained by the licensee as per 10 CFR 35.2026, as discussed later in this Summary.

The requirements for those individuals working under the supervision of authorized personnel are discussed in the regulations at 10 CFR 35.27. Those people who receive, possess, use or transfer radioactive material under the supervision of an authorized user shall receive the general radiation safety instruction provided for in 10 CFR 19.12, as proposed to be incorporated by reference at N.J.A.C. 7:28-50 and discussed earlier in this Summary, be instructed in the licensee's written radiation protection procedures, written directive procedures, applicable regulations and the applicable license conditions and follow the instructions of the authorized user in regards to these listed matters.

Those people who prepare radioactive material for medical use under the supervision of an authorized nuclear pharmacist or authorized user shall receive the general radiation safety instruction provided for in 10 CFR 19.12, as proposed to be incorporated by reference at N.J.A.C. 7:28-50 and discussed earlier in this Summary, receive instruction on the proper preparation of the material, and follow the instructions of the supervising authorized nuclear pharmacist or authorized user in regards to such preparation, the licensee's established radiation protection procedures, applicable regulations and license conditions. Licensees are responsible for the actions or omissions of their supervised personnel.

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The Federal rule at 10 CFR 35.40 provides the regulations for written directives. An authorized user must date and sign a written directive prior to the administration of greater than 30 microcuries of iodine-131 sodium iodide, any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material. In an emergency, the directive may be provided orally, but must be followed up with a written directive within 48 hours. Written directives are required to contain the patient's or human research subject's name, dosage of iodine 131 and the drug, dosage and route of administration if unsealed material other than iodine-131 was used.

Written directives for gamma stereotactic radiosurgery must include the total dose, treatment site and values of the setting for each treatment site for each treatment. Teletherapy treatments require information on total dose, dose per administered fraction, number of fractions and the treatment site. High dose rate remote afterloading brachytherapy written directives require information on the radioactive material used, treatment site, dose per fraction, number of fractions and the total dose. Written directives for all other brachytherapy, including low, medium, and pulsed rate remote afterloaders require, prior to the implantation, information on treatment site, the radioactive material and the dose. After implantation, but before the procedure is completed, information on the radioactive material used, the treatment site, the number of sources and total source strength and exposure time (or the total dose) is required.

Written revisions to existing written directives are allowed if the revision is dated and signed by an authorized user prior to the administration of the unsealed radioactive material, the dose from an exposure to radioactive material or the next such fractional dose. In an emergency, revisions to the written directive may be provided orally, but must be followed up with a revised

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written directive within 48 hours. Licensees are to retain copies of written directives, as per 10 CFR 35.2040 discussed later in this summary.

When administration of byproduct material requires a written directive, the Federal rule at 10 CFR 35.41 requires the licensee to develop, implement and maintain written procedures to ensure that the patient's or human research subject's identity is verified prior to each administration and the administration occurs in accord with the written directive. These procedures must also require that any manual and computer generated dose calculations are checked and that any computer generated dose calculations have been correctly entered into the remote afterloader, teletherapy or gamma stereotactic radiosurgery unit in question. A copy of the procedures is to be retained as per 10 CFR 35.2041, as discussed later in this Summary.

The Federal regulations at 10 CFR 35.49 require licensees, for medical purposes, to only use sealed sources that have been manufactured, labeled, packaged and distributed by a facility licensed for these activities as per 10 CFR Part 30, as proposed to be incorporated by reference at N.J.A.C. 7:28-51, and 10 CFR 32.74, as proposed to be incorporated by reference at N.J.A.C. 7:28-53, and discussed earlier in this Summary. Sealed sources transferred from another facility licensed by this subchapter may also be used. Teletherapy sources are to have been manufactured and distributed by a facility licensed for these activities as per 10 CFR Part 30, as proposed to be incorporated by reference at N.J.A.C. 7:28-51.

The required training for Radiation Safety Officers is provided in 10 CFR 35.50. With the exception of those experienced radiation safety officers regulated by 10 CFR 35.57, as discussed later in this Summary, a person named as a Radiation Safety Officer must meet one of the specified criteria. The first option is that the named person be certified by a specialty board whose certification has been recognized by the Department, the NRC or another Agreement State, has

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obtained a written attestation signed by a preceptor Radiation Safety Officer that the person has adequate training and experience specified by the regulations and is sufficiently knowledgeable to function independently as the Radiation Safety Officer for a medical use license, and the individual has training in the radiation safety, regulatory issues and emergency procedures for the types of use for which the licensee seeks approval.

The second option is that the named person has completed an educational program consisting of at least 200 hours of formal classroom education in different aspects of radiation safety and science as specified, and one year of full-time radiation safety experience as specified, under the supervision of an individual identified as the Radiation Safety Officer on a Department, NRC or other Agreement State license or permit issued by an NRC master material license.

The final option is that the named individual be a medical physicist who has been certified by a specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and has radiation safety experience for the types of uses for which the licensee is seeking approval, or the named individual be an authorized user, authorized medical physicist or authorized nuclear pharmacist identified on the licensee's license and having radiation safety experience for the types of uses for which the licensee is seeking approval. Any named person previously discussed in this paragraph must also have obtained a written attestation signed by a preceptor Radiation Safety Officer that the person has adequate training and experience specified by the regulations and is sufficiently knowledgeable to function independently as the Radiation Safety Officer for a medical use license, and the individual has training in the radiation safety, regulatory issues and emergency procedures for the types of use for which the licensee seeks approval.

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The required training for authorized medical physicists is provided in 10 CFR 35.50. With the exception of those experienced authorized medical physicists regulated by 10 CFR 35.57, as discussed later in this summary, a person named as an authorized medical physicist must meet one of the specified criteria. The first option is that the named person be certified by a specialty board whose certification has been recognized by the Department, the NRC or another Agreement State, has obtained a written attestation signed by a preceptor authorized medical physicist that the person has adequate training and experience specified by the regulations and is sufficiently knowledgeable to function independently as the authorized medical physicist for each type of therapeutic medical unit for which the person wishes to be so named, and the individual has training for the types of use for which the licensee seeks approval.

The second option is that the named person holds a master's or doctor's degree in one of the specified disciplines, has completed one year of full-time training in medical physics and an additional year of full-time work experience, as specified, as a medical physicist under the supervision of an individual identified as an authorized medical physicist. Any person named under this option must also have obtained a written attestation signed by a preceptor authorized medical physicist that the person has adequate training and experience specified by the regulations and is sufficiently knowledgeable to function independently as the authorized medical physicist for each type of therapeutic medical unit for which the person wishes to be so named, and the individual has training for the types of use for which the licensee seeks approval.

The required training for authorized nuclear pharmacists is provided in 10 CFR 35.55. With the exception of those experienced authorized nuclear pharmacists regulated by 10 CFR 35.57, as discussed later in this summary, a person named as an authorized nuclear pharmacist must meet one of the specified criteria. The first option is that the named person be certified by a specialty

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board whose certification has been recognized by the Department, the NRC or another Agreement State and has obtained a written attestation signed by a preceptor authorized nuclear pharmacist that the person has adequate training and experience specified by the regulations and is sufficiently knowledgeable to function independently as the authorized nuclear pharmacist.

The second option is that the named person has completed an educational program consisting of at least 700 hours in a structured educational program, 200 hours of which shall be formal classroom education in different aspects of radiation safety and science as specified, and the remainder consisting of supervised practical experience as specified. The individual also has to obtain a written attestation signed by a preceptor authorized nuclear pharmacist that the person has adequate training and experience specified by the regulations and is sufficiently knowledgeable to function independently as the authorized nuclear pharmacist.

The training requirements for experienced Radiation Safety Officers, teletherapy or medical physicists, authorized medical physicists, authorized users, nuclear pharmacists and authorized nuclear pharmacists are presented in 10 CFR 35.57. Individuals who were named as Radiation Safety Officers, teletherapy or medical physicists or nuclear pharmacists prior to October 24, 2002, do not need to comply with the requirements of 10 CFR 35.50, 51 or 55, as previously discussed. Individuals who were named as Radiation Safety Officers, authorized medical physicists or authorized nuclear pharmacists between October 24, 2002, and April 25, 2005, do not need to comply with the requirements of 10 CFR 35.50, 51 or 55, as previously discussed.

Physicians, dentists or podiatrists identified as authorized users prior to April 29, 2005, who are performing only those medical uses for which they were authorized on that date, do not need to comply with the training requirements of 10 CFR 35.190, 290, 390, 490, 590 or 690, as discussed later in this Summary.

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The recentness of training is regulated by 10 CFR 35.59. The training and experience requirements specified in 10 CFR 35.50 through 57, 190, 290, 390, 490 and 590 must have occurred within the seven years prior to the date of the application. If the training and experience occurred more than seven years prior to the date of the application, the individual must have related continuing education and experience since the required training was completed.

The Federal rule at 10 CFR 35.60 governs the possession, use and calibration of instruments used to measure the activity of unsealed byproduct material. For direct measurements of unsealed material for medical use, a licensee must possess and use instrumentation to measure the activity of the radioactive material before it is administered to patients or human research subjects. This instrument must be calibrated according to nationally recognized standards or the manufacturer's instructions. Records of instrument calibrations must be retained by the licensee as per 10 CFR 35.2060, as discussed later in this Summary.

The calibration of survey instruments is regulated by 10 CFR 35.61. Licensees are required to calibrate their survey instruments before first use, annually and following a repair that could affect the calibration. Instruments may not be used if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent. Records of calibrations need to be retained as per 10 CFR 35.2061, as discussed later in this Summary.

The Federal regulation at 10 CFR 35.63 provides language on the determination of dosage of unsealed radioactive material for medical use. Licensees are required to determine and record the activity of each dosage prior to its administration. For unit dosages, the Federal regulations permit the dosage to be measured either directly by the licensee at its facility, or by the licensee using a decay correction based on the activity that was measured by the manufacturer or preparer of the material prior to shipment to the licensee's facility.

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The Department, however, does not believe that the second option provides sufficient safeguards to the public. Therefore, the Department proposes to require a licensee to directly measure all unit dosages at its facility prior to administration. Further justification for this decision is provided in the Federal Standards Analysis section of this Summary.

Unless specifically directed by an authorized user, the licensee may not use a dosage if it differs from the prescribed dosage by more than 20 percent, or if it falls outside of the prescribed dosage range. Records of the dosage determination shall be retained as required by 10 CFR 35.2063, as described later in this Summary.

The Federal rule at 10 CFR 35.65 provides the regulations on authorization for calibration, transmission and reference sources. Any authorized person may use sealed sources and byproduct material, with quantities and half-lives specified in the regulations, as well as technetium-99m, in amounts as needed for checking, calibrating transmission and reference use.

Requirements for the possession of sealed sources and brachytherapy sources are covered in 10 CFR 35.67. Licensees are required to follow the manufacturer's safety and handling instructions for these sources. Additionally, licensees are required to perform leak tests on sealed sources every six months, as stipulated in the regulations. If the test results indicate that the source is leaking, the licensee is to immediately remove it from use and arrange to have it stored, properly disposed or repaired. A report on a leaking source is to be sent to the Department at the address provided at N.J.A.C. 7:28-1.5(a). Records of leak test results are to be retained by the licensee as per 10 CFR 35.3067, as discussed later in this Summary. Leak tests do not need to be performed on sources not being used and designated as "In storage," seeds of iridium-192 encased in nylon ribbon, sources containing only radioactive material in a gaseous state, sources containing

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radioactive material with a half-life of less than 30 days and sources containing 100 microcuries or less of beta or gamma emitting material or 10 microcuries of alpha emitting material.

The Federal regulations at 10 CFR 35.69 concern the labeling of vials and syringes. Each syringe or vial must be labeled to identify the radioactive drug it contains. Syringe shields and vial shields must also be labeled, unless the label on the syringe or vial is visible when shielded.

The Federal rule at 10 CFR 35.70 concerns surveys of ambient exposure rates. Licensees are required to survey all areas where unsealed material that requires a written directive was prepared or administered at the end of each day of use. Licensees are not required to perform these surveys in areas where patients or human research subjects are confined and cannot be released from the licensee's control. Records of surveys are to be retained as per 10 CFR 35.2070, as discussed later in this subchapter.

The release of individuals containing unsealed byproduct material or implants containing byproduct material is covered by the requirements of 10 CFR 35.75. Licensees may release from their control any person who has been administered radioactive material, if the total effective dose equivalent to any other person is not likely to exceed 0.5 rem. The licensee shall provide to the released patient recommendations, including written instructions, on how to keep doses as low as reasonably achievable, if the potential exposure to any person is 0.1 rem or higher. If the total effective dose equivalent to a nursing infant or child could exceed 0.1 rem, the instructions must include guidance on the interruption or stoppage of breast-feeding and information on the potential consequences of not following the guidance. Records of the basis used to release the person shall be kept as per 10 CFR 35.2075, as discussed later in this Summary. A record of the instructions provided to breast-feeding women is also to be maintained as per 10 CFR 35.2075(b), as discussed later in this Summary.

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The Federal regulations at 10 CFR 35.80 concern the provisions for mobile medical service. Licensees are required to obtain letters signed by the management from each of their client facilities. The letters are to clearly state that the licensee has the client's permission to use radioactive material at their facility, and delineates each parties authority and responsibilities. Licensees are also required to check instruments used to measure the activity of unsealed radioactive material before use at each client's address or on each day of use, whichever is more frequent, and to check their survey instruments for proper operation with a dedicated check source before use at each client facility. Before leaving a client's address, licensees are required to survey all areas of use to make sure no radioactive contamination is present.

Licensees are not permitted to arrange to have radioactive material delivered to the client, unless the client is licensed to possess such material. Letters and surveys are to be retained by the licensee as per the requirements of 10 CFR 35.2080, as discussed later in this Summary.

Decay-in-storage requirements are covered on 10 CFR 35.92. Licensees are permitted to hold radioactive material for decay-in-storage if it has a physical half-life of less than 120 days. The licensee is required to monitor the waste to ensure it cannot be distinguished from background prior to its release. The waste is to be surveyed with an appropriate survey meter set to its most sensitive scale with nothing that would provide any shielding. Additionally, all radiation labels are to be removed or defaced prior to release of that waste, unless the waste will be inside another container that will be disposed of as biohazard waste. Records are to be retained as per 10 CFR 35.2092, as discussed later in this Summary.

The Federal rule at 10 CFR 35.100 covers the use of unsealed byproduct material for uptake, dilution and excretion studies for which a written directive is not required. Licensees are permitted to use radioactive material for these medical uses as long as the materials are obtained

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from a source licensed under 10 CFR 32.72, as previously discussed in this Summary, or from an authorized nuclear pharmacist, a physician who is an authorized user as specified in 10 CFR 35.290 or 390, as discussed later in this Summary, or an individual under the supervision of an authorized nuclear pharmacist or an authorized user. Material may also be obtained from and prepared by an NRC or Agreement State licensee for use in research as per an approved radioactive Drug Research Committee protocol or an Investigational New Drug protocol accepted by the U.S. Food and Drug Administration.

The Federal rule at 10 CFR 35.190 covers the training requirements for uptake, dilution and excretion studies. Except for experienced authorized users covered in 10 CFR 35.57, as previously discussed in this Summary, authorized users for these medical studies are physicians who are required to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and who have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be signed by a preceptor authorized user who meets the requirements of 10 CFR 35.190 or of 10 CFR 35.290 or 390, as discussed below in this Summary. Authorized users under 10 CFR 35.290 and 390 or equivalent Agreement State requirements are also authorized for the medical uses of 10 CFR 35.190.

The use of unsealed byproduct material for imaging and localization studies for which a written directive is not required is covered under 10 CFR 35.200. Except for those quantities that require a written directive, licensees are permitted to use radioactive material for these medical uses as long as the materials are obtained from a source licensed under 10 CFR 32.72, as previously discussed in this Summary, or from an authorized nuclear pharmacist, a physician who is an

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authorized user as specified in 10 CFR 35.290 or 390, as discussed later in this Summary, or an individual under the supervision of an authorized nuclear pharmacist or an authorized user.

Material may also be obtained from and prepared by an NRC or Agreement State licensee for use in research as per an approved radioactive Drug Research Committee protocol or an Investigational New Drug protocol accepted by the U.S. Food and Drug Administration.

The Federal regulation at 10 CFR 35.204 provides the permissible molybdenum-99 concentration. Licensees are not permitted to administer to humans a radiopharmaceutical that contains more than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m. Licensees that use molybdenum-99 generator kits for preparing technetium-99m are required to measure the molybdenum-99 concentration of the first eluate after receipt of the generator and are required to keep records of these measurements as per 10 CFR 35.2204, as discussed later in this Summary.

The Federal regulations at 10 CFR 35.290 provide the training for imaging and localization studies. Except for experienced authorized users covered in 10 CFR 35.57, as previously discussed in this Summary, authorized users for these medical studies are physicians who are required to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and who have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be signed by a preceptor authorized user who meets the requirement of 10 CFR 35.290 or of 10 CFR 35.390, as discussed below in this Summary. Authorized users under 10 CFR 35.290 and 390 or equivalent Agreement State requirements are also authorized for the medical uses specified in 10 CFR 35.100.

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The Federal rule at 10 CFR 35.300 provides the requirements for the use of unsealed byproduct material for which a written directive is required. Licensees are permitted to use radioactive material for these medical uses as long as the materials are obtained from a source licensed under 10 CFR 32.72, as previously discussed in this Summary, or from an authorized nuclear pharmacist, a physician who is an authorized user as specified in 10 CFR 35.290 or 390, as discussed later in this Summary, or an individual under the supervision of an authorized nuclear pharmacist or an authorized user. Material may also be obtained from and prepared by an NRC or Agreement State licensee for use in research as per an approved radioactive Drug Research Committee protocol or an Investigational New Drug protocol accepted by the U.S. Food and Drug Administration.

The Federal regulation at 10 CFR 35.310 provide the requirements for safety instruction to personnel caring for patients or human research subjects that cannot be released from the licensee's control. Licensees are to provide safety training initially and at least annually to such personnel. Training records are to be retained as per 10 CFR 35.2310, as discussed below in this Summary.

Safety precautions are provided in 10 CFR 35.315. For each patient or human research subject that cannot be released from a licensee's control, the licensee is required to assign the individual to a private room with private bathroom facilities or a room with another person who has received therapy with unsealed radioactive material and cannot be released from the licensee's control. This room is also to have private bathroom facilities and be posted with a "Radioactive Materials" sign. Information on where and for how long visitors may be permitted in the room must be posted on the door or in the patient or human research subject's chart. Materials and items that leave the room must either be surveyed to ensure they are not radioactively contaminated or be

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treated as radioactive waste. Licensees are required to notify their Radiation Safety Officer, or that person's designee, if the patient or human research subject has a medical emergency or dies.

The training for the use of unsealed byproduct material for which a written directive is required is covered in the Federal regulations at 10 CFR 35.390. Except for experienced authorized users covered in 10 CFR 35.57, as discussed above, authorized users for these medical studies are physicians who are required to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and who have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be signed by a preceptor authorized user who meets the requirement of 10 CFR 35.390 or equivalent Agreement State requirements. As an alternative, a physician can also be an authorized user if they have completed 700 hours of training and experience, which includes 200 hours of classroom and laboratory training, as well as work experience under the supervision of an authorized user.

The Federal regulations at 10 CFR 35.392 concern the training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries. Except for experienced authorized users covered in 10 CFR 35.57, as discussed above, authorized users for these medical studies are physicians who are required to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and who have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be signed by a preceptor authorized user who meets these requirements or the requirements of 10 CFR 35.390, 392 or 394, as discussed below in this Summary. As an alternative, the authorized user can be a physician who has successfully completed 80 hours of

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classroom and laboratory training in the medical use of sodium iodide I-131 and has work experience under the supervision of an authorized user as appropriate for these studies.

Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) is converted by the Federal rule at 10 CFR 35.394. Except for experienced authorized users covered in 10 CFR 35.57, authorized users for these medical studies are physicians who are required to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and who have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be signed by a preceptor authorized user who meets the requirement of 10 CFR 35.394 or of 10 CFR 35.390.

As an alternative, the authorized user can be a physician who has successfully completed 80 hours of classroom and laboratory training in the medical use of sodium iodide I-131 and has work experience under the supervision of an authorized user as appropriate for these studies. A final option is that the physician is an authorized user under 10 CFR 35.390 or the equivalent regulations of another Agreement State.

The Federal rule at 10 CFR 35.396 concerns training for the parenteral administration of unsealed byproduct material requiring a written directive. Except for experienced authorized users covered in 10 CFR 35.57, as discussed above, authorized users for these medical studies are physicians who are required to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and who have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be

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signed by a preceptor authorized user who meets the requirement of 10 CFR 35.396 or of 10 CFR 35.390. The physician must also have successfully completed 80 hours of classroom and laboratory training applicable to parenteral administrations and has work experience under the supervision of an authorized user as appropriate for these studies.

As alternatives, the authorized users can be physicians who are qualified as per 10 CFR 35.390, as previously discussed in this Summary, or are qualified as authorized users per 10 CFR 35.490 or 690 and who meet the training, work experience and written attestation requirements as previously discussed in the Summary to this section.

The use of sources for manual brachytherapy is discussed in the Federal regulations at 10 CFR 35.400. Licensees can only use brachytherapy sources for therapeutic medical uses that are approved in the NRC's Sealed Source and Device Registry or for research purposes in accord with an "Investigational Device Exemption" that has been accepted by the U.S. Food and Drug Administration. The sources must be obtained from suppliers approved per 10 CFR 35.49, as previously discussed in this Summary.

The Federal rule at 10 CFR 35.404 concerns surveys after source implant and removal. Licensees are required to survey and account for all source that have not been implanted into a patient or human research subject, immediately after the implant procedure is completed. If the implants are temporary in nature, the licensee is to survey the patient or human research subject immediately after the sources have been removed to confirm that all the sources have been removed. Records of these surveys are to be retained as per 10 CFR 35.2404, as discussed below.

Brachytherapy sources accountability is covered by the Federal regulations at 10 CFR 35.406. These regulations require that licensees account for all brachytherapy sources in their possession, whether in use or in storage, at all times. As soon as possible after removing sources

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from a patient or human research subject, the sources are to be returned to a secure storage area.

Licensees are required to maintain records related to source accountability, as per 10 CFR 35.2406, as discussed later in this subchapter.

The Federal rule at 10 CFR 35.410 concerns safety instructions. In addition to the general instructions to workers provided as per 10 CFR 19.12, the licensee is required to provide additional radiation safety instructions, initially and annually, to those persons who are involved in the care of patients or human research subjects who are receiving brachytherapy and cannot be released from the licensee's control. The training is to include such topics as the size and appearance of the sources, safe handling of the sources and shielding control and that notification is to be provided to the Radiation Safety Officer or their designee if the person receiving the treatment has a medical emergency or dies. Training records are to be retained as per 10 CFR 35.2310, as discussed below in this Summary.

The Federal regulation at 10 CFR 35.415 covers safety precautions. For those patients or human research subjects who cannot be released from the licensee's control, the licensee cannot quarter them in a room with an individual who is not receiving brachytherapy. The room where they are quartered must be posted with a "Radioactive Materials" sign and a note must be placed on the door or in the patient or human research subject's chart that indicates where and for how long visitors may stay in the room. Emergency response equipment must be available near each room in the event a source is dislodged from the patient or lodged within the patient. The Radiation Safety Officer or their designee is to be notified as soon as possible if the patient or human research subject has a medical emergency or dies.

Calibration measurements of brachytherapy sources are discussed in the Federal rule at 10 CFR 35.432. On or after October 24, 2002, before the first use of a brachytherapy source, licensees

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are required to determine the activity or output from the source using a dosimetry system that meets the requirements of 10 CFR 35.630, as discussed later in this Summary. Licensees are also required to determine the source positioning accuracy within applicators. Protocols accepted by nationally recognized bodies are to be used to make these determinations. As an alternative, licensees may use the determinations provided by the source manufacturer by an accredited calibration laboratory. Source outputs or activities are to be corrected for decay at intervals consistent with one percent decay of the source. Records of calibrations are to be retained as per 10 CFR 35.2432, as will be discussed below.

The Federal rule at 10 CFR 35.457 concerns therapy related computer systems. A licensee is required to perform acceptance testing on the treatment planning system of therapy related computer systems. The acceptance testing is to be done in accord with protocols accepted by nationally recognized bodies. The testing is to include such things as the accuracy of dose, dwell time and treatment time calculations at representative points, as well as the accuracy of the software used to determine sealed source positions from radiographic images.

The Federal regulation at 10 CFR 35.490 governs training for use of manual brachytherapy sources. Except for experienced authorized users covered in 10 CFR 35.57, as discussed above, authorized users for these medical studies are physicians who are required to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and who have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be signed by a preceptor authorized user who meets the requirements of this 10 CFR 35.490.

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As an alternative, the physician may have successfully completed a structured educational program applicable to manual brachytherapy that includes 200 hours of classroom and laboratory training and has 500 hours of work experience under the supervision of an authorized user as appropriate for these studies. Additionally, the physician wishing to qualify as an authorized user under this option must also have completed three years of supervised clinical experience in radiation oncology, under an authorized user, as part of an approved, formal residency training program.

Training for the ophthalmic use of strontium-90 is governed by the Federal rule at 10 CFR 35.491. Except for experienced authorized users covered in 10 CFR 35.57, as previously discussed in this Summary, an authorized user for these medical studies is a physician who is authorized under 10 CFR 35.490 or has successfully completed 24 hours of classroom and laboratory training applicable to this medical treatment, has received supervised clinical training in this treatment by an authorized user work experience under the supervision of an authorized user, which must involve the treatment of five individuals, and who has obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as an authorized user for these medical studies. The attestation is to be signed by a preceptor authorized user who meets the requirements of 10 CFR 35.491.

The use of sealed sources for diagnostic purposes is covered in 10 CFR 35.500. Licensees are only to use sealed sources for diagnostic purposes that have been approved in the NRC's Sealed Source and Device Registry.

Training for the use of sealed sources for diagnostic purposes is governed by the regulations in 10 CFR 35.590. Except for experienced authorized users covered in 10 CFR 35.57, as previously discussed, authorized users for these medical studies are physicians who are required

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to be certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State. As an alternative, the physician may have successfully completed eight hours of classroom and laboratory training applicable to the use of the sealed sources in question and has completed training in the use of the sealed sources.

The Federal regulations at 10 CFR 35.600 concern the use of a sealed source in remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units. Licensees shall only use sealed sources for these medical devices that have been approved and appear in the NRC's Sealed Source and Device Registry or have been approved as part of research conducted according to an active "Investigational Device Exemption" application that has been accepted by the U.S. Food and Drug Administration, provided the device has been manufactured in accord with the requirements of 10 CFR 35.49, as was discussed above.

Surveys of patients and human research subjects treated with a remote afterloader unit are governed by the rule at 10 CFR 35.604. Prior to release from their control, licensees are required to survey patients or human research subjects and the remote afterloader unit to ensure that the source has been removed from the patient and has returned to its storage location in the unit. Records of these surveys are to be retained by the licensee as per 10 CFR 35.2404.

The installation, maintenance, adjustment and repair of different units is discussed in 10 CFR 35.605. Only those people specifically licensed by the Department, the NRC or another Agreement State are permitted to install, maintain, adjust or repair remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units that involves such work as the source shielding or drive unit. Except for low-dose rate remoter afterloader units, only those people specifically licensed by the Department, the NRC or another Agreement State are permitted to install, replace, relocate or remove a source contained in a remote afterloader units, teletherapy units

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or gamma stereotactic radiosurgery unit. Only those people specifically licensed by the Department, the NRC or another Agreement State are permitted to install, replace, relocate or remove a source contained in a low dose-rate remote afterloader unit. Licensees are required to retain records of any such activities in accord with the regulations at 10 CFR 35.2605.

The Federal rule at 10 CFR 35.610 concerns the safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units. Licensees are required to take steps to ensure that the unit, the console, control keys and treatment room are secured when not in use or unattended. Only those individuals who have been approved by the Radiation Safety Officer, an authorized user or an authorized medical physicist are allowed to be present in the room during treatments. If there is more than one radiation producing device located in the room, only one is allowed to be operated at any one time. Licensees are also required to develop, implement and maintain written emergency procedures for responding to abnormal situations that may occur during treatments. A copy of these procedures is to be kept at the unit console at all times.

Instructions are to be posted at the unit's console to provide the operator with the location of the emergency procedures and the telephone numbers of authorized users, the authorized medical physicist and the Radiation Safety Officer to be contacted in the event the unit does not operate properly. Licensees are also required to inform workers, prior to their initial use of the unit and annually thereafter, on the emergency procedures and operating procedures for the unit. Drills on the emergency procedures are to be conducted with the operators, authorized users and authorized medical physicists initially and annually thereafter. Records of the instruction provided to individuals are to be retained as per 10 CFR 35.2310, and a copy of the emergency procedures is to be retained as per 10 CFR 35.2610.

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Safety precautions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units are covered in 10 CFR 35.615. There is to be a door at the entrance to each treatment room. Each entrance to a treatment room is also to be equipped with an electric interlock system to prevent exposure of the radioactive source if the door is open and to prevent the source from being exposed after an interlock interruption until the door is closed and the on-off control has been re-set. Licensees are to require any individual entering the treatment room to make sure the radiation readings are at background levels. Except for low-dose remote afterloaders, each treatment room is to be equipped with viewing and intercom systems to permit continuous observation of the room from the console. For licensed activities involving the placement of sources into an individual, only those treatments which allow for the quick removal of a jammed or decoupled source will be permitted.

In addition to these safety precautions, licensees are to take other safety precautions specific to the type of equipment being used. Licensees are further required to have emergency response equipment available near each treatment room to respond to sources that remain in an unshielded position or those that are lodged in a person following completion of treatment.

The Federal regulations at 10 CFR 35.630 govern dosimetry equipment. Except for low-dose remote afterloaders, licensees are required to have a calibrated dosimetry system available for use. The system has to have been calibrated appropriately by one of the listed methods, such as through a National Institute of Standards and Technology traceable source or system and published protocols accepted by nationally recognized bodies. Licensees shall also have a dosimetry system available to conduct any applicable spot-checks. Certain system comparisons would satisfy this requirement. Records of each calibration, intercomparison and comparison are to be retained as per 10 CFR 35.2630.

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The regulations for full calibration measurements on teletherapy units are provided in 10 CFR 35.632. Licensees authorized to use teletherapy units are required to perform full calibration measurements on each unit prior to the first medical use of the unit and before medical use under certain condition, such as following replacement of the source. A full calibration is also to be conducted annually. Full calibration measurements must include the determination of a variety of factors, including timer accuracy and linearity over the range of use and on-off error.

The output for one set of exposure conditions is required to be measured by a dosimetry system that satisfies the requirements of 10 CFR 35.630, as described above. The remaining measurements may be made with a system that indicates relative dose rates. Full calibration measurements are to be made in accord with published protocols accepted by nationally recognized bodies. Outputs are required to be mathematically corrected for the physical decay of the source. The full calibration measurements and physical decay corrections are to be conducted by the authorized medical physicist. Records of each calibration are to be retained as per the requirements of 10 CFR 35.2632, as discussed below.

Full calibration of remote afterloader units is covered by the Federal rule at 10 CFR 35.633. Licensees authorized to use remote afterloader units are required to perform full calibration measurements on each unit prior to the first medical use of the unit, before medical use under certain condition, such as following replacement of the source, and at intervals specific to the type of remote afterloader unit in question. Full calibration measurements must include the determination of a variety of factors, including timer accuracy and linearity over the range of use and length of the applicators.

The output is required to be measured by a dosimetry system that satisfies the requirements of 10 CFR 35.630, as described above. Full calibration measurements are to be made

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in accord with published protocols accepted by nationally recognized bodies. Licensees are also required to perform an audiograph of the source to verify inventory and source arrangement on a quarterly basis. Outputs are required to be mathematically corrected for the physical decay of the source. The full calibration measurements and physical decay corrections are to be conducted by the authorized medical physicist. Records of each calibration are to be retained as per the requirements of 10 CFR 35.2632, as discussed later in this Summary.

The Federal regulations at 10 CFR 35.635 govern the full calibration of gamma stereotactic radiosurgery units. Licensees authorized to use gamma stereotactic radiosurgery units are required to perform full calibration measurements on each unit prior to the first medical use of the unit, before medical use under certain condition, such as following replacement of the source, and annually, except for relative helmet factors, which only need to be determined prior to first medical use and following any damage to a helmet. Full calibration measurements must include the determination of a variety of factors, including timer accuracy and linearity over the range of use and on-off error.

The output for one set of exposure conditions is required to be measured by a dosimetry system that satisfies the requirements of 10 CFR 35.630, as described above. The remaining measurements may be made with a system that indicates relative dose rates. Full calibration measurements are to be made in accord with published protocols accepted by nationally recognized bodies. Outputs are required to be mathematically corrected for the physical decay of the source. The full calibration measurements and physical decay corrections are to be conducted by the authorized medical physicist. Records of each calibration are to be retained as per the requirements of 10 CFR 35.2632, as discussed later in this Summary.

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The periodic spot-checking of teletherapy units is governed by the Federal regulations at 10 CFR 35.642. Licensees authorized for the medical use of teletherapy units are required to perform output spot-checks on each unit once per calendar month. These spot-checks are to include such items as timer accuracy and timer linearity over the range of use and on-off error. These spot-check measurements are to be conducted according to written procedures established by the authorized medical physicist, though that person is not required to perform the actual spot-check. The authorized medical physicist is required to review the results of the spot-checks and is required to inform the licensee of the results of each spot-check.

Safety spot-checks of each teletherapy unit are to be conducted once per calendar month and after each source installation to ensure the proper operation of such things as the electrical interlocks at each teletherapy room entrance and viewing and intercom systems. If the results of the checks indicate the malfunction of any system, the control console for that system is required to be locked in the off position and the unit is not to be used except as is necessary to repair, replace or check the system. Spot-check records and a copy of the procedures established by the authorized medical physicist are to be retained as per 10 CFR 35.2642.

The Federal rule at 10 CFR 35.643 establishes the requirements for periodic spot-checks of remote afterloader units. Licensees authorized for the medical use of remote afterloader units are required to perform spot-checks on each remote afterloader facility and on each unit before the first use of the unit on each day of use for high, medium and pulsed dose-rate remote afterloaders, before each patient treatment for low dose rate remote afterloaders and after each source installation. These spot-check measurements are to be conducted according to written procedures established by the authorized medical physicist, though that person is not required to perform the actual spot-check. The authorized medical physicist is required to review the results of the spot-checks and is

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required to inform the licensee of the results of each spot-check. These spot-checks are to include such items as electrical interlocks at each remote afterloader room entrance and timer accuracy.

If the results of the checks indicate the malfunction of any system, the control console for that system is required to be locked in the off position and the unit is not to be used except as is necessary to repair, replace or check the system. Spot-check records and a copy of the procedures established by the authorized medical physicist are to be retained as per 10 CFR 35.2643.

Periodic spot-checks for gamma stereotactic radiosurgery units are governed by the Federal regulations at 10 CFR 35.645. Licensees authorized for the medical use of gamma stereotactic radiosurgery units are required to perform spot-checks on each gamma stereotactic radiosurgery facility and on each unit monthly, before the first use of the unit on each day of use, and after each source installation. These spot-check measurements are to be conducted according to written procedures established by the authorized medical physicist, though that person is not required to perform the actual spot-check. The authorized medical physicist is required to review the results of the spot-checks and is required to inform the licensee of the results of each spot-check. These spot-checks must assure the proper operation of such items as helmet microswitches and emergency timing circuits and determine such items as timer accuracy and linearity over the range of use and on-off error.

Spot-checks must also assure proper operation of items such as the electrical interlocks at each gamma stereotactic radiosurgery room entrance and the viewing and intercom systems. Arrangements for the repair of any system that is not operating properly shall be made as soon as possible. If the results of the checks indicate the malfunction of any system, the control console for that system is required to be locked in the off position and the unit is not to be used except as is

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necessary to repair, replace or check the system. Spot-check records and a copy of the procedures established by the authorized medical physicist are to be retained as per 10 CFR 35.2645.

The Federal Rule at 10 CFR 35.647 provides additional technical requirements for mobile remote afterloader units. Licensees providing mobile remote afterloader services are required to check their survey instruments prior to medical use at each address of use or on each day of use, whichever is more frequent and to make sure all sources are accounted for prior to departure from a client's facility. In addition to the periodic spot-checks required by 10 CFR 35.643, as discussed above, checks on each unit shall be made prior to use at each client facility. At a minimum, the checks are to include such items as the electrical interlocks on treatment area access points.

Additionally, the licensee is required to conduct a simulated cycle of treatment prior to use at each client location. If the results of the checks indicate the malfunction of any system, the control console for that system is required to be locked in the off position and the unit is not to be used except as is necessary to repair, replace or check the system. Spot-check records are to be retained as per 10 CFR 35.2647.

The Federal regulation at 10 CFR 35.652 concerns radiation surveys. In addition to the survey requirements stipulated in 10 CFR 20.1501, proposed to be incorporated by reference at N.J.A.C. 7:28-6, licensees are required to ensure that radiation levels from the surface of the main source safe, with the source in the shielded position, do not exceed the levels listed in the NRC's Sealed Source and Device Registry. Such surveys are to be conducted upon the installation of a new source and following repairs to any component that could expose the source, reduce the shielding around the source or compromise the radiation safety of the source or the unit. Records of these surveys are to be retained in accord with 10 CFR 35.2652.

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Requirements for five-year inspections for teletherapy and gamma stereotactic radiosurgery units are presented in the regulations at 10 CFR 35.655. A licensee is required to have each of these types of units fully inspected and serviced during source replacement or at least every five years, whichever comes first. These activities are only to be conducted by a person specifically licensed to do so by the Department, the NRC or another Agreement State. Records of these activities are to be retained as per 10 CFR 35.2655.

The rule at 10 CFR 35.657 concerns therapy-related computer systems. A licensee is required to perform acceptance testing on such systems according to published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing is to include the verification of such things as the accuracy of isodose plots and graphic displays.

The training for the use of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units is covered by the regulations in 10 CFR 35.690. Except for experienced authorized users covered in 10 CFR 35.57, as previously discussed in this summary, authorized users for these medical studies are physicians who are authorized under 10 CFR 35.600 and are certified by a medical specialty board whose certification has been recognized by the Department, the NRC or another Agreement State and have obtained a written, signed preceptorship statement attesting to their training, experience and competency to function independently as authorized users for these medical studies. The attestation is to be signed by a preceptor authorized user who meets the requirements of 10 CFR 35.690. The authorized user will also have received training in the operation, safety procedures and clinical use of the types of units in question.

As an alternative, the requested authorized user can satisfy the training requirements by completing a structured educational program applicable to the uses for which authorization is sought. The program must include 200 hours of classroom and educational training, 500 hours of

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applicable work experience and three years of supervised clinical experience. The work and clinical experience are under the supervision of a physician authorized under 10 CFR 35.690. Additionally, the requested physician must meet the attestation and specific device training requirements discussed in the preceding paragraph.

The rule at 10 CFR 35.1000 concerns other medical uses of byproduct material or radiation from byproduct material. A licensee may use radioactive material for a medical use not specifically addressed in other sections of 10 CFR Part 35 if they have submitted an application that meets the requirements of 10 CFR 35.12, as previously discussed, have received approval from the Department and use the material according to the regulations and any specific condition(s) the Department considers necessary.

Records of the authority and responsibilities for radiation safety programs are regulated by 10 CFR 35.2024. These records are to be retained for five years and include a summary of the action taken and be signed by the licensee's management. Copies of the authority, duties and responsibilities of the Radiation Safety Officer, as well as a signed copy of each Radiation Safety Officer's agreement to take responsibility for the program are to be retained for the duration of the license. These records are to include the signature of the Radiation Safety Officer and management.

Records of radiation protection program changes are covered in 10 CFR 35.2026. These records are to be retained for five years and include such things as the signature of the management representative that reviewed and approved the change.

Records of written directives are governed by the regulations at 10 CFR 35.2040. Records of written directives required by 10 CFR 35.40 are to be retained for three years.

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As required by the Federal rule at 10 CFR 35.2041, records for procedures for administrations requiring a written directive are to be retained by the licensee for the duration of the license.

The rule at 10 CFR 35.2060 concerning the records of calibrations of instruments used to measure the activity of unsealed byproduct material requires a licensee to retain such records for three years. The record is to include several items, including the model and serial number of the instrument.

Radiation survey instrument calibration records are to be retained by the licensee for three years, as per 10 CFR 35.2061. The record is to include several pieces of information, including the model and serial number of the instrument.

Records of dosages of unsealed byproduct material for medical use are to be retained by the licensee for three years as per 10 CFR 35.2063. These records are to contain such items as the radiopharmaceutical used and the date and time of the dosage determination.

The Federal rule at 10 CFR 35.2067 concerns records of leak tests and inventory of sealed sources and brachytherapy sources. Leak test records are required to be retained for three years and are to include such information as the model and serial number of the source. Inventory records are also to be retained for three years and are to contain information such as the location of each source and the name of the person who performed the inventory.

Records of surveys for ambient radiation exposure are stipulated at 10 CFR 35.2070. These records are to be retained for three years and are to contain information such as the name of the person who performed the survey and the instrument used for the survey.

Records concerning the release of individuals containing unsealed byproduct material or implants containing byproduct material are regulated by 10 CFR 35.2075. These records are to be

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retained for three years after the date the person is released from the licensee's control. The records are to contain the basis used to authorize the release of the individual and whether the person was provided with instruction concerning the continuance of breast-feeding, if applicable.

The regulations at 10 CFR 35.2080 concern records of mobile medical services. A licensee is required to retain a copy of each agreement with a client location for three years. The letter is to clearly define the authority and responsibilities of the licensee, as compared those of the client. Records of required surveys are also to be retained for three years and are to include such items as the date and results of the survey.

At the regulation stipulated in 10 CFR 35.2092, licensees are required to keep records of waste held for decay-in-storage for three years. The record is to contain such items as the date of disposal and the name of the person who performed the survey.

Records of molybdenum-99 concentration are to be retained for three years, as per the regulations at 10 CFR 35.2204. These records are to contain such information as the time and date of the molybdenum-99 concentration measurement and the name of the person who performed the measurement.

Safety instruction records are covered by the rule at 10 CFR 35.2310. These records are to be retained for three years. Among the items included in the records are the date of the instruction and the name of the attendee.

The rule at 10 CFR 35.2404 provides the requirements for records of surveys after source implant removal. These records are to contain such information as the date and results of the survey and are to be retained for three years.

The Federal regulation at 10 CFR 35.2406 concerns brachytherapy source accountability. These records are to be retained for three years. Records of temporary implants are to contain

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information such as the number and activity of sources removed from storage and the number and activity of sources returned to storage. Records of permanent implants are to include such information as the date sources were removed from storage and the number and activity of sources permanently implanted into a patient or human research subject.

The rule at 10 CFR 35.2432 concerns records of calibration measurements of brachytherapy sources. These records are to include information on the date of the calibration and the source output, among others. These records are to be retained by the licensee for three years.

At 10 CFR 35.2433, a licensee is required to retain records of the decay of strontium-90 sources used for ophthalmic treatments for the life of the source. These records include the date and initial activity of the source, among others.

Records of installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units are discussed at 10 CFR 35.2605. Records of the installation, maintenance, adjustment and repair of these units are to be retained by the licensee for three years. Each record is to include information such as the date and description of the service provided.

Records of the safety procedures referenced in 10 CFR 35.2610 are to be retained by the licensee until they no longer possess the unit in question.

The Federal rule at 10 CFR 35.2630 concerns records of dosimetry equipment used with remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units. A licensee is required to retain a record of the calibration, intercomparison and comparisons of such units for the duration of their license. For each such activity, the record is to include information on the date and the name of the person who performed the activity, among others.

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Recordkeeping requirements for teletherapy, remote afterloader and gamma stereotactic radiosurgery full calibrations are presented at 10 CFR 35.2632. The licensee is to retain these records for three years. Among the information to be included is the date of the calibration and the results and an assessment of the full calibration.

At the Federal rule at 10 CFR 35.2642, recordkeeping requirements for periodic spot-checks for teletherapy units are provided. A licensee is required to retain these records for three years and among the information to be recorded is the date of the spot-check and the calculated on-off error. A copy of the referenced procedures must be retained for as long as the licensee possesses the unit.

At the Federal rule at 10 CFR 35.2643, recordkeeping requirements for periodic spot-checks for remote afterloader units are provided. A licensee is required to retain these records for three years and among the information to be recorded is the date of the spot-check and an assessment of timer accuracy. A copy of the referenced procedures must be retained for as long as the licensee possesses the unit.

At the Federal rule at 10 CFR 35.2645, recordkeeping requirements for periodic spot-checks for gamma stereotactic radiosurgery units are provided. A licensee is required to retain these records for three years and among the information to be recorded is the date of the spot-check and an assessment of timer linearity and accuracy. A copy of the referenced procedures must be retained for as long as the licensee possesses the unit.

The requirements for records of the additional technical requirements for mobile remote afterloader units are presented in 10 CFR 35.2647. Among the items to be recorded are the date of the check and an accounting of all sources prior to departure from a client facility. These records are to be retained for three years.

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At 10 CFR 35.2652, the requirements for records of surveys of therapeutic treatment units are stipulated. These records are to be retained by the licensee for the duration of use of the unit. Among the items to be included in the records are the date of the measurement and the signature of the person who performed the test.

At the Federal rule at 10 CFR 35.2655, the requirements for records of the five-year inspection for teletherapy and gamma stereotactic radiosurgery units are presented. The licensee is to retain these records for the length of time they use the unit. Among the items to be included in the record are the date of the inspection and the signature of the inspector.

Reports and notifications of medical events are covered by the regulations at 10 CFR 35.3045. Except for those instances where an event has occurred due to a patient's interference with a procedure, licensees are required to report any event where the administration of radioactive material, or the radiation from radioactive material, results in a dose or dosage that differs from that prescribed by any of the listed exposure levels and percentages. Reports are also required for administrations where the dose exceeds specified exposure levels due to mistakes made during the administration, such as the wrong drug administered to a patient or a dose delivered to the wrong patient. Leaking sealed sources also need to be reported.

Reports are also required for any event where a patient or human research subject interfered in an administration and that interference caused unintended permanent damage to an organ or physiological system. Licensees are required to notify the Department no later than the next calendar day of any event that satisfies any of the reporting criteria. Within 15 days after the discovery of the event, the licensee is required to submit a written report on the event to the Department at the address listed in N.J.A.C. 7:28-1.5(a). Among the items to be included in the

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written report are the licensee's name and a brief description of the event. The name of the individual in question is not to be mentioned in the report.

Within 24 hours of the event, licensees are also required to report an event to the referring physician and to the individual subject to the event. The licensee is not required to inform the person subject to the event of the event, if the referring physician says they will inform the patient or that informing the patient would be harmful. The licensee is not required to inform the person until they have discussed the matter with the physician. If the physician cannot be contacted within 24 hours, the person subject to the event should then be notified as soon as possible. No medical treatment to the person subject to the event should be delayed due to the notification requirement. Notification of the event to this person's responsible relative or guardian also satisfies the notification requirement. If a verbal notification is made, the licensee shall state that a written notification can also be provided.

A licensee is required to annotate the copy of the report sent to the Department with the name of the person subject to the event and any identification number assigned to them. If the referring physician is not the licensee, they shall also be provided with the annotated identification of the person subject to the event within 15 days of the discovery of the event.

The rule at 10 CFR 35.3047 involves reports and notifications of a dose to an embryo/fetus or a nursing child. Licensees are required to report a dose of greater than five rem to an embryo/fetus, unless that dose was specifically approved in advance by an authorized user. Licensees are required to report a dose to a nursing child that is greater than five rem or has resulted in unintended permanent damage to an organ or physiological system. Licensees are required to notify the Department no later than the next calendar day of any event that satisfies any of the reporting criteria. Within 15 days after the discovery of the event, the licensee is required to submit

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a written report on the event to the Department at the address listed in N.J.A.C. 7:28-1.5(a). Among the items to be included in the written report are the licensee's name and a brief description of the event. The name of the individual or child in question is not to be mentioned in the report. The licensee is also required to provide a notification within 24 hours to the referring physician and the mother. The details of this notification are as was described above for medical events to individuals, as with the specifics of any required annotated copy.

Requirements related to reports of a leaking source are provided at 10 CFR 35.3067. Licensees are required to send a report to the Department, at the address listed in N.J.A.C. 7:28-1.5(a), within five days if the results of a leak test reveal that the source is leaking. The report is to include such items as the date of the test and the results of the test.

In order to prevent a violation of the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, as amended, or regulations or order issued pursuant to those Acts, including the proposed new and amended rules, 10 CFR 35.4001 allows the Department to obtain an injunction or other court order. In addition, a court order may be obtained for the payment of civil penalties.

Lastly, as described in 10 CFR 35.4002, criminal sanctions are authorized for violations of certain portions of Subchapter 55. These provisions are the same as at 10 CFR Part 50, discussed above.

Subchapter 56: Licenses and Radiation Safety Requirements for Irradiators

Proposed new Subchapter 56 incorporates by reference provisions of 10 CFR Part 36, except those specified in N.J.A.C. 7:28-56.1(b). Subchapter 56 contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to

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irradiate objects or materials using gamma radiation. The regulations in 10 CFR Part 36 apply to panoramic irradiators that have either dry or wet storage of radioactive sealed sources and to underwater irradiators in which both the source and product being irradiated are under water. These regulations exclude dry-source-storage irradiators, medical radiology or teletherapy, radiography, gauging, or open-field irradiations. Only OMB requirements are excluded from incorporation.

The following provisions of 10 CFR 36.2, definitions, are incorporated by reference: "annually," "doubly encapsulated sealed source," "irradiator," "irradiator operator," "panoramic dry-source-storage irradiator," "panoramic irradiator," "panoramic wet-source-storage irradiator," "pool irradiator," "product conveyor system," "radiation room," "seismic area," and "underwater irradiator."

Specific licensing requirements for irradiators are contained in 10 CFR 11 through 19, proposed to be incorporated by reference. A person that was defined in 10 CFR 30.4 must, in accordance with 10 CFR 36.11, file an application for a specific license on a form available from the Department. The fee for the application is set forth at proposed N.J.A.C. 7:28-64. The Department's requirements for the approval of an application for an irradiator specific license are outlined in 10 CFR 36.13. The general requirements for a specific license are specified in 10 CFR 30.33, which is incorporated by reference in Subchapter 51. Additional requirements at 10 CFR 36.23 through 36.61 are proposed to be incorporated by reference.

According to 10 CFR 36.15, an applicant is not allowed to begin construction of a new irradiator unless an application for an irradiator license, along with appropriate fees, has been received by the Department. Any activities undertaken prior to the issuance of a license are entirely

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at the risk of the applicant and have no bearing on the issuance of the license with respect to the requirements of the Department.

Department may grant an exemption from the requirements of proposed new Subchapter 56, with the approval of the Commission, in accordance with 10 CFR 36.17, if the Department determines the exemption is authorized by law and is in accordance with N.J.A.C. 7:28-2.8. Additionally, the Department may approve proposed alternatives, such as the use of teletherapy-type units for the requirements of proposed Subchapter 56. The applicant requesting such alternatives must demonstrate the adequate rationale for the alternatives and the adequate level of safety for workers and public.

The Department's authority to request further information from the applicant to determine whether the application should be granted or denied is set forth in 10 CFR 36.19. Additionally, the Department may request from the licensee, at any time prior to expiration of the license, to submit written statements to the Department to determine whether such license should be modified, suspended, or revoked.

Design and performance requirements for irradiators and the radioactive sealed sources that are contained in them are addressed at 10 CFR 36.21 through 41, proposed to be incorporated by reference. This section applies to sealed sources that were installed after July 1, 1993.

A certificate of registration is required at 10 CFR 32.210, to be incorporated by reference at proposed new Subchapter 53. The sealed source is to be doubly encapsulated, and the radioactive material must be as non-dispersible as practical and as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator. The encapsulation of the radioactive material must be resistant to general and localized corrosion if the sources are used in irradiator pools. A prototype testing of the sealed source must have been leak tested and determined to be found leak

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free after specific temperature, pressure, impact, vibration, puncture, and bend tests have been conducted.

To prevent the inadvertent entry of personnel when the sources are not in the shielded position, 10 CFR 36.23 addresses the control of access at a panoramic irradiator. The rule requires an alarm to detect personnel entry while the source is exposed. It also requires alarms, door locks, and barriers to prevent entry into high radiation fields. Other requirements include safeguards to prevent personnel exposure when the source is unshielded. Each entrance to the radiation room of the panoramic irradiator and entrance within the personnel access barrier of an underwater irradiator must be posted in accordance with proposed new Subchapter 6.

The radiation dose rate requirements contained in 10 CFR 36.25, stipulate that the areas occupied by personnel during normal operations of the irradiator can not exceed 0.02 millisievert (2 millirems) per hour at any location 30 centimeters or more from the wall of the room when sources are exposed. Dose rates in regards to specific dimensions and locations are also stipulated in this section.

The requirements for the radiation room at a panoramic irradiator to have heat and smoke detectors that will activate an audible alarm are addressed in 10 CFR 36.27. Sources must be automatically shielded when a fire detected. Additionally, a fire extinguishing system capable of extinguishing a fire in a room without entry by persons and a shut off valve to prevent flooding into uncontrolled areas are to be installed.

The requirement for irradiators with an automatic product conveyor system to have a radiation monitor with an audible alarm to detect any loose radioactive sources that have been carried towards the product exit are addressed in 10 CFR 36.29. An exemption to this requirement is given to underwater irradiators in which the product moves within an enclosed stationary tube.

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An underwater irradiator that is not contained in a shielded radiation room is to have a radiation monitor with an audible alarm and visible indicators at personnel access barriers around the pool.

The irradiator facility's alarm system and the lock and key system for controlling the radioactive source movement when the source is shielded and unshielded is addressed in 10 CFR 36.31. The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position. Each control for a panoramic irradiator must be clearly marked as to its function.

Irradiator pools are addressed at 10 CFR 36.33, which sets forth specific safeguards to minimize personnel exposure to radiation. These include physical barriers, a visible indicator to signal when water levels in the pool have dropped, and construction designed to minimize the likelihood of substantial leakage. The specific safeguards required depend on when the licensee's license was initially issued. A licensee whose license was initially issued after July 1, 1993 will be subject to additional requirements.

The Federal rule at 10 CFR 36.35 requires that if the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

If electrical power at a panoramic irradiator is lost for longer than 10 seconds, 10 CFR 36.37 requires the sources must automatically return to the shielded position. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

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Irradiators whose construction began after July 1, 1993, must meet design requirements for shielding, foundations, pool integrity, water handling systems, radiation monitors, source rack, access control, fire protection, source return, seismic, and wiring, set forth at 10 CFR Part 36.39. Similarly, 10 CFR 36.41 requires irradiators whose construction began after July 1, 1993, to meet specific requirements for shielding, foundations, pool integrity, water handling systems, radiation monitors, source rack, access control, fire protection, source return, and computer systems, before the source is loaded into the irradiator.

Operation of irradiators is addressed at 10 CFR 36.51 through 69, proposed to be incorporated by reference. The training requirements for operators of irradiators are set forth at 10 CFR 36.51. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in the fundamentals of radiation protection applied to irradiators, the requirements of 10 CFR Parts 19 and 36 (incorporated by reference at proposed new Subchapters 50 and 56), the operation of the irradiator, operating and emergency procedures that the individual is responsible for performing, and case histories of accidents or problems involving irradiators. In addition, before an individual is permitted to operate an irradiator without a supervisor present, the individual must pass a written test, and receive on-the-job training or simulator training in the use of the irradiator. The individual must demonstrate his or her ability to perform those portions of the operating and emergency procedures that he or she is to perform.

The licensee must conduct safety reviews for irradiator operators at least annually. The safety review includes a brief written test, as well as information on changes in operating and emergency procedures since the last review, if any; changes in regulations and license conditions since the last review, if any; reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any; relevant results of inspections of operator safety performance; relevant results of

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the facility's inspection and maintenance checks; and a drill to practice an emergency or abnormal event procedure.

Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in how to avoid radiation exposure, and the appropriate response to alarms.

Operating and emergency procedures are set forth at 10 CFR 36.53. An irradiator licensee must have and follow written operating procedures for the operation of the irradiator. He or she must also have and follow emergency or abnormal event procedures, appropriate for the irradiator type. The Federal rule sets forth ten specific abnormal events for which procedures are required. If revisions to the operating or emergency procedures are required, Department approval is necessary, unless the proposed revisions meet specific criteria, set forth at 10 CFR 36.53(c).

The requirement for irradiator operators to wear a personnel dosimeter while operating a panoramic processor irradiator or while in the area around the pool of an underwater irradiator is set forth in 10 CFR 36.55. The dosimeters are required to be processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP). The personnel dosimeter processor must be accredited for high energy photons in the normal and accident dose ranges. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly. Requirements are given for other individuals who enter the radiation room of a panoramic irradiator, such as groups of visitors.

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A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator is required under 10 CFR Part 36.5 and must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates. If the radiation levels specified in 10 CFR 36.25, which is incorporated by reference in Subchapter 56 are exceeded, the facility must be modified to comply with these requirements. Portable radiation survey meters must be calibrated at least annually for the gamma energy of the sources in use. Specific requirements regarding calibration are also provided. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release and must not exceed the effluent limits specified in 10 CFR part 20, Table 2, Column 2 or Table 3 of appendix B which have been incorporated by reference in Subchapter 6. Resins may be released for unrestricted use, only if the survey does not detect radiation levels above background radiation levels.

Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months according to 10 CFR 36.59, using a leak test kit or method approved by the Department. The sealed source may not be used unless it has been tested within the last six months. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using an alarming radiation monitor on a pool water circulating system or by

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analysis of a sample of pool water, provided the results of the analysis are available within 24 hours.

If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a licensee that is authorized to perform these functions. Additional requirements are included in this section regarding decontamination and disposal as a result of a leaking source.

The Federal rule at 10 CFR 36.61 identifies specific requirements for performing inspection and maintenance checks including, the operability of each aspect of the access control system, the functioning of the source position indicator, the operability of the radiation monitor and the operability of the over-pool radiation monitor at underwater irradiators. Any malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

The irradiator pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances as required by 10 CFR 36.63. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

The Federal rule at 10 CFR 36.65 concerns the attendance of personnel during the operation of the irradiator. Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite whenever the irradiator is operated using an automatic product conveyor system, and whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a trained person must be onsite. At an underwater

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irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool.

Upon first entering the radiation room of a panoramic irradiator after an irradiation, 10 CFR 36.67 requires that the irradiator operator shall use a functioning survey meter to determine that the source has returned to its fully shielded position. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall visually inspect the entire radiation room to verify that no one else is in it; and activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor is operating with backup power.

Unless the licensee has received prior written authorization from the Department, 10 CFR 36.69 prohibits the irradiation of explosive or flammable material. Authorization will not be granted unless the licensee can demonstrate that either detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel; or a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

The irradiator licensee is required according to 10 CFR 36.81 to maintain a copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license. Some

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documents, including records of surveys, have different retention requirements specified in this subchapter.

In addition to the reporting requirements in other sections of Subchapter 56, 10 CFR Part 36.83 requires other reports which include a source stuck in an unshielded position, any fire or explosion in a radiation room, damage to the source racks, failure of the cable or drive mechanism used to move the source racks, and inoperability of the access control system. These reports must include a telephone report within 24 hours as and a written report within 30 days.

General discussions related to violations and criminal penalties are as was discussed in the summary to subchapter 50.

Subchapter 57: Licenses and Radiation Safety Requirements for Well Logging

Proposed new Subchapter 57 incorporates by reference the Federal regulations at 10 CFR Part 39.

The Federal rule at 10 CFR 39.1 sets forth the scope of proposed new Subchapter 39. The subchapter establishes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers, and uranium sinker bars in well logging in a single well. This subchapter also prescribes radiation safety requirements for persons using licensed materials in these operations. The provisions and requirements of this subchapter are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of N.J.A.C. 7:28-6, 50, 51, 58, and 60 through 62 apply to applicants and licensees subject to this subchapter. The requirements set out in this subchapter do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple

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wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.

The Federal definitions proposed to be incorporated by reference are “energy compensation source,” “field station,” “fresh water aquifer,” “injection tool,” “irretrievable well logging source,” “licensed material,” “logging assistant,” “logging supervisor,” “logging tool,” “personal supervision,” “radioactive marker,” “safety review,” “sealed source,” “source holder,” “subsurface tracer study,” “surface casing for protecting fresh water aquifers,” “temporary jobsite,” “tritium neutron generator target source,” “uranium sinker bar,” “well” and “well logging.”

The Federal rule at 10 CFR 39.11 requires the licensee to file an application for a specific license authorizing the use of licensed material in well logging. Proposed Subchapter 57 identifies the Department’s form that is comparable to the NRC Form 313, "Application for Material License." The applicant must submit the appropriate fee as outlined in proposed Subchapter 64.

The Federal rule at 10 CFR 39.13 provides the requirements that need to be met before the Department will approve an application for a specific license for the use of licensed material in well logging. The applicant must meet these requirements including those specified in proposed Subchapter 51 for byproduct material, proposed Subchapter 58 for source material, and in proposed Subchapter 60 for special nuclear material, as appropriate, and any additional special requirements.

The Federal regulations at 10 CFR 39.13 also provide certain training requirements for logging supervisors and logging assistants an applicant must demonstrate, as well as certain programmatic elements of its operation. These include, but are not limited to, initial training, on-the-job training, annual safety reviews, and operating and emergency procedures. The applicant will also be required to demonstrate adequate operating and safety procedures, as well as annual

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inspection procedures. Inspection records will be required to be kept for 3 years after each annual internal inspection. The applicant will also be required to submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility. Leak testing of sealed sources will be allowed to be performed by the applicant, provided that the manufacturers and model numbers of the leak test kits are identified. An applicant may analyze its own wipe samples if he supplies the Department a description of the procedures which shall include instruments to be used, methods of performing the analysis, and experience of the person who will analyze the wipe samples.

The Federal rule at 10 CFR 39.15 addresses agreements between the well owner or operator and the licensee. The Department will allow for the licensee to perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator which identifies who will meet the requirements at 10 CFR 39.15. The licensee will be required to retain a copy of the written agreement for three years after the completion of the well logging operation. Additional provisions of 10 CFR 39.15 allow for the licensee to abandon an irretrievable source, only if it is immobilized and sealed in place with a cement plug, there is a means to prevent inadvertent intrusion, and a permanent identification plaque is mounted on the surface of the well. The plaque must contain the work "CAUTION," the radiation symbol, the date the source was abandoned and other pertinent information outlined in 10 CFR 39.15. Written agreements between the licensee and the well owner or operator will not be required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated, however, the licensee will still have to meet the requirements in this proposed subchapter.

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The Federal requirements at 10 CFR 39.17 address requests for written statements for license modifications. The Department will issue each license with the condition that the licensee will, at any time before expiration of the license, upon the Department's request, submit written statements, signed under oath or affirmation, to enable the Department to determine whether or not the license should be modified, suspended, or revoked.

Labeling, security, and transportation requirements are addressed in 10 CFR 39.31. The Department will require labeling of each source, source holder, or logging tool according to the provisions of proposed new N.J.A.C. 7:28-6. The Department will not allow the licensee to transport licensed material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in proposed Subchapter 61. The licensee will be required to store each source containing licensed material in a manner which adheres to the requirements detailed in 10 CFR 39.31 which include a locked and physically secured container to prevent tampering or unauthorized removal. The licensee shall store the licensed material in a manner which will minimize danger from explosion or fire.

The Federal rule at 10 CFR 39.33 establishes specific requirements for radiation survey instrumentation such as instrument sensitivity (0.1 mrem per hour through at least 50 mrem per hour) and calibration accuracy. The licensee will be required to maintain and calibrate instruments as set forth in this Federal regulation. The Department will require that the licensee retain calibration records for a period of 3 years after the date of calibration for inspection by the Department.

The requirements for leak testing of sealed sources are provided in 10 CFR 39.35, and include conditions such as testing intervals, detection limits, and decontamination measures.

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Certain sealed sources, as described at 10 CFR 39.35, will be exempted from the periodic leak test requirements. Removal of a leaking source from service is as described in the summary to Subchapter 63. Several types of sealed sources are exempt from the periodic leak test requirements including Hydrogen-3 sources; sources containing licensed material with a half-life of 30 days or less; and sealed sources containing licensed material in gaseous form.

Semi-annual physical inventory requirements are specified in 10 CFR 39.37. The Department will require that each licensee conduct a semi-annual physical inventory to account for all licensed material received and possessed under the license, in accordance with the specific requirements of 10 CFR 39.37, such as quantity and kind of material, and physical location of material. The licensee will be required to retain records of the inventory, including quantity and kind, for three years from the date of the inventory for inspection by the Department.

The Federal rule at 10 CFR 39.39 sets for the requirements for records of material use, such as serial number, and radionuclide quantity. The licensee will be required to make the records available for inspection by the Department, and must keep the records for three years from the date of the recorded event.

The Federal regulation at 10 CFR 39.41 specifies acceptable physical source characteristics that meet specific physical testing criteria, such as shock, vibration, and temperature, for sources used in well logging applications. These specific requirements will not apply to sealed sources that contain licensed material in gaseous form, or to energy compensation sources (ECS). ECSs must be registered with the Department under proposed Subchapter 53.

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Under the Federal rule at 10 CFR 39.43, a licensee is required to inspect and maintain sources and source holders in accordance with specific conditions, such as periodic visual checks of equipment, maintenance operations, and record keeping.

Subsurface tracer studies are addressed in 10 CFR 39.45, and set forth the specific requirements for the licensee to safely handle and work with these trace materials, such as the use of protective equipment. This section will also prohibit the injection of licensed material into fresh water aquifers unless authorized to do so by the Department.

Licensees under 10 CFR 39.47 will be authorized to use radioactive markers in wells, provided that they meet specific requirements such as quantity limits, as outlined in 10 CFR 39.37..

Licensees under 10 CFR 39.49 will be authorized to use a uranium sinker bar in well logging applications provided it is labeled with the words “CAUTION--RADIOACTIVE--DEPLETED URANIUM” and “NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND.”

The Federal rule at 10 CFR 39.51 authorizes a licensee to use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows procedures, approved by the Department, for reducing the probability of the source becoming lodged in the well.

The Federal rule at 10 CFR 39.53 provides the requirements for using an energy compensation source provided it contains less than 100 microcuries.

The Federal rule at 10 CFR 39.55 provides the requirements of tritium neutron generator target sources provided the sources contain less than 30 curies.

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In order for a licensee to permit an individual to act as a logging supervisor or logging assistant, they must comply with 10 CFR 39.61, which sets forth specific training requirements, which include training in subject areas that cover the safe use of licensed materials; radiation characteristics; radiation hazards; detection instruments; instrument calibration; applicable State and Federal regulations; operating and emergency procedures; remote handling procedures; and survey techniques. The licensee will also have to demonstrate the individual's understanding of the subject matter through the use of written exams or tests, and conduct annual safety reviews with each individual. The licensee will be required to maintain a record of each individual's training and annual safety review, including all exam results, for a period of at least three years.

Operating and emergency procedure requirements are identified in 10 CFR 39.63. Each licensee shall develop and follow written operating and emergency procedures that cover areas such as handling and use of licensed materials and tools; conducting radiation surveys; locking and securing stored licensed materials; personnel monitoring; transportation and packaging of licensed materials; receipt of packages containing licensed materials, in accordance with Subchapter 6; decontamination; source inspection; accident notification, and records maintenance.

Specific requirements for personnel monitoring are set forth in 10 CFR 39.65. The Department will require that logging supervisors or logging assistants wear a personnel dosimeter that meets certain requirements such as being processed and evaluated by an accredited processor, and that are replaced at least monthly. The licensee will be required to provide bioassay services to individuals using licensed materials in subsurface tracer studies if required by the license. The licensee shall retain records of personnel dosimeters and bioassay results for inspection until the Department authorizes disposition of the records.

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The requirements for performing radiation surveys in areas where licensed materials will be used or stored are set forth in 10 CFR 39.67 and include frequency of monitoring, reporting requirements, and specific conditions under which surveys are necessary. The licensee shall retain records of surveys for inspection by the Department for three years after they are made.

The Federal regulations regarding radioactive contamination control are set forth in 10 CFR 39.69. If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by 10 CFR 39.63. If contamination results from the use of licensed material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas. During efforts to recover a sealed source lodged in the well, the licensee must continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

The licensee will be required to comply with the security measures at 10 CFR 39.71, which include provisions for supervision and surveillance of source operations and obtaining assistance in the event of a source becoming lodged in a well.

The Federal rule at 10 CFR 39.73 discusses the documents and records required at field stations. Each licensee is required to maintain records such as copies of Subchapters 6, 50 and 57; all records and documents required by this subchapter such as operating and emergency procedures; the record of radiation survey instrument calibrations; the record of leak test results; physical inventory records; utilization records; records of inspection and maintenance; training records; and survey records.

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The Federal rule at 10 CFR 39.75 details the documents and records required to be kept at temporary jobsites until the well logging operation is complete. These include all records and documents required by this subchapter that pertain to operating and emergency procedures; evidence of latest calibration of the radiation survey instruments in use at the site; the latest survey records; the shipping papers for the transportation of radioactive materials; and when operating under reciprocity pursuant to proposed Subchapter 62, a copy of the NRC or Agreement State license authorizing use of licensed materials.

Requirements for notification of incidents and lost sources and abandonment procedures for irretrievable sources are detailed in 10 CFR 39.77. A licensee will be required to immediately notify the Department by telephone at the number provided at N.J.A.C. 7:28-1.5 and subsequently, within 30 days, by confirmation in writing, if the licensee knows or has reason to believe that a sealed source has been ruptured. The written confirmation must be specific in its description of the well or other location, magnitude and extent of the escape of licensed materials, and must assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences. The licensee shall notify the Department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by proposed Subchapters 6 and 51.

In the event that a sealed source becomes lodged in a well, the licensee must notify the Department, as well as the well owner, and ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures. Within 30 days after a sealed source has been classified as irretrievable, the licensee will be required to submit a report in writing to the

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Department at the address in N.J.A.C. 7:28-1.5(a) with copies to each appropriate State or Federal agency that issued permits or otherwise approved of the drilling operation. The report must contain information such as date of incident occurrence; source description (radionuclide, quantity, physical form); and location and identification of the well.

Violations and criminal sanctions are as discussed in Subchapter 50.

Subchapter 58: Domestic Licensing of Source Material

The Department and the Commission propose, at new Subchapter 58, to incorporate by reference 10 CFR Part 40, which governs domestic licensing of source material.

The Federal rule at 10 CFR 40.1 sets forth the purpose of the subchapter, which is to establish procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source and byproduct materials, as defined in this subchapter, and establish and provide for the terms and conditions upon which the Department will issue such licenses. These regulations also provide for the disposal of byproduct material and for the long-term care and custody of byproduct material and residual radioactive material. The regulations in this subchapter also establish certain requirements for the physical protection of import, export, and transient shipments of natural uranium. Additional requirements applicable to the import and export of natural uranium are set forth in 10 CFR Part 110.

The subchapter applies to all persons in the United States and gives notice to anyone who knowingly provides to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities, that they may be individually subject to enforcement actions. No person who is subject to the subchapter may receive title to, own, receive, possess, use, transfer, provide for long-term care,

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deliver or dispose of byproduct material or residual radioactive material or any source material after removal from its place of deposit in nature, unless authorized in a specific or general license issued by the Commission under the regulations.

The Department and the Commission propose to incorporate definitions of “agreement state,” “alert,” “byproduct material,” “commencement of construction,” “corporation,” “Department” and “Department of Energy,” “depleted uranium,” “effective kilogram,” and “government agency.” Additional definitions include “persons,” “pharmacist” for the purpose of this subchapter, “physician” for the purpose of this subchapter, “principal activities,” “residual radioactive material,” “site area emergency,” “source material,” “special nuclear material,” “transient shipment,” “United States,” “unrefined and unprocessed ore,” “uranium enrichment facility” and “uranium milling.”

"Byproduct material" is defined differently in Subchapter 58 than in Subchapter 6. In Subchapter 58, byproduct material refers to the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. At present, New Jersey does not have any material that falls under this definition, nor is the State assuming authority for the regulation of this material. Accordingly, the Department and Commission do not propose to incorporate by reference those portions of 10 CFR Part 40 that relate to such material, such as 10 CFR 40.2a, 26 through 28, portions of 40.32, 65 and Appendix A. The Department proposes to identify these sections at proposed N.J.A.C. 7:28-58.1(b), which contains the portions of the Federal rule that the Department and Commission are not incorporating by reference.

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General discussions related to interpretations and discrimination against an employee for engaging in certain protected activities are as was discussed in the summary to subchapter 50.

General discussions related to completeness and accuracy of information and deliberate misconduct are as was discussed in the summary to subchapter 51.

The Federal rule at 10 CFR 40.11 exempts any prime contractor of the U.S. Department of Energy from the requirements for a license for source material for work performed for the Department at a United States Government-owned or controlled site, including the transportation of source material to or from such site. In addition any prime contractor or subcontractor of the U.S. Department of Energy or the Department is exempt from the requirements for a license if they are performing work under their prime contract or subcontract, that the exemption is authorized by law, and there is adequate assurance that the work can be accomplished without undue risk to the public health and safety.

The Federal rule at 10 CFR 40.12 exempts common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service from the regulations in this Subchapter to the extent that they transport or store source material for another in the regular course of their transportation duties.

Unimportant source material is described in the Federal rule at 10 CFR 40.13 and exempts persons from the regulations if the source material is by weight less than one-twentieth of 1 percent (0.05 percent) of the mixture, compound, solution or alloy. Because some materials have greater than 0.05 percent by weight of source material, but are also considered unimportant quantities of source material, they are individually listed in the regulation. Examples of such materials include unrefined and unprocessed ore containing source material; provided, that, none refines or processes

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the ore; any quantities of thorium in incandescent gas mantles, vacuum tubes, or welding rods;

various glazes, glassware and optical lenses; and photographic film and counterweights installed in aircraft, rockets, or similar vessels. The Federal rule lists all the unimportant quantities along with the specific stipulations for exemption.

The Federal rule at 10 CFR 40.14 establishes that the U.S. Department of Energy is exempt from the requirements of this subchapter to the extent that its activities are subject to the requirements of 10 CFR Parts 60 or 63 regarding high level waste disposal at Yucca Mountain. Any licensee is exempt from the requirements of this subchapter to the extent that its activities are subject to the requirements of Subchapter 59, Land disposal of radioactive waste.

The Federal rule at 10 CFR 40.20 specifies that licenses for source material are of two types: general and specific. Licenses for long-term care and custody of residual radioactive material at disposal sites are general licenses. The Department does not have the authority to regulate residual radioactive materials as defined in this subchapter. The Department will issue licensing documents to particular persons. Specific licenses are issued to named persons upon applications filed pursuant to the regulations in this subchapter.

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The Federal rule at 10 CFR 40.21 issues a general license authorizing the receipt of title to source or byproduct material. Because the Department does not have the authority to regulate byproduct material as defined in this subchapter, these words have been deleted under N.J.A.C.7:28-58(c). A general license is issued authorizing the receipt of title to source material without regard to quantity, but does not authorize anyone to receive, possess, deliver, use, or transfer source material.

The Federal rule at 10 CFR 40.22 issues a general license authorizing commercial and industrial firms, research, educational and medical institutions and Federal, State and local government agencies to use and transfer not more than 15 pounds of source material at any one time for research, development, educational, commercial or operational purposes, but not for administering to humans either internally or externally. A person may not receive more than a total of 150 pounds of source material in any one calendar year. Persons who receive, possess, use, or transfer source material pursuant to the general license are exempt from the provisions of Subchapters 6 and 50, to the extent that such receipt, possession, use or transfer are within the terms of such general license. This exemption does not apply to any person who is also in possession of source material under a specific license issued pursuant to this subchapter.

The Federal rule at 10 CFR 40.25 issues a general license to receive, acquire, possess, use, or transfer depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device. This general license applies only to industrial products or devices which have been manufactured or initially transferred in accordance with a specific license issued by the NRC or an Agreement State.

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Persons who receive, acquire, possess, or use depleted uranium under this general license shall complete NRC Form-244 or its State equivalent, "Registration Certificate--Use of Depleted Uranium Under General License," with the Department within 30 days after the first receipt or acquisition of such depleted uranium. The form must contain contact information for the radioactive materials registrant (RMR) and its representative, a statement that the RMR has developed and will maintain procedures designed to establish physical control over the depleted uranium and to prevent transfer of depleted uranium to persons not authorized to receive it. The RMR must report any changes in information furnished to the Department in writing within 30 days after the effective date of any change.

A person who receives, acquires, possesses, or uses depleted uranium under this general license shall not introduce such depleted uranium into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium; shall not abandon such depleted uranium; and shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 10 CFR 40.51, which is incorporated by reference. In the case where the transferee receives the depleted uranium, the transferor shall furnish the transferee a copy of this section and a copy of the NRC Form-244 or equivalent State form, which is available on the Department's website at www.dep.state.nj.us/rpp/index.htm. In addition, the transferor shall furnish the transferee a note explaining that use of the product or device is regulated by the Agreement State to which he is sending the depleted uranium, under requirements substantially the same as those in 10 CFR 40.25.

Within 30 days of any transfer, the RMR shall report in writing to the Department, the name and address of the person receiving the source material. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to this general license is exempt from

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the requirements of N.J.A.C. 7:28-6 and N.J.A.C. 7:28-50 with respect to the depleted uranium covered by the general license.

The Federal rule at 10 CFR 40.31 outlines the provisions for an application for a specific license to be filed on a form supplied by the Department. Information contained in previous applications, statements or reports filed with the Department may be incorporated by reference provided that the reference is clear and specific.

The Department may require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked. Applications and documents submitted to the Department in connection with applications will be made available for public inspection in accordance with the provisions of the Open Public Records Act (P.L. 2001, c. 404).

Each application for a source material license shall be accompanied by the fee prescribed in N.J.A.C. 7:28-64. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in Subchapter 64. Also, certain applications for specific licenses must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

The Federal rule at 10 CFR 40.32 lists the requirements for issuance of a specific license. An application for a specific license will be approved if the applicant has adequate training and experience to use the source material in such manner as to protect health and minimize danger to life or property; the applicant's proposed equipment, facilities and procedures are adequate to protect health and minimize danger to life or property; and the applicant satisfies any applicable special requirements contained in 10 CFR 40.34.

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The Federal rule at 10 CFR 40.34 lists special requirements for issuance of specific licenses. An application for a specific license to manufacture industrial products and devices containing depleted uranium, or to initially transfer such products or devices, will be approved if the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and proposed uses. The applicant must also provide reasonable assurance that use of the industrial product or device is not likely to cause any individual to receive in one year a radiation dose in excess of 10 percent of the annual limits specified in N.J.A.C. 7:28-6, and demonstrate that the public will benefit from the presence of depleted uranium in the device or product.

In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

The Department may deny an applicant for a specific license if the end uses of the industrial product or device cannot be reasonably foreseen.

The Federal rule at 10 CFR 40.35 provides conditions for specific licenses issued pursuant to 10 CFR 40.34, governing special requirements for specific licenses. Each licensee shall maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device.

Each licensee shall label or mark each unit to identify the manufacturer of the product or device, the license number, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and state that the receipt, possession, use,

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and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or of an Agreement State. Each licensee shall assure that the depleted uranium, before being installed in each product or device, has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium."

Each licensee shall furnish a copy of the general license contained in 10 CFR 40.25 and a copy of NRC Form-244 or equivalent to each person to whom he transfers source material in a product or device for use. If a copy of the general license in 10 CFR 40.25 and a copy of Form NRC 244 or equivalent are furnished to such person, they shall be accompanied by a note explaining that use of the product or device is regulated by an Agreement State under requirements substantially the same as those in 10 CFR 40.25.

Each licensee shall report to the Department, all transfers of industrial products or devices to persons for use under the general license in 10 CFR 40.25. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made the report shall so indicate.

Each licensee shall report to the responsible Agreement State Agency all transfers of industrial products or devices to persons for use under the general license in the Agreement State's regulation equivalent to 10 CFR 40.25. Such report shall include the same information as identified in the previous paragraph.

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Each license shall keep records showing the name, address, and a point of contact for each general license to whom he or she transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 10 CFR 40.25. The records must be retained for three years from the date of transfer and must show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 10 CFR 40.35.

The Federal rule at 10 CFR 40.36 provides requirements for financial assurance and recordkeeping for decommissioning. Financial assurance requirements are as discussed in the summary for Subchapter 51. However, there are different specific criteria for providing financial assurance for source material decommissioning.

Each applicant for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan. Each applicant for a specific license authorizing possession and use of quantities of source material greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form shall either submit a decommissioning funding plan or submit a certification that financial assurance for decommissioning has been provided in the amount of \$225,000 by June 2, 2005 using one of the methods described below.

Financial assurance for decommissioning must be provided by prepayment; surety or insurance; sinking fund; or, in the case of a Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the quantity of material, and indicating that funds for decommissioning will be obtained when necessary. When a governmental entity is assuming custody and ownership of a site, there can be

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another arrangement that is acceptable to the governmental entity. The rule proposed for incorporation contains requirements for each of these types of financial assurance.

Each person licensed under this 10 CFR Part 40 shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned, licensees shall transfer all records to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning include information related to spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. As-built drawings and modifications of structures and equipment in restricted areas, former restricted areas or areas where wastes are or have been buried, where radioactive materials are used and/or stored, and locations of possible inaccessible contamination such as buried pipes which may be subject to contamination are also considered important information, as is information on all areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in N.J.A.C. 7:28-12, or apply for approval for disposal under N.J.A.C. 7:28-6.

Other important documents include records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

The Federal rule at 10 CFR 40.41 provides for the terms and conditions of licenses such as language that the licensee is subject to all rules, regulations, and order of the Department, and that

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neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Atomic Energy Act of 1954, as amended.

In addition, each person licensed by the Department shall confine his or her possession and use of source or byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license shall carry with it the right to receive, possess, and use source or byproduct material. Preparation for shipment and transport of source or byproduct material shall be in accordance with the provisions of N.J.A.C. 7:28-61 of this chapter.

The Department may incorporate in any license at the time of issuance, or thereafter, by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of source or byproduct material as it deems appropriate or necessary in order to: promote the common defense and security; protect health or to minimize danger of life or property; protect restricted data; require reports, and provide for inspections.

Each licensee shall notify the Department immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy). This notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

The Federal rule at 10 CFR 40.42 addresses expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated

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in the existing license, the existing license expires at the end of the day on which the Department makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

Each specific license that has an expiration date after July 1, 1995, has an expiration date that is five years after the expiration date stated in the current license except for certain types of licenses which comply with specific dates listed in 10 CFR 40.42. Examples of these types of licenses include specific licenses for which an evaluation or an emergency plan is required, which need an environmental assessment or environmental impact statement, and whose holders have been cited for violations.

Each specific license revoked by the Department expires at the end of the day on the date of the Department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of source material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall limit actions involving source material to those related to decommissioning; and continue to control entry to restricted areas until they are suitable for release in accordance with Department requirements;

If the license has expired, the licensee has decided to permanently cease principal activities, or no principal activities have been conducted for 24 months, then the licensee must notify the Department within 60 days and either begin decommissioning or submit, within 12 months of notifying the Department, a decommissioning plan if such a plan is required by 10 CFR 40.42(g)(1).

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The licensee shall maintain in effect all decommissioning financial assurances in conjunction with a license issuance or renewal. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Department.

The Department may grant a request to delay or postpone initiation of the decommissioning process if the Department determines that such relief is not detrimental to the public health and safety and is otherwise in the public interest.

A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or to the public, such as if procedures would involve techniques not applied routinely during cleanup or maintenance operations; workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation; procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

The Department may approve an alternate schedule for submittal of a decommissioning plan if the Department determines that the alternative schedule is necessary to the effective conduct of

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decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

The proposed decommissioning plan for the site or separate building or outdoor area must include a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan, a description of planned decommissioning activities, procedures to ensure protection of workers and the environment during decommissioning activities, and a description of the planned final radiation survey. The decommission plan must also have an updated detailed cost estimate for decommissioning, compared to the present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning. A justification for any delays must be submitted.

The proposed decommissioning plan will be approved by the Department if the information submitted demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning. When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

The Department may consider and approve an alternate schedule for completion of decommissioning of the site or separate building or outdoor area if warranted. Some of the considerations include whether it is technically feasible to complete decommissioning within the allotted 24-month period, whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period, whether a significant volume

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reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay, or whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay. Examples of other site-specific factors which the Department may consider appropriate on a case-by-case basis are the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

As the final step in decommissioning, the licensee shall certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information. A radiation survey must be conducted and a report of the results of this survey of the premises where the licensed activities were carried out must be submitted, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in N.J.A.C. 7:28-12.

The licensee shall report levels of gamma radiation in units of millisieverts (microrentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters removable and fixed for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines that source material has been properly disposed, reasonable effort has been made to eliminate residual radioactive contamination, if present, a

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radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in N.J.A.C. 7:28-12, other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in N.J.A.C. 7:28-12, and all required records have been received.

The Federal rule at 10 CFR 40.43 requires that applications for renewal of a specific license must be filed on NRC Form 313 or equivalent and in accordance with 10 CFR 40.31. Licensees whose licenses were extended by 10 CFR 40.42(a)(2) automatically have their renewal application withdrawn and fee refunded.

The Federal rule at 10 CFR 40.44 requires that applications for amendment of a license be filed on NRC Form 313 or equivalent in accordance with 10 CFR 40.31 and shall specify the respects in which the licensee desires the license to be amended and the grounds for the desired amendment.

The Federal rule at 10 CFR 40.45 requires the Department to apply the applicable criteria in 10 CFR 40.32 in considering an application by a licensee to renew or amend his license.

The Federal rule at 10 CFR 40.46 states that no license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Department shall after securing full information, find that the transfer is in accordance with the provisions of the Atomic Energy Act of 1954, as amended, and shall give its consent in writing.

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The Federal rule at 10 CFR 40.51 provides for the transfer of source material. No licensee shall transfer source or byproduct material except to the Department of Energy, to the agency in any Agreement State which regulates radioactive materials, to any person exempt from the licensing requirements, to any person in an Agreement State subject to the jurisdiction of that State who has been exempted from the licensing requirements and regulations of that State, to any person authorized to receive such source or byproduct material under terms of a specific license or a general license or their equivalents issued by the NRC or an Agreement State, or as otherwise authorized by the Department in writing. It is the responsibility of the licensee transferring the material to ensure that the transferee's license authorizes receipt of the type, form, and quantity of source or byproduct material to be transferred.

The Federal rule elaborates on the types of verification required before a licensee can transfer source material. Verification includes the possession of a current copy of the transferee's specific license or registration certificate, and a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of source or byproduct material to be transferred, specifying the license or registration certification number, issuing agency and expiration date. Oral certification by the transferee is acceptable for emergency shipment, provided that the oral certification is confirmed in writing within 10 days. Other sources of information that can be used for verification are those compiled by a reporting service from official records of the NRC, Department or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations. When none of the methods of verification described above are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may

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obtain and record confirmation from the Department, NRC, or the licensing agency of an

Agreement State that the transferee is licensed to receive the source or byproduct material.

The Federal rule at 10 CFR 40.60 describes how to report events and incidents. Each licensee shall notify the Department as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits. The Federal rule lists the events that require reporting to the Department within 24 hours after the discovery of the event involving licensed material. These events include an unplanned contamination event that requires access to the contaminated area to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area, involves a quantity of material greater than five times the lowest annual limit on intake specified in N.J.A.C. 7:28-6 for the material, and has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination. An event in which equipment is disabled or fails to function as designed when the equipment is required to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident also requires a report to the Department within 24 hours. Other events requiring 24 hour notification to the Department are when equipment is required to be available and operable when it is disabled or fails to function and no redundant equipment is available and operable to perform the required safety function, an event requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body, or an unplanned fire or explosion damages any licensed material or any device, container, or equipment containing licensed material when the quantity of material involved is greater than five times the

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lowest annual limit on intake specified in N.J.A.C. 7:28-6 and the damage affects the integrity of the licensed material or its container.

Immediate and 24 hour reports made by licensees in response to the requirements of 10 CFR 40.60 must be made by telephone to the Department. To the extent that the information is available at the time of notification, the information provided in these reports must include the caller's name and call back telephone number, a description of the event, including date and time, the exact location of the event, the isotopes, quantities, and chemical and physical form of the licensed material involved, and any personnel radiation exposure data available.

Each licensee who makes an immediate or 24 hour report shall submit a written follow-up report to the Department within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. In addition to the information required by telephone, the reports must include the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned, the exact location of the event, corrective actions taken or planned and the results of any evaluations or assessments, and the extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

The Federal rule at 10 CFR 40.61 sets requirements for records. Each person who receives source or byproduct material shall keep records showing the receipt, transfer, and disposal of this source or byproduct material. The licensee shall retain each record of receipt of source or byproduct material as long as the material is possessed and for three years following transfer or disposition of the source or byproduct material. The licensee who transferred the material shall retain each record

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of transfer or source or byproduct material until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement. The licensee shall retain each record of disposal of source or byproduct material until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement. If source or byproduct material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out), to make the records that account for 100 percent of the material received.

The licensee shall retain each record for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, each record must be maintained until the Department terminates the license that authorizes the activity that is subject to the recordkeeping requirement.

Records may be the original or reproduced copy or microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

If there is a conflict between the Department's regulations, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record,

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the retention period specified in the regulations shall apply unless the Department has granted a specific exemption from the record retention requirements specified in the regulations in this part.

Prior to license termination, each licensee authorized to possess source material, in an unsealed form, shall forward the records pertaining to disposal of licensed material and records required by N.J.A.C. 7:28-6 to the Department.

If licensed activities are transferred, each licensee authorized to possess source material, in an unsealed form, shall transfer records of disposal of licensed material made under N.J.A.C. 7:28-6, including burials, to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated.

Prior to license termination, each licensee shall forward the records required by 10 CFR 40.36(f) to the Department.

The Federal rules at 10 CFR 40.62 require each licensee to afford to the Department at all reasonable times, the opportunity to inspect source or byproduct material and the premises and facilities wherein source or byproduct material is used or stored. Each licensee is also required to make available to the Department, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

The Federal rules at 10 CFR 40.63 requires each licensee to perform, or permit the Department to perform, such tests as the Department deems appropriate or necessary including tests of source or byproduct material, facilities wherein source or byproduct material is utilized or stored, radiation detection and monitoring instruments, and other equipment and devices used in connection with the utilization and storage of source or byproduct material.

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The Federal rule at 10 CFR 40.71 sets forth the terms and conditions for modification and revocation of licenses. The Department may refuse to grant a license, or the license may be revoked, suspended, or modified, for any material false statement in the application or any statement of fact, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a license on an original application. The Department may also revoke, suspend, or modify the license for violation of, or failure to observe any of, the terms and conditions of the Atomic Energy Act of 1954, or the license, or of any rule, regulation or order of the Department.

Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless the situation has been called to the attention of the licensee in writing and the licensee has been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

General discussions related to violations and criminal penalties are as was discussed in the summary discussion for subchapter 50.

The Federal regulations found at 10 CFR 40.2a, 40.8, 40.12(b), 40.23, 40.26 through 40.28, 40.31(j) through 40.31(l), 40.32(d), 40.32(e), 40.32(g), 40.33, 40.38, 40.51(b)(6) and 40.64 through 40.67 cannot be relinquished to the State by the NRC and are remaining under Federal jurisdiction. Appendix A to 10 CFR 40 is also remaining under Federal jurisdiction because the State has decided not to assume regulatory responsibility for uranium mills and the associated wastes generated by such facilities.

SUBCHAPTER 59. Licensing Requirements for Land Disposal of Radioactive Waste

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Proposed new Subchapter 59 governs the licensing requirements for land disposal of radioactive waste, and incorporates by reference 10 CFR Part 61. The proposed subchapter establishes, for land disposal of radioactive waste, the procedures, criteria, and terms and conditions upon which the Department issues licenses for the disposal of radioactive wastes containing byproduct, source and special nuclear material received from other persons. There are no radioactive waste facilities located in the State, nor does the Department plan on licensing any such facilities in the foreseeable future. However, these regulations need to be in place as mandated by the NRC for a state to become an Agreement State.

The proposed subchapter does not apply to disposal of high-level waste, which is regulated under 10 CFR Parts 60 and 63. Nor does it apply to disposal of uranium or thorium tailings or wastes (byproduct material as defined in 10 CFR 40.4 (a-1)), which is regulated under 10 CFR Part 40, incorporated by reference at proposed N.J.A.C. 7:28-58, in quantities greater than 10,000 kilograms and containing more than five millicuries of radium-226. Disposal of licensed material is regulated at N.J.A.C. 7:28-6. The Department does not regulate nuclear reactors, special nuclear materials in quantities sufficient to form a critical mass, high-level waste disposal facilities, or byproduct material defined in Section 11e(2) of the Atomic Energy Act of 1954, as amended. Insofar as the incorporated rules refer to these facilities and/or materials, they do not apply.

Persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities subject to this subchapter, may be individually subject to Department enforcement action for violation of 10 CFR 61.9b, incorporated by reference at proposed N.J.A.C. 7:28-59.

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The Federal regulations at 10 CFR 61.2 include definitions of “active maintenance,” “buffer zone,” “chelating agent,” “commencement of construction,” “custodial agency,” “director,” “disposal,” “disposal site,” “disposal unit,” “engineered barrier,” “explosive material,” “government agency,” “hazardous waste,” “hydrogeologic unit,” “inadvertent intruder,” “Indian tribe,” “intruder barrier,” “land disposal facility,” “license,” “monitoring,” “near-surface disposal facility,” “person,” “pyrophoric liquid,” “site closure and stabilization,” “state,” “stability,” “surveillance,” “tribal governing body” and “waste.”

According to 10 CFR 61.3, no person may receive, possess, and dispose of radioactive waste containing source, special nuclear, or byproduct material at a land disposal facility unless authorized by a license issued by the Department, or unless an exemption has been granted by the Department. Each person shall file an application with the Department and obtain a corresponding license before commencing construction of a land disposal facility. If not, the license application may be denied.

In accordance with 10 CFR 61.6, the Department may, with the approval of the Commission on Radiation Protection, upon application by any interested person, or upon its own initiative, grant any exemption from the requirements of this subchapter if it determines that the exemption is in accordance with the provisions of N.J.A.C. 7:28-2.8.

As set forth in 10 CFR 61.7, this subchapter is intended to apply to land disposal of radioactive waste, and not to other methods, such as sea or extraterrestrial disposal. The proposed subchapter contains procedural requirements and performance objectives applicable to any method of land disposal. It also contains specific technical requirements for near-surface disposal of radioactive waste, which includes disposal in engineered facilities that may be built totally or partially above-grade provided that such facilities have protective earthen covers.

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The Federal rule at 10 CFR 61.7 details the concepts underling the subchapter. The concepts discuss the purpose of the rules, the goal of protecting the public both now and in the future, and the means that such protection shall be accomplished.

The Federal rules at 10 CFR 61.9 contain antidiscrimination provisions similar to those at 10 CFR Part 30, incorporated at proposed N.J.A.C. 7:28-51. The rule protects employees from retaliation for “whistleblower” activities, as well as retaliation for actions that assist the Department in an investigation. General discussions related to discrimination against an employee for engaging in certain protected activities are as was discussed in the summary to subchapter 50.

The Federal regulations at 10 CFR 61.9a require all information submitted to the Department to be complete and accurate. If there is specific information that the applicant or licensee provides that has a significant implication for public health and safety or common defense and security, the applicant or licensee must notify the Department.

Deliberate misconduct is subject to 10 CFR 61.9b, which prohibits deliberate misconduct that causes, or would cause if not detected, a violation of a Department requirement. The rule also prohibits deliberate submission of false or inaccurate information. A violation is subject to enforcement action.

The Federal regulations at 10 CFR 61.10 require that an application to receive from others, possess and dispose of wastes containing or contaminated with source, byproduct or special nuclear material by land disposal must consist of general information, specific technical information, institutional information, and financial information. An environmental report prepared in accordance with subpart A of 10 CFR Part 51 must accompany the application.

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The general information required in an application for a license is addressed at 10 CFR 61.11, and must include contact information for the applicant; the applicant's qualifications for a license; a description of the location of the proposed disposal site; the types and quantities of radioactive waste to be received, possessed, and disposed of; plans for use of the land disposal facility for purposes other than disposal of radioactive wastes; and a description of the proposed facilities and equipment. The proposed schedules for construction, receipt of waste, and first emplacement of waste at the proposed land disposal facility must also be included.

The Federal rule at 10 CFR 61.12 requires specific technical information relating to the site and the operation of the facility to demonstrate that the performance objectives and applicable technical requirements of the proposed subchapter will be met. Specific technical information, demonstrating that the performance objectives of the proposed subchapter are met, is required at 10 CFR 61.13.

The requirement of 10 CFR 61.14 include a certification by the Federal or State government that owns the disposal site that the Federal or State government is prepared to accept transfer of the license. If the Federal or State government does not own the site, a certification is required that indicates that arrangements have been made to transfer ownership to the Federal or State government following closure and a period of post-closure observation and maintenance.

Under Federal rule 10 CFR 61.15, financial information must be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out license activities.

The Federal rules at 10 CFR 61.16 through 22 govern additional information on physical security measures for special nuclear materials; applications and amendments to applications. Application, amendment, and inspection fees applicable to a license under this proposed subchapter

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are set forth at proposed new N.J.A.C. 7:28-64. An amendment to an application must be filed in the same manner as an application, and is subject to the same review criteria. (See 10 CFR 61.26.)

The Department will issue a license if the conditions at 10 CFR 61.23 are met. The issuance of the license must not be inimical to the common defense and security, and must not constitute an unreasonable risk to the health and safety of the public. The rule sets forth the qualifications of the applicant and the site that are necessary in order that the conditions are satisfied.

Each license is subject to the terms and conditions of 10 CFR 61.24. The license may not be transferred without the Department's consent. License amendment requests must be written. Site owner only receives the license after successful completion of the final closure plan. The licensee shall be subject to the provisions applicable regulations, license amendments and regulation changes. Any license may be revoked, suspended or modified for any material false statement in the application or any statement of fact. Material may only be located and handled under license conditions. No radioactive waste may be disposed of until the Department approval of the license. The Department may incorporate in any license at the time of issuance, or thereafter, additional requirements and conditions and reports to promote the common defense and security; protect health; or to minimize danger to life or property. Any licensee who receives and possesses special nuclear material under this part in quantities that would be subject to the requirements of proposed new N.J.A.C. 7:28-60 shall comply with the requirements of that section. The licensee shall not consider the quantity of special nuclear material that has been disposed of. The licensee must hold a non-expired license to dispose of waste. Each licensee shall notify the Supervisor of the Radioactive Materials Section, in writing, immediately following the filing of a voluntary or

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involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code.

Under 10 CFR 61.25, a licensee shall not make changes in the land disposal facility or procedures described in the license application. The license, however, will include conditions restricting subsequent changes to the facility and the procedures authorized that are important to public health and safety.

Application process for license renewal or site closure is described in 10 CFR 61.27. Failure to renew the license shall not relieve the licensee of responsibility for carrying out site closure, postclosure observation and transfer of the license to the site owner. An application for renewal or for closure must be filed at least 30 days prior to license expiration. The application process for renewal is similar to that for an initial license, except that continued operation is allowable when application is timely renewed.

Applications for closure of a site must comply with the requirements of 10 CFR 61.28, including any updates to site characteristics and an updated environmental report in accordance with 10 CFR Part 51. The Department shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives this subchapter will be met.

In accordance with 10 CFR 61.29, following completion of closure authorized as above, the licensee shall, for a period of approximately five years, observe, monitor, and carry out necessary maintenance and repairs at the disposal site until the license is transferred.

The licensee may then apply for an amendment to transfer the license to the site owner following the requirements of 10 CFR 61.30. These include assurances that the site was closed

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according to submittals to the Department, that the performance objective of subpart C of this part are met, that the proper funds have been transferred to the site owner, and that the site owner is prepared to assume responsibility for the site.

Under 10 CFR 61.31, after the required period of institutional controls, the licensee may apply for an amendment to terminate the license and the Department may terminate the license.

Performance objectives, Subpart C, are in 10 CFR 61.40 through 10 CFR 61.44. These Federal regulations describe land disposal facility requirements to protect the general population from releases of radioactivity, protect the inadvertent intruder, protect individuals during operation and assure the stability of the site after closure.

Technical requirements for land disposal facilities, Subpart D, are in the Federal rule at 10 CFR 61.50 through 10 CFR 61.59. The minimum characteristics a disposal site must have to be acceptable to isolate the waste are identified at 10 CFR 61.50. The site shall be capable of being characterized, modeled, analyzed and monitored. The projected surrounding area development, facilities and geological processes will not affect the ability of the disposal facility to meet the performance objectives. Areas of known natural resources, flooding, close proximity to groundwater, water flow, tectonic processes, and groundwater discharge must be avoided.

Site design features under 10 CFR 61.51 enhance the long-term isolation of the waste and diminish the active maintenance after site closure. The site design and operation must assure the performance objectives of this subchapter. Covers and surface features must be designed to minimize the contact of water with the waste.

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Land disposal facility operation and disposal site closure are the subject of 10 CFR 61.52.

Class A wastes must be segregated from other wastes unless they meet the stability requirements of this subchapter. Class C wastes must be disposed of under a minimum of five meters of the cover or with intruder barriers with an effective life of at least 500 years. Wastes must be emplaced in a manner that maintains the package integrity during emplacement and void spaces between waste packages must be filled fill. At the time of license transfer, the radiation dose rate at the surface of the cover complies with proposed amended N.J.A.C. 7:28-6. The boundaries and locations of each disposal unit must be accurately located and mapped. A buffer zone of land must be maintained between any buried waste and the disposal site boundary and beneath the disposed waste, so that environmental monitoring and remediation activities may be conducted. Once filled and covered, each trench must be closed and stabilized. Active waste disposal operations must not have an adverse effect on completed closure and stabilization measures. Only wastes containing or contaminated with radioactive materials shall be disposed of at the disposal site.

The license application shall include disposal site ecology, meteorology, climate, hydrology, geology, geochemistry, and seismology. Federal regulation 10 CFR 61.53 requires plans to take corrective measures if migration of radionuclides would jeopardize the performance objectives of this subchapter. This must include an environmental monitoring program during operations and closure that is capable of providing early warning of releases of radionuclides from the disposal site before they leave the site boundary.

The Department, under 10 CFR 61.54, may approve alternative requirements for design and operations if the requirements meet the performance objectives of this subchapter.

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Waste classification is addressed in 10 CFR 61.55. Class A waste is usually segregated from other waste classes at the disposal site unless it meets the stability requirements set forth in this subchapter. Class B waste must meet more rigorous requirements on waste form to ensure stability after disposal. Class C waste must meet more rigorous requirements on waste form to ensure stability and also requires additional measures at the disposal facility to protect against inadvertent intrusion. Waste that is not generally acceptable for near-surface disposal must usually be disposed of in a geologic repository as defined in 10 CFR Part 60 or 63. Class A waste has concentrations less than 0.1 times the values in Table 1. Class C waste has concentrations between 0.1 and 1.0 times the values in Table 1. If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.

If radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. If radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A. Class A waste has concentrations less than the value in Column 1 of Table 2. If the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste is Class B. If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C. If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

For wastes with radionuclides in both Tables 1 and 2, the class shall be determined by the concentration of nuclides listed in Table 2, if the concentration of a nuclide listed in Table 1 does not exceed 0.1 times the value listed in Table 1. If the concentration of a nuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1 but does not exceed the value in Table 1, the waste shall be Class C, provided the concentration of nuclides listed in Table 2 does not exceed the value

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shown in Column 3 of Table 2. If radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.

The sum of fractions must be less than 1.0 for wastes with more than one radionuclide. The concentrations may be determined by methods such as scaling factors and may be averaged over the volume of the waste.

Waste characteristics are subject to the requirements in 10 CFR 61.56. Waste must not be packaged for disposal in cardboard or fiberboard boxes. Liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid. Any liquid must not exceed one percent of the volume. Waste must not be explosive or be able to generate toxic gases, vapors or fumes. Waste must not be pyrophoric. Waste in a gaseous form must be packaged under limited pressure and concentration. Waste containing hazardous, biological, pathogenic, or infectious material must be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials. Waste must have structural stability by means of the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal. Noncorrosive liquid shall not exceed one percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5 percent of the volume of the waste for waste processed to a stable form. Void spaces within the waste and between the waste and its package must be reduced to the extent practicable.

Under 10 CFR 51.57, each package of waste must be clearly labeled to identify whether it is Class A waste, Class B waste, or Class C waste. Alternate classification and characteristics may be authorized by the Department under 10 CFR 61.58, if the performance objectives in subpart C of

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this subchapter are met. Requirements for land ownership and institutional controls are described in 10 CFR 61.59.

The Federal rule at 10 CFR 61.61 requires the applicant to have necessary funds or assurance of obtaining necessary funds to conduct all licensed activities.

Disposal Site closure and stabilization funding requirements are addressed in 10 CFR 61.62. This includes decontamination or dismantlement of structures, closure and stabilization of the disposal site so that active maintenance is eliminated except for custodial care, surveillance and monitoring are eliminated. The rule also discusses the licensee's surety mechanism and the change in funding relative to updated cost estimates.

Under 10 CFR 61.63, the license application must include a binding arrangement between the applicant and the site owner to ensure funding for monitoring and maintenance during the institutional control period.

Participation by State Governments and Indian Tribes is described in 10 CFR 61.70 through 61.73. In accordance with 10 CFR 61.71, Department staff will be available to discuss application submittals, regulations, and schedules with representatives of the State government or tribal governing body. A State or tribal governing body whose interest is affected by a near-surface disposal facility at the proposed site may submit to the Manager of the Bureau of Environmental Radiation a proposal for participation in the review of a license application. Federal rule 10 CFR 61.72 also includes time periods within which the proposals must be submitted. These proposals must be made in writing and must be signed by the Governor of the State or the official otherwise provided for by State or tribal law. Proposals must include the issues to be discussed; description of information, activities, and public awareness initiatives that the requested will contribute in support

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of the licensing process. Preliminary estimate of impacts to the community and requests for educational and informational services must also be included.

The Federal rule at 10 CFR 61.73 describes required meetings, approval requirements and method of Department approval for above proposals. Participation by a State or Indian tribe shall not affect their rights to participate in an adjudicatory hearing as provided by the Department adjudicatory hearing process.

Under 10 CFR 61.80, each licensee shall maintain any required records for a period specified by the appropriate regulations in this proposed subchapter or by license condition. The licensee shall record the location and the quantity of radioactive wastes contained in the disposal site, and transfer these records upon license termination to government entities as designated by the Department. Records must be kept of each receipt of waste including shipping information, waste inspection results, and disposal location. Each licensee shall comply with the safeguards reporting requirements of proposed new N.J.A.C. 7:28-51, N.J.A.C. 7:28-58, and 10 CFR Part 74 if the quantities or activities of materials received or transferred exceed the limits found in these two subchapters and this part.

The licensee of the disposal facility will annually submit its financial report to the Department. The licensee must also submit annually to the Department a report of environmental monitoring data; classes, activities, and quantities of radionuclides disposed of; and changes in site characteristics. Each licensee shall report any case of accidental criticality in accordance with the requirements of 10 CFR Part 52, which is not proposed to be incorporated. Any transfer of byproduct, source, and special nuclear materials by the licensee is subject to the requirements in N.J.A.C. 7:28-51, 58, and 60. Electronic recordkeeping requirements are also discussed.

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In accordance with 10 CFR 61.81, each licensee shall perform, or permit the Department to perform, any tests as the Department deems appropriate or necessary for the administration of the regulations in this proposed subchapter, including tests of radioactive wastes and corresponding facilities; radiation detection and monitoring instruments; and other equipment and devices used in connection with site operations.

Federal regulations 10 CFR 61.82 allow the Department to inspect radioactive waste not yet disposed of; site premises, equipment, operations, and facilities; and records kept by the licensee pursuant to proposed amended N.J.A.C. 7:28. The Department and the Commission do not propose to incorporate 10 CFR 61.4, 61.8, 61.16, 61.23(i) and 61.23(j). These rules relate to programs or activities that cannot be relinquished to the State by the NRC and are remaining under Federal jurisdiction.

Subchapter 60: Domestic Licensing of Special Nuclear Material

The Department and the Commission propose at new Subchapter 60, to incorporate by reference 10 CFR Part 70, which governs domestic licensing of special nuclear material. The Federal rule at 10 CFR 70.1 sets forth the purpose of the subchapter, which is to establish procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver special nuclear material and establish and provide for the terms and conditions upon which the Department will issue such licenses.

The Federal regulation at 10 CFR 70.2 give notice to all persons who knowingly provide to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities, may be individually subject enforcement action.

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No person subject to the regulations in this proposed subchapter shall receive title to, own, acquire, deliver, possess, use or transfer special nuclear material except as authorized in a license issued by the Department.

The Federal regulation at 10 CFR 70.4 includes definitions of “Act,” “agreement state” and “non-agreement state,” “alert,” “atomic energy,” “atomic weapon,” “commencement of construction,” “common defense and security,” “contiguous sites,” “corporation,” “decommission,” “Department and Department of Energy,” “effective dose equivalent,” “effective kilograms of special nuclear material,” “formula quantity,” “government agency,” “license,” “person,” “plutonium processing and fuel fabrication plant,” “principal activities,” “produce,” “research and development,” “restricted data,” “sealed source,” “site area emergency,” “source material,” “special nuclear material,” “special nuclear material of low strategic significance,” “special nuclear material of moderate strategic significance,” “special nuclear material scrap,” “strategic special nuclear material,” “transient shipment,” “United States” and “uranium enrichment facility.”

General discussions related to interpretations and discrimination against an employee for engaging in certain protected activities are as discussed in the summary of proposed new Subchapter 50, above.

General discussions related to completeness and accuracy of information and deliberate misconduct are as discussed in the Summary of proposed new Subchapter 51, above.

The Federal rule at 10 CFR 70.11 exempts any prime contractor of the U.S. Department of Energy from the requirements for a license for special nuclear material for work performed for the Department at a United States Government-owned or controlled site, including the transportation of special nuclear material to or from the site. In addition, any prime contractor or subcontractor of the U.S. Department of Energy or the Department is exempt from the requirements for a license if they

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are performing work under their prime contract or subcontract, that the exemption is authorized by law, and there is adequate assurance that the work can be accomplished without undue risk to the public health and safety.

An exemption to the requirements of proposed new Subchapter 60 for common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are addressed at 10 CFR 70.12 to the extent that they transport or store special nuclear material in the regular course of their transportation duties. This exemption does not apply to the storage in transit or transport of material by persons covered by a general license that will continue to be issued by NRC.

As described in 10 CFR 70.18, there are two types of licenses issued for special nuclear material: general and specific. Any general license provided is effective without the filing of applications with the Department or the issuance of licensing documents to particular persons. Specific licenses are issued to named persons upon an application filed pursuant to the regulations in this proposed subchapter.

A general license is issued in accordance with 10 CFR 70.19 to receive title to, own, acquire, deliver, receive, possess, use and transfer plutonium in the form of calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the Department or other Federal agency. A general license is issued to a person who holds a specific license issued by the Department which authorizes him to receive, possess, use and transfer byproduct material, source material, or special nuclear material. Additionally, persons who receive title to, own, acquire, deliver, receive, possess, use or transfer one or more calibration or reference sources under this general license shall not possess at any one time, at any one location of storage or use, more than five microcuries of plutonium in such sources. Persons authorized under the general license shall not receive, possess, use or transfer such source

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unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement: "The receipt, possession, use and transfer of this source, Model-- -- , Serial No.-----, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission, or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS PLUTONIUM. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE. (Name of Manufacturer or Initial Transferor)." The persons authorized under the general license shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the NRC, or an agreement state to receive the source. The source shall be stored, except when the source is being used, in a closed container adequately designed and constructed to contain plutonium that might otherwise escape during storage. The source shall not be used for any purpose other than the calibration of radiation detectors or the standardization of other sources. The general license in this section does not authorize the manufacture, import, or export of calibration or reference sources containing plutonium.

A general license is issued under 10 CFR 70.20 authorizing the receipt of title to and ownership of special nuclear material without regard to quantity, but does not authorize anyone to acquire, receive, possess, deliver, use, or transfer special nuclear material.

The Federal rule at 10 CFR 70.21 outlines the provisions for an application for a specific license to be filed on a form supplied by the Department. Information contained in previous applications, statements or reports filed with the Department may be incorporated by reference provided that the reference is clear and specific. Applications and documents submitted to the Department in connection with applications will be made available for public inspection in

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accordance with the provisions of the Open Public Records Act, N.J.S.A. 47:1 A-1, et seq. Each application for a special nuclear material license shall be accompanied by the fee prescribed in proposed new N.J.A.C. 7:28-64. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in proposed new Subchapter 64.

The Federal rule at 10 CFR 70.22 states the requirements for a license application including the full name, address, age (if an individual), and citizenship of the applicant and the names and addresses of three personal references are to indicated, the State where a corporation or other entity was incorporated or organized, the location of the principal office, the names, addresses, and citizenship of its principal officers. The applicant must also include information concerning the control or ownership, if any, exercised over the applicant by any alien, foreign corporation, or foreign government. All information concerning the physical form, amount, isotopic content, and the period of time for which the license is requested must be provided, as well as a description of the activity for which the special nuclear material is requested, or in which special nuclear material will be produced, the place at which the activity is to be performed and the general plan for carrying out the activity. The applicant must demonstrate that he or she has adequate training and experience to use the special nuclear material in such manner as to protect health and minimize danger to life or property, and the applicant's proposed equipment, facilities and procedures are adequate to protect health and minimize danger to life or property.

Certain applications must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. The Department may require further statements to determine whether the application should be granted or denied or whether a license should be modified or revoked. All applications and statements shall be signed by the applicant or

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licensee or a corporate officer. Each application and statement shall contain complete and accurate disclosure as to all matters and things required to be disclosed.

The Federal rule at 10 CFR 70.23 lists the requirements for the approval of an application for a special nuclear material license by the Department. The Department will approve the application if the special nuclear material is to be used for the conduct of research or development activities of a certain type, if the applicant has adequate training and experience to use the material, if the applicant has the appropriate facilities and equipment, procedures adequate to protect health and minimize danger to life or property, and if the applicant appears to be financially qualified to engage in the proposed activities.

The Federal rule at 10 CFR 70.25 provides requirements for financial assurance and recordkeeping for decommissioning. Financial assurance requirements are as discussed in the Summary of proposed Subchapter 51, above. However, there are different specific criteria for providing financial assurance for special nuclear material decommissioning. The amount of the financial assurance for decommissioning varies, depending on the quantity of special nuclear material to be decommissioned. The financial assurance amounts range from \$113,000 to \$1,125,000 based on a factor times the applicable quantities of Appendix B to 10 CFR Part 30. Financial assurance for decommissioning must be provided by prepayment; surety or insurance; sinking fund; or, in the case of a Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the quantity of material, and indicating that funds for decommissioning will be obtained when necessary. Records of information important to decommissioning are as discussed in the Summary of proposed Subchapter 58, above.

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In accordance with 10 CFR 70.31, the Department will issue a license, upon a determination that an application meets the requirements of the Atomic Energy Act of 1954 and the regulations of the Department. The license will take such form and contain such conditions and limitations as the Department deems appropriate or necessary.

Under Federal rule 10 CFR 70.32, a license shall contain and be subject to conditions ensuring that the special nuclear material will not be conferred, assigned or transferred by the licensee, the licensee shall be subject to and shall observe all applicable rules, regulations and orders of the Department and the licensee is required to notify the Department, in writing, immediately following the filing of voluntary or involuntary petition for bankruptcy. Each licensee shall notify the Department immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 of the United States Code (Bankruptcy). This notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

The Department may incorporate in any license such additional requirements and conditions with respect to the licensee's ownership, receipt, possession, use, and transfer of special nuclear material as it deems appropriate or necessary in order to protect health or to minimize danger of life or property; require reports, and provide for inspections.

The Federal regulations at 10 CFR 70.33 requires the application for a renewal license to be filed in accordance with 10 CFR 70.21. Information contained in previous applications, statements, and reports filed with the Department may be incorporated by reference provided that the references are clear and specific.

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As described in 10 CFR 70.34, an amendment of a license shall be filed in accordance with 10 CFR 70.21. Under 10 CFR 70.35, the Department will apply the criteria in 10 CFR 70.23 when considering a renewal or amendment to a license.

The Federal rule in 10 CFR 70.36 prohibits the transfer, assignment, disposal or transfer of control of any license issued to possess or utilize special nuclear material to any person unless the Department gives its consent in writing.

The Federal rule at 10 CFR 70.38 addresses expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas. A summary of these requirements is as discussed in the Summary of proposed Subchapter 58, above.

The Federal rule at 10 CFR 70.39 addresses specific licenses for the manufacture or initial transfer of calibration or reference sources containing plutonium. Applicants will be able to manufacture or initially transfer these calibration or reference sources provided they submit sufficient information, including the chemical and physical form and maximum quantity of plutonium in the source, details of construction and design, procedures and results of prototype testing of sources, and a description of labeling to be affixed to the source or storage container.

Each source will contain no more than 5 microcuries of plutonium. For any type of source containing more than 0.005 microcuries, the Department determines that the plutonium will not be released or be removed from the source under normal conditions of use, and that the source has satisfactorily been subjected to and passed the prototype tests. Each of five prototypes of sources containing more than 0.005 microcuries of plutonium must have the following tests performed in the order listed: initial measurement, dry wipe test, wet wipe test, water soak test, and dry wipe test. Removal of more than 0.005 microcurie of activity in any test shall be cause for rejection of the

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source design. Results of the prototype tests shall be submitted to the Department in terms of microcuries and percent removal from the total amount of radioactivity affixed to the source.

Each person shall affix to each source or storage container a label that contains the following statement: "CAUTION--RADIOACTIVE MATERIAL--THIS SOURCE CONTAINS PLUTONIUM. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE." (Name of Manufacturer or Initial Transferor)

Each licensee shall perform a dry wipe test for each source that contains more than 0.1 microcurie of plutonium prior to transferring the source to a general licensee. The wipe paper shall be analyzed by using radiation detection instrumentation capable of detecting 0.005 microcuries of plutonium. If the results of the analysis disclose more than 0.005 microcuries of radioactive material, the source shall be deemed to be leaking or losing plutonium and shall not be transferred to a general licensee.

The Federal rule at 10 CFR 70.41 limits the possession and use of the special nuclear material to the locations and purposes authorized in the license, and is subject to the provisions of the license and regulations in this subchapter.

Transfer of special nuclear material is described in 10 CFR 70.42 and is as discussed in the Summary of proposed Subchapter 58, above.

Reporting requirements at 10 CFR 70.50 are as discussed in the Summary of proposed Subchapter 58, above.

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As described in 10 CFR 70.51, before a license is terminated, the licensee is to forward records of disposal of licensed material, and all other records required under the regulations to the Department.

As provided for in 10 CFR 70.73, applications for renewal of a license must be filed in accordance with the regulations. Information contained in previous applications, statements, or reports filed with the Department may be incorporated by reference, provided they are clear and specific.

The Federal rule at 10 CFR 70.56 requires the license to perform tests, or allows the Department to perform tests, of special nuclear material and radiation detection and monitoring instruments.

The modification and revocation of licenses at 10 CFR 70.81 is as discussed in the Summary of proposed Subchapter 58, above. In addition, upon revocation, suspension, or modification of a license, the Department may immediately take possession of all special nuclear material held by the licensee.

General discussions related to violations and criminal penalties are as was discussed in the Summary of proposed Subchapter 50, above.

The Federal regulations found at 10 CFR 70.1(c) through (e), 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)1, (c), (f) through (h), 70.22(b), (c), (f) through (n), 70.23(a)(6) through (12), (b), 70.23a, 70.24, 70.25(a), 70.31(c) through (e), 70.32(a)(1), (4) through (7), (b)(1), (3), (4), (c) through (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), 70.52, 70.55(c), 70.56 (b) and (c) in list of tests, 70.59 through 70.62, 70.64 through 70.66, 70.72, 70.74, 70.76, 70.82 and Appendix A cannot be relinquished to the State by the NRC and are remaining under Federal jurisdiction.

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Subchapter 61: Packaging and Transportation of Radioactive Material

Proposed new Subchapter 61 establishes requirements for packaging, preparation for shipment, and transportation of licensed material, and incorporates by reference 10 CFR Part 71. Packaging and transportation of licensed material are also subject to proposed N.J.A.C. 7:28-6, 51, 58, and 60, 10 CFR Parts 21 and 73, and to the regulations of other agencies (for example, the New Jersey Department of Transportation (NJ DOT), the U.S. Department of Transportation (DOT) and the U.S. Postal Service (USPS)) having jurisdiction over means of transport.

The Federal rule at 10 CFR 71.0 identifies the scope of the proposed new subchapter. These regulations apply to any specific or general licensee authorized by the Department. Activities regulated by the proposed subchapter include delivery of licensed material to a common carrier for transport, transporting licensed material outside the site of usage specified in a State license, or transporting licensed material on public highways. Authorization for possession of licensed material is regulated under other subchapters of N.J.A.C. 7:28.

Application for package approval must demonstrate that the design of the package to be used satisfies the package approval standards contained in this subchapter. A licensee transporting licensed material, or delivering licensed material to a carrier for transport, shall comply with the operating control requirements, the quality assurance requirements; and the general provisions of this subchapter, including DOT regulations.

In addition to general and specific licensees, any person required to possess or obtain a certificate of compliance for a package intended for the transportation of radioactive material or an approved compliance plan if the person delivers radioactive material to a common or contract carrier for transport.

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Finally, 10 CFR 71.0 establishes that this subchapter also gives notice to all persons who knowingly provide to any licensee, certificate holder, quality assurance program approval holder, applicant for a license, certificate, or quality assurance program approval, or to a contractor, or subcontractor of any of them, components, equipment, materials, or other goods or services, that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this subchapter, that they may be individually subject to Department enforcement action for violation of N.J.A.C. 7:28-61.

Under the Federal rule at 10 CFR 71.1(b) records may be kept in various media forms, so long as they retain all pertinent information (such as stamps, initials and signatures), are clear and legible and are maintained to safeguard against tampering.

The proposed new rules mandate that no licensee may transport licensed materials or deliver licensed material to a carrier for transport, unless authorized by a general license or a specific license issued by the Department, or as exempted in this proposed subchapter.

Federal regulations at 10 CFR 71.4 define terminology specific to the administration of this subchapter. The definitions that are proposed to be incorporated by reference include; "A₁," "A₂," "carrier," "certificate holder," "certificate of compliance (CoC)," "close reflection by water," "consignment," "containment system," "conveyance" for "transport by public highway or rail" or "transport by water" or "transport by aircraft," "criticality safety index," "deuterium," "DOT," "exclusive use," "fissile material," "graphite," "licensed material," "low specific activity (LSA) material," "LSA-I," "LSA-II," "LSA-III," "low toxicity alpha emitters," "maximum normal operating pressure," "natural thorium," "normal form radioactive material," "optimum interspersed hydrogenous moderation," "package" including "fissile material package," "type A package" and "type B package," "packaging," "special form radioactive material," "specific activity of a

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radionuclide,” “spent nuclear fuel or spent fuel,” “state,” “surface contaminated object (SCO),” “transport index (TI),” “type A quantity,” “type B quantity,” “unirradiated uranium” and “uranium – natural, depleted, enriched” including “natural uranium,” “depleted uranium” and “enriched uranium.”

The Federal rule at 10 CFR 71.5 establishes that each licensee transporting, or delivering to a carrier for transport, licensed material is required to comply with the applicable requirements of DOT regulations pertaining to packaging, marking and labeling, placarding, accident reporting, shipping papers and emergency information, hazardous material employee training, security plans, shipper/carrier registration and requirements specific to the mode of transport as required in 49 CFR Parts 107, 171 through 180, and 390 through 397. Should a shipment of licensed material be exempted from the DOT regulations referenced above, the licensee must still conform to DOT requirements as if the shipment were designated as radioactive under the requirements of the DOT. However, a licensee may file a request to the Department for modification, waiver, or exemption from those requirements.

The Federal rule at 10 CFR 71.7 provides requirements pertaining to completeness and accuracy of information. Information provided to the Department by a licensee, certificate holder, or an applicant for a license or Certificate of Compliance (CoC) must be complete and accurate in all material respects. In addition, a licensee, certificate holder, or applicant for a license or CoC must, within two working days following discovery, notify the Department of information identified as having a significant implication for public health and safety or common defense and security. Failure to notify the Department of such information within the specified timeframe will be considered a violation of this rule.

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The Federal rule at 10 CFR 71.8 and 71.9 provide for regulations regarding deliberate misconduct and discrimination and are as discussed in the Summary to proposed new Subchapters 50 and 51.

The Federal regulations at 10 CFR 71.13 exempt physicians who are licensed under proposed new Subchapter 55 from the requirements of 10 CFR 71.5 with respect to transporting licensed material in the practice of medicine.

The Federal rule at 10 CFR 71.14 exempts low level materials, such as natural ores containing naturally occurring radioactive materials that are not intended to be processed and are under certain activity concentrations.

The Federal rule provides an exemption from classification as fissile material in 10 CFR 71.15. If the fissile material meets at least one of several criteria listed, it will be exempt from the fissile material packaging standards of this Subchapter. The exemptions are based on quantity of fissile material.

General licenses are issued under 10 CFR 71.17, and 71.21 through 71.23 to any licensee of the Department to transport or to deliver to a carrier, licensed material in a package. All general licensees are required to have an approved quality assurance program as well as a copy of their CoC or other approval of the package, and must comply with the terms and conditions of the license, and all applicable requirements in the regulations. A general license for an approved package is provided for in 10 CFR 71.17. A general license for a DOT specification Type B package for transport of fissile material is provided for in 10 CFR 71.20.

The Federal rule at 10 CFR 71.21 issues a general license to any licensee for transport to and from locations outside of the United States provided the package design has been approved and issued a certificate by a foreign national competent authority.

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Fissile material packaging requirements for a general license are provided in 10 CFR

71.22. Limitations of the amounts of plutonium, uranium-235, and uranium-233, and beryllium, graphite, or hydrogenous material enriched in deuterium are provided.

The Federal rule at 10 CFR 71.23 issues a general license for transporting plutonium-beryllium special form sealed sources. Such material must be shipped in a Type A package and must meet the quantity limitations specified.

External radiation standards are provided at 10 CFR 71.47. Each package must be prepared for shipment so that the dose rate at any point on the external surface of the package does not exceed 200 mrem per hour and the transport index does not exceed 10. An exclusive use shipment may exceed these dose rates provided the shipment is made in a closed transport vehicle and there are no loading or unloading operations between the beginning and end of the transportation.

Under 10 CFR 71.81, licensees must comply with the general requirements and quality assurance requirements of this subchapter.

When the isotopic abundance, mass, concentration, degree of irradiation, or other pertinent properties of fissile material is unknown, the licensee is required, under 10 CFR 71.8, to package the material as if the unknown properties have credible values that would cause maximum neutron multiplication.

Before the first use of a package, the requirements in 10 CFR 71.85 must be met, which include marking the package with its model number, serial number, gross weight, and package identification number assigned by the NRC; inspecting for cracks, pinholes, or other defects; and testing the containment system under pressure.

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Routine determinations before shipping are provided in 10 CFR 71.87, and include the licensee determining that the package is proper for the contents to be shipped, the package is in unimpaired conditions, each closure device of the packaging is properly installed and secured and free of defects, and any pressure relief device is operable and set in accordance with procedures.

The Federal rule at 10 CFR 71.88 provides requirements for air transportation of plutonium. Plutonium must not be transported by air unless it is contained in a medical device, and it meets the specified quantity limits and specific activity limits.

Opening instructions are provided in 10 CFR 71.89. The licensee must ensure that any special instructions on opening a package are provided to the consignee.

Recordkeeping requirements are described in 10 CFR 71.91 and include maintenance of records for three years after shipment, of each shipment of licensed material that is not exempt. Records must include identification of the packaging by model number and serial number, volume and identification of coolant, type and quantity of licensed material in each package, and date of shipment. The licensee must make all records required available to the Department for inspection. Records are only valid if they are stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

The Federal rule at 10 CFR 71.93 provides requirements for inspection and tests. The licensee is required to allow the Department to inspect licensed material, packaging, premises, and facilities in which the licensed material is used, tested, stored or shipped. The licensee must permit the Department to perform any tests that Department deems necessary.

Reporting requirements are contained in 10 CFR 71.95. A licensee must report to the Department of instances in which there was a significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging, details of any defects with safety significance, or instances

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when conditions for approval of the CoC were not observed during shipment. If instances when conditions for approval of the CoC were not followed, a written report is required within 60 days which includes a narrative description of the event; any major occurrences during the event, including all component or system failures; dates and approximate times of occurrence; an assessment of the safety consequences and implications; and reference to any similar event.

The Federal rule at 10 CFR 71.97 requires advance notification of a shipment of irradiated reactor fuel and nuclear waste to the governor, or designee, of a state through which it passes. Advanced notification is also required for other licensed material meeting certain conditions including quantity specifications. The notifications must be delivered by mail and postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is to occur, and must contain the point of origin of the shipment, contact information of the shipper and receiver, and a point of contact for current shipment information.

Violations and criminal penalties, at 10 CFR 71.99 and 100 are the same as discussed above in the Summary of Subchapter 50.

Quality assurance requirements are at 10 CFR 71.101 through 71.105, as are the requirements for a quality assurance organization and a quality assurance program. Handling, storage and shipping control, inspections, tests and operating status tests on packaging components, procedures to prevent the use of nonconforming materials, parts or components, a statement concerning the licensee's corrective action policy, quality assurance records and audits are all included in the Federal regulations at 10 CFR 71.127 through 137. Also proposed for incorporation is Appendix A, which includes the determination of A_1 and A_2 values, referenced in many of the previously discussed regulations.

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The Federal regulations found at 10 CFR 71.0(d), 71.6, 71.14(b), 71.19, 71.31 through 71.45, 71.51, 71.55 through 71.77, 71.101(c)2, (d) and (e), and 71.107 through 71.125 relate to programs or activities that cannot be relinquished to the State by the NRC and are, therefore, remaining under Federal jurisdiction.

Subchapter 62: Exemptions and Continued NRC Regulatory Authority in Agreement States and in Offshore Waters under Section 274

This proposed new subchapter incorporates by reference only the portions of the Federal regulation at 10 CFR Part 150 that relate to reciprocity. Other sections that are proposed to be incorporated, such as definitions, are an integral part of the requirements of reciprocity. The proposed new subchapter also defines activities in the State and in offshore waters, over which the NRC retains authority.

The proposed new subchapter applies to all persons in New Jersey and gives notice to anyone who knowingly provides to any licensee, applicant, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's or applicant's activities, that they may be individually subject to enforcement actions.

Federal regulations incorporated by reference include definitions of “Act,” “agreement state,” “byproduct material,” “foreign obligations,” “government agency,” “offshore waters,” “person,” “production facility,” “source material,” “special nuclear material,” “state,” “uranium enrichment facility” and “utilization facility.”

For the purpose of determining if the requirements in this subchapter are applicable, the Federal regulations at 10 CFR 150.11 provide the formula for determining whether a critical mass

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exists. The NRC will retain jurisdiction over special nuclear material sufficient to form a critical mass.

The Federal rule at 10 CFR 150.20, would grant a general license to individuals that are licensed in other Agreement States, or licensed by the NRC (in non-agreement states or areas of exclusive Federal jurisdiction), which would allow them to work in New Jersey at temporary job sites without getting a specific license from New Jersey. The licensee's activities would be limited to 180 days. Licensees could include those using source, special nuclear material in quantities not sufficient to form a critical mass, and byproduct material. Reciprocity for diffuse NARM licensees is addressed in proposed amended Subchapter 4.

The exception is for those specific Agreement State licenses that limit the authorized activities to a specific installation or location. The rule requires notice to the Department, submission of the appropriate form and a copy of the specific license, and payment of the fee specified at proposed new N.J.A.C. 7:28-64.

Changes in temporary work locations within New Jersey, radioactive material, or work activities require an amended NRC Form 241 or State equivalent and prior approval from the Department. Transfer or disposal of radioactive materials possessed or used under the general license is prohibited unless the radioactive material is transferred to a person who is specifically licensed to receive the material. The general license issued in this section can not be used for a period of more than 180 days in any calendar year. The exception to this is for activities in offshore waters authorized by this section for an unlimited period of time; however, the NRC retains jurisdiction over offshore waters. All the terms and conditions of the specific license issued by an Agreement State shall be complied with, except any condition that is contrary to the requirements of 10 CFR 150.20

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The Federal rules at 10 CFR 150.30 discuss violations, which are the same as at 10 CFR Part 50, discussed above.

The Department and the Commission do not propose to incorporate the provisions of 10 CFR 150.7, 150.10, 150.14 through 150.17a, 150.19, 150.20, 150.21, 150.31 and 150.32. These rules relate to programs that cannot be relinquished to the State by the NRC and/or are remaining under Federal jurisdiction.

Subchapter 63: Licenses for Industrial Radiography Using Sealed Sources and Radiation Safety Requirements for such Industrial Radiography Operations

Proposed new Subchapter 63 prescribes requirements for the issuance of licenses for the use of sealed sources containing byproduct material and radiation safety requirements for persons using these sealed sources in industrial radiography. The provisions and requirements of this subchapter are in addition to, and not in substitution for, other requirements of this subchapter. This subchapter does not apply to medical uses of byproduct material. This proposed subchapter incorporates by reference the Federal regulations found at 10 CFR Part 34.

Federal regulations at 10 CFR 34.3, proposed to be incorporated by reference, include definitions of “ALARA,” “annual refresher safety training,” “associated equipment,” “Becquerel,” “certifying entity,” “collimator,” “control (drive) cable,” “control drive mechanism,” “control tube,” “exposure head,” “field station,” “gray,” “guide tube (projection sheath),” “hands-on experience,” “independent certifying organization,” “industrial radiography (radiography),” “lay-barge radiography,” “offshore platform radiography,” “permanent radiographic installation,” “practical examination,” “radiation safety officer for industrial radiography,” “radiographer,” “radiographer’s assistant,” “radiographer certification,” “radiographic exposure device,” “radiographic operations,”

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“S-tube,” “sealed source,” “shielded position,” “Sievert,” “source assembly,” “source changer,” “storage area,” “storage container,” “temporary jobsite” and “underwater radiography.”

In order to apply for a specific license for use of sealed sources in industrial radiography, an applicant must submit a form that is available from the Department at the address and/or website listed at N.J.A.C. 7:28-1.5.

Minimum requirements for an application for a specific license for industrial radiography are in 10 CFR 34.13 and include the general requirements for a byproduct material license, specific training, training certifications, specific procedures, program of inspections, and organizational structure as it applies to radiation safety, and identification and qualifications of the radiation safety officer. Also to be included in the application are specific leak testing procedures when depleted uranium is used as shielding for the sealed sources. If appropriate, “in-house” calibration program and permanent radiographic installations will be described. Record storage information will also be included.

The Federal regulations at 10 CFR 34.20 describe the minimum criteria used in industrial radiography operations. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet appropriate American National Standards Institute requirements. An applicant or licensee may submit an engineering analysis to demonstrate the applicability of previously performed testing on similar radiography equipment components which the Department may or may not find acceptable. In addition, each radiographic exposure devices, source changer, source assembly and sealed source has specific labeling requirements, comply with 10 CFR Part 71 requirements when Type B transport containers are used, and allow no modifications that would compromise safety. Radiographic exposure devices, source assemblies,

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and associated equipment that allow the source to be moved out of the device for radiographic operations, and source changers have additional requirements. They include requirements for integrity of mechanisms, automatic source security mechanisms, safety plugs, labeling, guide tube integrity, guide tube use, guide tube stops, and alternate endurance testing.

The maximum exposure rate limits, 200 mrem per hour at any exterior surface and 10 mrem per hour at one meter from any exterior surface, for storage containers and source changers are stated in 10 CFR 34.21.

The Federal rule at 10 CFR 34.23 describes the required locking mechanism and locking procedures for the sealed sources in radiographic exposure devices, storage containers and source changers to prevent unauthorized or accidental removal of the sealed source from its shielded position.

Radiation survey instruments are required to survey the areas where these devices are used and stored. Requirements for instrument measurement capability, calibration and record keeping are in the Federal regulations at 10 CFR 34.25.

The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source is described in 10 CFR 34.27. The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Department, NRC, or other Agreement State. Leak testing for sealed sources not in storage must be performed at intervals not to exceed six months, by an approved individual, and using an approved method that can detect 0.005 microcuries. The licensee shall maintain records of the leak tests in accordance with this subchapter. If the wipe sample of the leak test reveals greater than 0.005 microcuries, the licensee must remove the equipment from service, decontaminate and repair

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it, or dispose of the source. A report must be filed with the Department at the address in N.J.A.C.

7:28-1.5(a) within five days.

Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination. Leak testing for these shields not in storage must be performed at intervals not to exceed twelve months, by an approved individual, and using an approved method that can detect 0.005 microcuries. Should such testing reveal the presence of 0.005 microcuries or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. A record of the DU leak-test must be made in accordance with this subchapter.

Under Federal regulation 10 CFR 34.29, each licensee shall conduct a quarterly physical inventory to account for all sealed sources and for devices containing depleted uranium received and possessed under this license. The licensee shall maintain records of the quarterly inventory in accordance with this subchapter.

In accordance with 10 CFR 34.31, the licensee shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used. If equipment problems are found, the equipment must be removed from service until repaired. This equipment shall have written procedures for inspection and routine maintenance at intervals not to exceed 3 months or before the first use. If equipment problems are found, the equipment must be removed from service until repaired. The inspection and maintenance for Type B packages must assure

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shipping and maintenance in accordance with the certificate of compliance or other approval.

Records of equipment problems and of any maintenance performed must be made in accordance with this subchapter.

Permanent radiographic installations have specific requirements found in 10 CFR 34.33. They include that each personnel access entrance to the high radiation area must have either an entrance control of the type described in N.J.A.C. 7:28-6 that reduces the radiation level upon entry into the area, or both conspicuous visible and audible warning signals to warn of the presence of radiation. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. Entrance control devices must be tested monthly. If this equipment is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee implements the continuous surveillance requirements of this subchapter and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarm must be maintained in accordance with this subchapter.

A source changer or a container to store licensed material may not be used unless labeled per the requirements in 10 CFR 34.35. Transport of licensed material must be in accordance with proposed new Subchapter 61. Storage and transport of locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. Storage must be done in a manner that will minimize danger from explosion or fire.

The Federal regulation 10 CFR 34.41 states that whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an assistant as defined in this subchapter. All

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radiographic operations conducted at locations of use must be conducted in a permanent radiographic installation, unless specifically authorized by the Department. A licensee may conduct lay-barge, offshore platform, or underwater radiography only with NRC, Agreement State, or Department-approved procedures.

The Radiation Safety Officer (RSO) ensures that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements and must comply with the requirement of 10 CFR 34.42. The RSO must meet the qualifications, training, and experience in this subchapter. The RSO will establish and oversee all ALARA procedures required by N.J.A.C. 7:28-6; oversee and approve the training program for radiographic personnel; ensure that required radiation surveys and leak tests are performed and documented; ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by this subchapter; and ensure that operations are conducted safely and to assume control for instituting corrective actions, including stopping of operations when necessary.

The Federal regulations at 10 CFR 34.43 require that each radiographer receive training in the subjects of this section, in addition to a minimum of two months of on-the-job training, and is certified through a radiographer certification program. The radiographer must also receive copies of and instruction in the requirements described in this subchapter, applicable regulations in proposed new N.J.A.C. 7:28-6, 50, and 51, and 61, and the requirements in the license, including the operating and emergency procedures. The radiographer shall also be able the use and understand the use of the licensee's radiographic exposure devices, sealed sources, associated

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equipment and radiation survey instrumentation. A written test will document this knowledge.

Refresher training will be provided at intervals not to exceed 12 months.

The RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to include observation of one's performance during an actual industrial radiographic operation, at intervals not to exceed six months; and if one has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements in this subchapter by a practical examination before the individual can next participate in a radiographic operation. The Department may consider alternatives in those situations where the individual serves as both radiographer and RSO, including not requiring an inspection program. The licensee shall maintain records of the above training. Subjects and instruments to be included in the above training can also be found in 10 CFR 34.43.

The list of operating and emergency procedures required in 10 CFR 34.45 includes appropriate handling and use of licensed sealed sources and radiographic exposure devices; methods and occasions for conducting radiation surveys; methods for controlling access to radiographic areas; methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources; personnel monitoring and the use of personnel monitoring equipment; transporting sealed sources to field locations; inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers; response to elevated personnel monitoring readout; identifying and reporting defects and noncompliance; notification of proper persons in the event of an accident; minimizing

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exposure of persons in the event of an accident; source recovery; and maintenance of records. The licensee shall maintain copies of current operating and emergency procedures.

When a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys, 10 CFR 34.46 requires the radiographer to be present, be available for assistance, and observe the assistant's performance.

Federal regulations in 10 CFR 34.47 require that personnel wear a direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter during radiography operations. Each personnel dosimeter must be assigned to and worn only by one individual. Dosimeters must be processed and evaluated by an approved processor and exchanged at periods not to exceed one month. Direct reading dosimeters must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with this subchapter. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with this subchapter. If an individual's pocket chamber is found to be off-scale or reads greater than 200 millirems, and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation exposure has been made. If a personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter is provided and the exposure is calculated for the time period from issuance to the loss or damage. The records of any calculated exposure and dosimetry reports must be maintained in accordance with this subchapter.

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Each alarm ratemeter must be checked to ensure that the alarm sounds before using at the start of each shift; be set to give an alarm signal at a preset dose rate of 500 millirems per hour; require special means to change the preset alarm function; and be calibrated at periods not to exceed 12 months. Alarm ratemeter calibration records must be kept in accordance with this subchapter.

Radiation surveys must be performed in accordance with 10 CFR 34.49. A calibrated and operable radiation survey instrument that meets the requirements of this subchapter must be used on the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube, and any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area. These surveys ensure that the sealed source is in its shielded position. Records must be maintained in accordance with this proposed subchapter.

The Federal rule at 10 CFR 34.51 requires one radiographer to maintain continuous direct visual surveillance of the radiographic operation to protect against unauthorized entry into a high radiation area, except at permanent radiographic installations.

Under the Federal rule at 10 CFR 34.53, all areas in which industrial radiography is being performed must be conspicuously posted as required by N.J.A.C. 7:28-6. There are no exceptions permitted.

In accordance with 10 CFR 32.61, each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Department, or until the Department terminates the license.

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Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using DU for shielding and retain each record for three years after it is made. Data to be included in the records are in 10 CFR 34.63.

Under 10 CFR 34.65, each licensee shall maintain records of the calibrations of radiation survey instruments that are required under this subchapter and retain each record for three years after it is made.

The Federal rule at 10 CFR 34.67 requires three year retention of leak test results for sealed sources and for devices containing DU.

Records of quarterly inventory, as required under 10 CFR 34.29, of sealed sources and of devices containing depleted uranium must be retained for three years. The date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate must be included in the records.

Utilization logs for sealed sources are described in 10 CFR 34.71. They are to include a description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located; the identity and signature of the radiographer writing the log; and the location where the used and dates of use. Logs are to be maintained for three years.

Records of equipment problems found in daily checks, and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source

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changers, and survey instruments shall be retained for three years. Under 10 CFR 34.73, the record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

Each licensee shall maintain records of alarm system and entrance control device tests for three years, according to 10 CFR 34.75.

Records of training of each radiographer and each radiographer's assistant and records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant must be kept for three years. The items to be kept in each record are in 10 CFR 34.79 and include copies of written tests, dates of examinations, and names of instructors and attendees.

The Federal regulations at 10 CFR 34.81 require each licensee to maintain a copy of current operating and emergency procedures until the Department terminates the license. Superseded material must be retained for three years after the change is made.

Records to be maintained according to 10 CFR 34.83 include direct reading dosimeter readings and yearly operability checks and records of alarm ratemeter calibrations for three years after the record is made. Personnel dosimeter results received from the accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor; and records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters must be kept until the Department terminates the license.

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Records of each exposure device survey conducted before the device is placed in storage, if that survey is the last one performed in the workday, must be maintained for three years according to 10 CFR 34.85.

Each record required by this proposed subchapter must be legible throughout the specified retention period according to 10 CFR 34.87. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Under 10 CFR 34.89, copies of records required by this subchapter must be located at the location specified in this subchapter. The following shall be kept at each location of radiographic use: the radioactive material license; copies of Subchapters 6, 50, and 63; utilization records for each device at that location; records of equipment problems identified in daily checks of equipment; records of alarm system and entrance control checks, if applicable; records of direct reading dosimeters; operating and emergency procedures; evidence of the latest calibration of the radiation survey instruments in use at the site; evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters; latest survey records; and the shipping papers for the transportation of radioactive materials.

Under the Federal rule at 10 CFR 34.101, in addition to the reporting requirements specified in N.J.A.C. 7:28-51 and this subchapter, each licensee shall send a written report to the Department within 30 days of an unintentional disconnection of the source assembly from the control cable; an inability to retract the source assembly to its fully shielded position and secure it in this position; or a failure of any component (critical to safe operation of the device) to properly perform its intended function. Each report of these occurrences or of overexposure shall include a description of the equipment problem; cause of each incident, if known; name of the manufacturer and model number

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of equipment involved in the incident; place, date, and time of the incident; actions taken to establish normal operations; corrective actions taken or planned to prevent recurrence; and qualifications of personnel involved in the incident. Any licensee conducting radiographic operations or storing radioactive material at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the Department prior to exceeding the 180 days.

The Federal rule at 10 CFR Part 34 also contains provisions relating to violations, criminal penalties and interpretation of the regulations, which are the same as discussed in the Summary of Subchapter 50, above.

Requirements for an independent certifying organization for radiographer certification are in Appendix A of 10 CFR Part 34. Requirements for a certification program and for written examinations are also in this appendix.

Several regulatory cross references in the incorporated Federal rules are proposed to be changed so that they will refer to the Department's regulations, rather than the Federal regulations. Except when specifically noted, any reference in the incorporated rules to the NRC shall mean the Department, and, except in those instances where Federal jurisdiction is retained by the NRC, all required reports shall be forwarded to the Department at the address provided in N.J.A.C. 7:28-1.5(a), rather than to the NRC. Additionally, except when specifically noted, all communication will be with the Department as discussed in N.J.A.C. 7:28-1.5, rather than with the NRC.

Subchapter 64: Radioactive Materials License Fees

The Department is proposing a new Subchapter 64, "Radioactive Materials License Fees," which contains the fee schedule for radioactive material licensees. The existing fee schedule at N.J.A.C. 7:28-4 is proposed to be deleted. The proposed fees will enable the Department to recover

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the cost of administering the Agreement State program. The fees will apply once New Jersey becomes an Agreement State, in accordance with the schedules at proposed N.J.A.C. 7:64.3 and 64.4, discussed below.

As set forth in proposed new N.J.A.C. 7:28-64.1, the proposed fees will be effective on the operative date of the rules. The Department issues invoices for current NARM licensees every July. When the Agreement is signed, the NRC will transfer its licenses to New Jersey and current NARM licenses will become either diffuse NARM licenses or byproduct material licenses. If a current Department licensee paid the annual fee, no fee adjustments will be made until July of the next year. For the NRC licenses that are transferred to New Jersey, the Department will issue an invoice that is prorated to July of the next year following the fee schedule in N.J.A.C. 7:28-64.2. For example, if New Jersey becomes an Agreement State in October, and a licensee holds both a Department and NRC license, the Department will issue the licensee an invoice for the NRC material that is prorated to nine months. The following July, the Department will issue an annual fee for all material according to the fee schedule in N.J.A.C. 7:28-64.2.

To make the transition for NRC licensees seamless, the Department proposes to incorporate by reference at proposed new N.J.A.C. 7:28-64.2 the categories identified in the table in 10 CFR 171.16 entitled "Schedule of materials annual fees and fees for government agencies licensed by NRC." The Department does not propose to incorporate the fees in the Federal table, but proposes its own fees for each category (Tables 1 and 2). The Department proposes formulas at N.J.A.C. 7:28-64.3 and 4 to calculate a fee for any category that is added to the table at 10 CFR 171.16 in the future, for which a fee is not now proposed. By this mechanism, the Department intends that it will charge a fee for every category for which the NRC would charge a fee. Numerous categories are reserved because the Department will not regulate the licensees of those

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categories, such as large quantities of special nuclear material. The Economic Impact below describes the fees in detail.

The Department proposes requirements for the application fee in N.J.A.C. 7:28-64.3.

Although the NRC charges an application fee and an annual fee, the Department proposes to charge just an application fee for the first year. Annual fees are discussed in N.J.A.C. 7:28-64.4 and reference the fee tables in N.J.A.C. 7:28-64.2. If a licensee has more than one license category, the full fee will be charged for each category. If a new category is added by the NRC that the Department will assume authority over, the new fee will be determined by the proposed formula. For purposes of calculating the fee for a new category, the Department proposes to incorporate by reference the fee provisions at 10 CFR Parts 170 and 171. Otherwise, the NRC fee provisions do not apply. An application fee is not refundable, unless the Department determines that a license is not required. Similarly, an annual fee is not refundable if a license is terminated.

The Department proposes N.J.A.C. 7:28-64.5 to assess a fee for inspection if there is a violation that could have implications regarding the worker or public dose limits at proposed Subchapter 6.

The Department proposes to charge fees for reciprocity applications, which fee will be one-half the fee listed in Tables 1 and 2 of N.J.A.C. 7:28-64.2. Without payment of the appropriate fee, the Department will not process the application. The Department will not issue reciprocity general licenses for periods of greater than 180 days. Instead, a specific license will be required.

Additional use sites are addressed in N.J.A.C. 7:28-64.7. An additional use site is not contiguous or adjacent to the main site requiring a license, but is operated by the same person, has the same license category or categories, and has one radiation safety officer and radiation safety

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committee. The Department must also be reasonably satisfied that the applicant will adequately control radioactive material at all sites listed in the application.

Non-profit educational institutions will be charged 25 percent of the annual fees specified in Tables 1 and 2 of N.J.A.C. 7:28-64.2 for each additional use site. Medical private practices will be charged 50 percent of the annual fees specified in Tables 1 and 2 of N.J.A.C. 7:28-64.2 for each additional use site. Medical private practices are limited to only three additional use sites per license.

The Department proposes to charge fees for certain license amendments as described in Table 2 of N.J.A.C. 7:28-64.2.

In accordance with proposed N.J.A.C. 7:28-64.9, the Department will not process an application without the appropriate fee. This section also authorizes the Department to take appropriate enforcement actions if renewal fees are not paid.

The proposed fees in Tables 1 and 2 of N.J.A.C. 7:28-64.2 are in 2008 dollars. The Department proposes that the fees will adjust annually, based upon the Consumer Price Index, all urban consumers, U.S. city average (CPI-U). The U.S. Department of Labor, Bureau of Labor Statistics, publishes the data monthly.

The baseline for the calculation is proposed to be the CPI-U for the period ending May 31, 2008. The CPI-U for 2008 will be inserted into the rule text when the rules are adopted, inasmuch as the May 31, 2008 figure is not yet available. The data for the period ending in May is customarily released in mid-June, making it the most up to date figure available at the time the annual fee is calculated in July.

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The annual fee the fee in Table 1 or 2, as applicable, increased by the percentage increase in the CPI-U from the 2008 figure. If after 2008 the inflation factor is negative, the fees will not decrease, but will remain at the same level as the previous year.

Social Impact

The Department and the Commission anticipate that the proposed new and amended rules will have a positive social impact. As discussed above, the Department and the Commission are proposing the within rules in order to become an Agreement State. If New Jersey does not become an Agreement State, the NRC will assume authority over all discrete naturally occurring and accelerator-produced radioactive material pursuant to Section 651(e) of the Energy Policy Act's expanded definition of byproduct material by 2009. This would result in higher fees for almost all facilities that currently have Department licenses for NARM. By becoming an Agreement State, New Jersey will continue its ability to regulate all NARM, and acquire the authority to regulate source, certain special nuclear and byproduct materials, which are currently regulated by the NRC.

The regulated community in New Jersey consists of Department and NRC licensed facilities and the public. Currently there are 511 State licensees and 492 NRC licensees. Since some NRC licensees are already State licensees, the combined total number of licensees will be approximately 700. These licensees are medical facilities, universities, research facilities, lead paint analyzers, pharmaceutical companies, and other industries that use radioactive materials.

The Department and the Commission anticipate that there will be a positive impact to the majority of licensees from the proposed new and amended rules. When New Jersey becomes an Agreement State, the State will have authority to regulate and enforce rules for all radioactive materials. Under the existing regulatory structure, whether the NRC or the Department regulates a licensee depends on the type of radioactive material. Streamlining of licensing and inspections will

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have a positive social impact on the licensees. In addition, there will be a positive social impact because the regulated community and the public will not be transferred between State and NRC regulators when they have a question related to radioactive materials that are subject to the existing dual regulation. The public perceives this dual authority as a weakness. The proposed rules are anticipated to increase the public's confidence in the ability of the Department, as sole regulator, to protect their health and safety.

If New Jersey does not become an Agreement State and is forced to relinquish its authority over NARM (approximately 500 licensees), the Department would lose most of its capability to respond to radiological incidents within the State because there would likely be a reduction in force due to lack of fees to support the trained radiological inspectors. These inspectors in the Department's Radioactive Materials Section are responsible under the existing regulatory system for responding to and investigating incidents involving non-nuclear power plant emergencies. There are approximately seven radiation-related incidents per month that require the Department to respond. If New Jersey does not become an Agreement State, and the NRC becomes the primary regulator of byproduct material which now encompasses discrete NARM., the NRC would be primarily responsible for responding to and investigating incidents that are not diffuse NARM responses. Currently, the majority of incidents are responses to source and byproduct material (including discrete NARM) rather than diffuse NARM. At present the NRC's closest office is in King of Prussia, Pennsylvania, which could result in a response that is less rapid than the Department's under the existing rules, if the NRC did not open a closer or more accessible office. While the Department would certainly respond, there would not be the capability available, in the form of trained radiological responders, that the Department has at present. Without licensing fees

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(which would be, instead, paid to the NRC), the Department would not have funds to support the salaries of trained responders.

A few licensees have questioned whether the Department is able to maintain oversight of all radioactive materials in the State. In order for a state to become an Agreement State, the NRC must be confident that the state agency's staff is fully trained and has the proper credentials. A period of joint inspections is required, as well as many hours of NRC-approved mandatory training of Department employees. Accordingly, once the NRC agrees to New Jersey's becoming an Agreement State, the public can be sure that the Department is qualified to undertake the tasks.

The proposed rules would also have a positive social impact on the public. The proposed new and amended rules require updated methods for determining the dose a person receives as a result of exposure to radiation. The Department and the Commission anticipate that the proposed methods will also have a positive social impact.

Humans are continuously exposed to background radiation from many sources, including cosmic radiation, terrestrial radiation from naturally occurring radioactive materials, food and water ingestion, radon, and medical exposures (such as x-rays, nuclear medicine, CT scans). The different types of radiation to which humans are exposed include alpha and beta particles, gamma rays and, to a lesser extent, neutrons, which result in differing amounts of energy being imparted to the body. In addition, the specific radionuclide that is emitting the radiation may be incorporated differently into the body (or not at all), thereby affecting different portions of the body in a different way.

A "dose equivalent" is the measure of the radiation that an exposed person receives. A dose equivalent is a common scale for doses from a variety of radiation sources. The millirem is the special unit of dose equivalent. A millirem is a measure of radiation dose that takes into account the amount of energy absorbed by the body from the radionuclide and its effectiveness in causing

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detrimental biological effects. A typical person incurs a radiation dose of about 360 millirem per year (mrem/y) from naturally occurring and man-made radioactivity. The general public dose limit is 100 mrem/y. Federal and State laws allow radiation workers to incur up to 5,000 mrem/y.

An accurate accounting of radiation doses ensures that they are kept within regulatory limits, which ensures that cancer risks remain at acceptable levels. The proposed new and amended rules require updated methods for determining dose, both internal and external. The proposed rules also include new reporting requirements, survey and record keeping requirements, and source control, as well as requirements that doses be kept “as low as reasonably achievable.” Accordingly, the proposed new and amended rules will allow both the public and occupationally exposed individuals to have more accurate information regarding their doses from licensed activities.

~~The Department proposes to adjust the fees in Tables 1 and 2~~ Economic Impact

Fees

The Department is proposing new fees so that it has the resources to implement a fully-staffed radioactive materials program. The Radiation Protection Act at N.J.S.A. 26:2D-9(*I*) authorizes the Department to establish and charge fees for the services it performs. The calculation of fees may be based on the actual or projected expense to be incurred by the Department in the performance of services. The proposed fee schedule at N.J.A.C. 7:28-64.2 is based on a cost analysis that takes into account the number and types of licensees and the amount of Department staff time and resources necessary to oversee these licensees and to engage in emergency preparedness activities. The current staffing level of the radioactive materials section is not adequate to absorb an estimated 200 to 300 more licensees, the number of additional licensees that would result from New Jersey’s becoming an Agreement State.

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To determine the number of full time equivalent (FTE) positions required for a fully staffed Radioactive Materials program, the Department used time estimates from the NRC, other Agreement States, and its own internal time studies. The other Agreement States included Pennsylvania, Texas, Wisconsin, Louisiana, Minnesota, Ohio, New Mexico, and Arizona. The amount of hours available for each FTE was calculated by taking into account holiday, vacation, sick, administrative, training, and meeting hours (Table 1). Tables 2 through 4, list the calculated FTEs for inspections, licensing, and regulation development. The Department's Radioactive Materials section currently employs seven FTEs; however, the Department has determined that it needs an additional six FTEs to run a fully staffed Agreement State program. The Department believes that the additional staff costs and the increase in operating costs justify the proposed fees.

Table 1: Hours per FTE

Staff Hours/year = 52 weeks x 5 days/week x 7 hours/day = 1820 hours/year

Description of Leave	Hours
13 holidays	-91
18 Vacation days	-126
10 days training	-70
Meetings (20 days)	-140
7 sick days	-49
3 Administrative leave days	-21
Hours/year for each FTE	1323

Table 2: Inspection Activities

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Inspection Activities	Average Hours Per	Average Activities	Average Total Hours
Activity		per Year	per Year
Core Inspection			
(Preparation and			
Documentation)	8	223	1784
Inspection Travel	3	223	669
Core Inspections	4	223	892
Normal Enforcement			
Activities	3	80	240
Escalated			
Enforcement			
Activities	24	15	360
Reactive Inspection			
(Preparation and			
Documentation)	8	16	128
Reactive Inspections	8	15	120
Allegation Follow-up	8	10	80
Allegation Follow-up			
Travel	6	10	60
Allegation Follow-up			
(Preparation and			
Documentation)	16	10	160
Other Routine Activities			

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Prelicensing

Inspections	8	20	160
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Increased Controls

Inspections	14	30	420
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Decommissioning

(Site visits, telephone
calls, review of

submittals)	10	60	600
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Total			5673
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$5673 \div 1323 \text{ hours per FTE} = \mathbf{4.3 \text{ FTE}}$

Table 3: Licensing Activities

Licensing Activities	Average Hours per Activity	Average Activities per Year	Average Total Hours per year
GENERAL LICENSE			
Registration	1.5	500	750
Tracking	0.5	500	250
Subtotal			1000
SPECIFIC LICENSE			
New	40	60	2400
Renewal	20	70	1400
Amendment	5	610	3050

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Termination	35	30	1050
Subtotal			7900
Total			8900

8900 hours ÷ 1323 hours per FTE = **6.75 FTE**

Table 4: Other Activities

Other Activities	Average Hours per Activity	Average Activities per Year	Average Total Hours per Year
Regulations Review and Comment	26	40	1040
Response to Incidents	24	80	1920
Total			2960

2960 hours ÷ 1323 hours per FTE = **2.2 FTE**

Grand Total FTE = 13.25

As a result of the anticipated additional licensees, the Department anticipates an increase in costs from the existing level of \$1,072,422 to \$2,413,333, which is more than a two-fold increase. Salaries are projected to be \$1,593,333 with an operating budget of \$820,000. A two-fold increase in fees from what the Department currently collects for the existing program is being proposed to cover the costs of a fully staffed Radioactive Materials Section, including an increase of six FTE. The expected amount of revenue that will be collected is estimated to be \$2,500,000 for the first full

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year of implementing the Agreement State program. The first year revenue will be less because of the way the Department and the Commission propose to adjust the fees based on when the Agreement is signed. This was discussed in the Summary of Subchapter 64.

The additional titles will perform inspections, review applications and amendment requests, respond to licensee inquiries, process reciprocity applications, calibrate instrumentation, collect samples upon decommissioning, inventory radioactive material sources, and work on rulemaking activities to keep current with the NRC proposed amendments.

Table 5 presents a comparison of the number of NRC and New Jersey licenses. The total projection of annual revenue is difficult to predict because of the overlap between NRC and Department licensees. For example, for Medical Private Practice, NRC has 166 licensees in New Jersey, and the Department has 272. When the State assumes responsibility for source, certain special nuclear material, and byproduct material (which will include discrete NARM) by becoming an Agreement State, these licenses would be combined under one license. If some of the NRC's licensees do not hold State licenses, then the number of State licensees would increase under the Agreement State regulatory framework in those categories.

Table 5 shows that there are many license categories where there are no New Jersey licenses at present because New Jersey does not yet have the authority to regulate these categories. All of these license categories will be added to the number of State licensees.

If the larger number of NRC or State licenses is assumed where there is overlap, it is predicted that the Department will have a total of approximately 729 licensees after it becomes an Agreement State. The estimated projected revenue is \$2,500,000. The projected salary costs that would result from the increase in State-issued licenses are presented in Table 6. The salary calculations include fringe benefits and indirect costs associated with the program. Fringe benefits

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include the Department's charges for pension, health benefits including prescription drug and dental care program, workers compensation temporary disability insurance, unused sick leave and the Federal Insurance Contributions Act (FICA) which is a United States payroll imposed by the Federal government on both employees and employers to fund Social Security and Medicare. Indirect costs are costs associated with the Offices of the Commissioner, the Division of Financial Management and General Services, and the Division of Personnel. The projected budget is presented in Table 7.

Table 5: Number of NRC and NJ licensees

Number of NRC Licenses	Number of NJ Licenses	Program Code Title
3	3	Academic Type A Broad
3	2	Medical institution Broad
41	86	Medical institution -QMP required
4		Medical Institution-QMP not required
24		Medical Private Practice - QMP required
166	272	Medical Private Practice-QMP not required
3	8	Mobile Nuclear Med Service
26		High Dose Rate Remote Afterloader

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1		Mobile HDR Remote Afterloader
3		Mobile Therapy
6		Veterinary Non-human
1		In Vitro Testing Laboratory
2	7	Nuclear Pharmacies
16		Measuring Systems Fixed gauges
		Measuring Systems Portable
64	2	Gauges
		Measuring Systems Analytical
2	83	Instruments
5		Measuring Systems – GC
6	1	Measuring Systems Other
		Manufacturing & Distribution Type
1	1	A Broad
		Manufacturing & Distribution Type
	1	C Broad
11		M&D Other
		Instrument Calibration Service
		Only- Source less than less than 100
1		curies
		Instrument Calibration Service
		Only- Source greater than 100
2		curies

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3	2	Other Services
		General License Distribution -
3		32.51
		Industrial Radiography Temporary
5		Job Site
		Irradiators Self Shielded less than
5		10000 curies
		Irradiators Other Less than 10000
2		curies
		Irradiators Self Shielded Greater
2		than 10000 Curies
		Irradiators other greater than 10000
3		curies
		Research & Development Type A
11		Broad
2		R&D Type B Broad
56	2	R&D Other
		Byproduct Material Possession
1	1	Only - Permanent Shutdown
		Byproduct Material Standby - No
1		Operations
		Source Material Other Less than
1		150 Kgs

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		Source Material Other Greater than
2		150 Kgs
		SNM Plutonium - Unsealed less
1		than a critical mass
		SNM Plutonium - Sealed Source
1		Less than a critical mass
		Pacemaker Byproduct and/or SNM
2		- Medical Institution
		Water Treatment Systems - Public
	15	Water Supplies
		Water Treatment Systems - Non-
	25	Transient Non Community Systems
492	511	Total

Table 6: Projected Salary Costs

Job	Percent of		
	Work Time		
Description	Spent on		
	Agreement		
	State Duties	Salary	Salary (\$)
Supervisor	100	105,000	105,000
Inspector	100	95,000	95,000

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Inspector	100	66,000	66,000
Inspector	100	60,000	60,000
Inspector	100	50,000	50,000
Inspector	100	50,000	50,000
Admin Support	100	60,000	60,000
Inspector	100	70,000	70,000
Inspector	100	70,000	70,000
Inspector	75	95,000	71,250
Inspector	100	105,000	105,000
Inspector	25	105,000	26,250
Admin Support	100	40,000	40,000

868,500

Decommissioning, Decontamination, Restoration

Inspector	30	105,000	31,500
Inspector	25	105,000	26,250
Inspector	25	95,000	23,750

Management/Administration

Manager	30	106,000	31,800
Admin Support	20	65,000	13,000
			126,300

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Total FTE	13.25	SALARY	994,800
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Fringe

Benefits at

33.15% per

dollar of

employee

salary	329,776
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Subtotal	1,324,576
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Indirect

Costs at

20.29% per

dollar of

employee

salary plus

fringe	268,757
--------	---------

Total	1,593,333
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Table 7: Projected Operating Costs

Agreement State Program	OPERATING COSTS
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Laboratory Costs	90,000
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Travel	75,000
Phone	20,000
Postage	15,000
Computers	25,000
Database	60,000
Vehicles	75,000
Maintenance	75,000
Equipment	80,000
Training	50,000
Professional Services	75,000
Legal	100,000
Other Assessments	80,000
TOTAL (\$)	820,000

Although the cost to administer the program is anticipated to increase because the number of licensees will also increase, most licensees will experience a decrease, or only a slight increase in fees. It is estimated that some licensees that have both NRC and State licenses under the existing rules may experience a 25 percent decrease in fees, since discrete naturally occurring and accelerator-produced radioactive material will be considered byproduct material and will be covered under one license category instead of two. Under the existing structure, both the Department and the NRC impose fees for such material. Under the proposed rules, the licensee would pay a fee only to the Department. The Department currently licenses approximately 85 licensees that do not have a NRC license. These include users of lead paint analyzers, community and non-community

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water treatment systems, users of radium-beryllium gauges, and other diffuse NARM users (mostly contaminated sites that are in the process of remediation).

The majority of these Department only licensees are lead paint analyzers, who have specific licenses for their operations. Under the proposed rules, based on the quantity of radioactive material in their devices, many of these licensees will be eligible for a general license, rather than the specific license required under the existing rules. Because the fee for a general license is less than the fee for the specific license that the lead paint analyzers now have, many of these licensees would experience a decrease in fees and administrative costs.

The Department issues licenses to approximately 15 water treatment systems. The proposed fees for Non-Transient Non-Community (NTNC) water systems and Community Water Systems (CWS) are based upon usage. The proposed licensee fees will decrease from \$2,500 to \$200.00 for the smallest NTNC water systems, and from \$2,500 to \$300.00 for the smallest CWS. The largest CWS's fees are proposed to remain the same (\$2,500).

The Department licenses three users of radium-beryllium gauges. The existing fee is either \$1,650 or \$2,500, depending on the quantity of radioactive material in the gauge. The proposed fee is \$2,025, regardless of the amount of material contained in the device. Some licensees will, therefore, incur an increase of \$475.00; however, others will see a decrease of \$375.00.

The Department currently licenses only two other diffuse NARM facilities and the proposed fee is the same as the existing fee of \$2,500.

Non-profit NRC licensees are currently exempted from application and annual licensing fees. In New Jersey, there are approximately 15 non-profit educational facilities with NRC licenses. Under 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

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Department does not have a mechanism to receive fee relief for those activities for which it does not charge fees or charges reduced fees. The Department is required to recover 100 percent of the cost of services it provides. Furthermore, if the Department were to continue the fee exemption for these facilities, it would have to recover its costs by charging the remaining licensees higher fees. Also, existing non-profit educational institutions are not now exempt from Department licensing fees. The range of proposed fees to educational institutions is from \$1,250 to \$22,000, with an average of \$5,000. The existing Department license fees for non-profit educational institutions are from \$1,250 to \$4,900.

The Department considered the added costs to non-profit educational institutions and is proposing relief in the form of 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. The Department is proposing to allow these additional use sites to operate at a reduced fee provided they meet all the requirements outlined in proposed N.J.A.C. 7:28-64.7.

Another consideration for comparing costs between the Department and the NRC is the way in which the NRC handles initial applicants. Currently, the NRC assesses an application fee as well as an annual fee. For example, a prospective NRC licensee seeking a license under the 3A category (as per 10 CFR Parts 170 and 171) would need to submit a \$12,000 application fee with the application. Then, depending on when the new license is approved, there may be additional annual fee costs. If the license is approved between October 1 and March 31 of the Federal fiscal year, then 50 percent of the annual fee is assessed. In the case listed above, an additional annual fee of \$14,400 would be assessed. Under the proposed regulatory framework, a prospective licensee in

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the same situation as described above would submit the application to the Department with the appropriate annual fee, which would be \$21,600 versus the NRC's combined application and annual fee of \$26,400.

Compliance Costs

Currently, licensees that have both an NRC and Department license have to provide information to both agencies in the form of license applications, renewals, amendments, reports, and responses to inspections. When New Jersey becomes an Agreement State, the compliance costs for these dual licensees will decrease because the time it takes for licensees to comply with the rules will decrease. For example, a licensee would renew only one license, rather than two, saving time in completing the paperwork. In addition, the Department proposes to extend the license renewal time from five years to 10 years. License renewal applications take a considerable effort on the part of licensees. This proposed amendment would have the effect of cutting this compliance cost in half.

Compliance costs for Department-only licenses can be divided into registrant and licensee compliance costs. Registrants will now have to abide by new occupational and individual member of the public dose limits and methods for determining dose. Because registrants deal with only external radiation, these costs are not anticipated to be significant because there will be no significant changes from how they are complying under the existing rules. Compliance costs for some Department-only licensees may increase due to new requirements in new proposed Subchapter 6. For example, PET production facilities will have to demonstrate compliance with the constraint on air emissions at 10 CFR 20.1101(d). Because these facilities can use publicly available modeling software from the US Environmental Protection Agency, this cost is expected to be minor.

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Other requirements, such as personnel monitoring, waste manifesting, recordkeeping, contamination control, and survey requirements are not materially different from the existing Department requirements, or are already being handled by consultants that abide by the NRC regulations. For example, in proposed new Subchapter 6 there is a requirement that all personnel dosimeters that require processing to determine the radiation dose must be processed and evaluated by a dosimetry processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology. There is no such requirement in the existing Department regulations; however, most dosimetry processors already comply with this requirement.

Most of the Department-only licensees are lead paint analyzers that use sealed sources. They are not required to comply with all of the proposed new rules. For example, proposed requirements pertaining to internal exposures, airborne emissions, control of effluents, disposal through domestic treatment works, or financial assurance would not be applicable to the lead paint analyzers.

Because of the proposed new financial assurance requirements at N.J.A.C. 7:28-4.16, and N.J.A.C. 7:28-12.12, a few Department-only licensees may have additional compliance costs. NRC licensees already must comply with the financial assurance requirements in proposed new N.J.A.C. 7:28-51, 58, 59, and 60. This includes NRC licensed non-profit educational institutions, because they are not exempt from the NRC's financial assurance requirements.

Under the proposed rules, Department-only licensees that possess NARM and diffuse NARM (those licensees that are not now regulated by the NRC) may incur costs associated with requirements for establishing a decommissioning funding plan. Proposed new N.J.A.C. 7:28-51 (incorporating 10 CFR 30.35) requires the licensees to post financial assurance so that the

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Department can be assured that there are sufficient funds for decommissioning at license termination. These financial assurance mechanisms are based on the quantity, the half-life, and form (sealed or unsealed) of the radioactive material. Typical amounts range from \$113,000 to over \$1 million, depending on the material that is being used. Although this financial assurance may be problematic for some licensees, the alternative could be even more costly to the citizens of the State, if they are required to use public funds to decommission sites. Also, if New Jersey does not become an Agreement State, the NRC will assume control over the discrete NARM licensees by 2009, in which case the licensees would, nevertheless, be required to comply with the financial assurance provisions of 10 CFR 30.35. In addition, the licensees would be required to pay the NRC licensing fees, which are 25 percent higher than the fees that the Department proposes.

Proposed diffuse NARM licensee financial assurance requirements are new and would be the same even if New Jersey did not become an Agreement State. One of the two NARM licensees in the State will be required to post financial assurance, because of the quantity of material it possesses. This will be an impact, but not a severe impact because this company is a large business. Furthermore, by the time the regulations go into effect, this license might be terminated because the licensee is in the process of remediating the site. The other diffuse NARM licensee does not have quantities above the threshold that requires financial assurance, so there will be no impact to that company. Community Water Systems that are licensed by the Department because they are treating for naturally occurring radium, uranium, and/or radon, are required only to provide a statement that funds will be available for decommissioning when necessary. Non-community water systems do not have quantities above the threshold that requires financial assurance.

The Department and the Commission did not incorporate the NRC's regulations on decommissioning (10 CFR 1401 through 1405) because the Department already has its own

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remediation standards for radioactive materials at existing N.J.A.C. 7:28-12. The existing requirements at Subchapter 12 include a dose criterion of 15 mrem/y, which is mandated by the Brownfields and Contaminated Site Remediation Act (N.J.S.A. 58:10B-12), and compliance with the State's ground and surface water standards.

Whether the Department's decommissioning requirements will have an economic impact on NRC licensees is not easily determined. On the surface, it appears that the Department's dose criterion of 15 mrem/y and compliance with ground and surface water standards are more stringent than the NRC's all pathways criterion of 25 mrem/y. The difference between the New Jersey remediation standard of 15 mrem/y and the NRC's all pathway 25 mrem/y standard will require those licensees with only NRC-issued licenses to meet the New Jersey standard when New Jersey becomes an Agreement State. Licensees with State-issued licenses must already meet the standard, which is in the existing rules. However, because of the current NRC requirement to decommission to levels that are ALARA, in most cases the NRC licensees already remediate to a level that satisfies the Department's dose criterion.

As part of the Federal National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4347) requirements to terminate a license, the NRC must generate either an Environmental Assessment (EA) or Environmental Impact Statement that determines if there is a "Finding of No Significant Impact" to the environment upon license termination. The State is required to submit its concurrence or non-concurrence so that the NRC can publish the findings in the Federal Register. The Department receives approximately one EA per month. To date, the Department has concurred with all but three EAs.

The three instances where the Department did not concur with the NRC's decision to terminate the licenses involved groundwater contamination above the Department's groundwater

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standards, and contaminated soil significantly above the Department's remediation standards. In one case involving soil, the site was grandfathered so it was allowed to comply with an old NRC guideline, which resulted in more than 25 mrem/y. Not only did the site not meet our dose criterion, it did not meet the NRC's current criterion of 25 mrem/y. In another case, the NRC considered the average of all the samples, rather than considering each sample individually, even though some areas of the site had significantly elevated concentrations. The NRC also released this particular site for unrestricted use, even though the licensee used an industrial scenario instead of a residential scenario to model the exposure. In none of these three cases was the fact that the Department's dose criterion is different than the NRC's at issue. Even if the Department's dose criterion were the same as the NRC's (25 mrem/y), the Department would not have concurred on the three EAs.

Also, as a practical matter, even if a site is operated by a licensee with only an NRC-issued license, under the existing regulatory framework if the site is to be redeveloped it will need to meet the New Jersey remediation standard. If NRC licensees did not meet the Department's 15 mrem/y dose criterion, additional cleanup would be necessary in accordance with the Technical Requirements for Site Remediation, N.J.A.C. 7:26E. If the site does not meet the remediation requirements, including the dose criterion, the Department would not issue a No Further Action letter. Without a No Further Action letter, the site cannot be redeveloped. Therefore, there will not be additional compliance costs for NRC licensees because, even under the existing regulatory framework, the Department's dose criterion must be met eventually.

In addition to a dose criterion for unrestricted release, both the Department and the NRC have restricted release criteria. Restricted release means that there are remaining contaminants at the site that require institutional (deed restrictions, for example), and/or engineering controls (fences or caps, for example) to meet the remediation dose criterion. Whether or not the Department's rules

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are more costly to implement than the Federal rules depends on the specific circumstances at a site, as discussed below.

In order to obtain release under the Federal rules, a licensee must demonstrate that further cleanup would result in net public or environmental harm. One of the purposes of the NRC requirement is to ensure that the licensee takes into account transportation of waste off-site and the potential for transportation fatalities. The NRC also allows a licensee to take cost into account for determining whether or not to clean up to unrestricted release. If the cost of cleaning up a site is more expensive than the cost of lives saved (the NRC has a formula for determining the cost per life from exposure to radiation), then further cleanup is not required. In the alternative, under the Federal rules a licensee can demonstrate that further cleanup is not necessary because the residual levels associated with restricted conditions were ALARA. The State's restricted release requirements have no similar provisions.

Because the Department does not have these conditions before restricted release is allowed, it may have the effect of allowing licensees to use restricted release standards more often than under NRC's authority. This would mean less expensive cleanups, resulting in a positive economic impact for some licensees.

However, another part of the Department's restricted release criteria is more stringent than the NRC criteria. The Department's rules at N.J.A.C. 7:28-12.10(e) require that a licensee must demonstrate that if all institutional and/or engineering controls fail, a dose of 100 mrem/y would not be exceeded. The existing NRC regulation at 10 CFR 20.1403(e) also has this requirement; however, the NRC allows licensees a dose limit of up to 500 mrem/y at 10 CFR 20.1403(e)(2) if the licensee can demonstrate further cleanup is not technically achievable, would be prohibitively expensive, or would result in net public harm.

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Under the Departments rules, the licensee would also have to provide for durable institutional controls and provide sufficient financial assurance to enable a responsible government entity or independent third party to carry out checks of the facility every five years and to maintain the controls. When modeling the all controls fail scenario, the Department interprets failure of all institutional and engineering controls strictly. This means that no credit for any engineering controls, such as a fence or cover, can be taken when performing the model to determine if the 100 mrem annual dose is exceeded. The NRC, however, allows the licensee to take credit for controls that have degraded, but not completely failed. So the NRC would allow a small hole in a cover rather, for example, which could result in a significant difference in the resultant dose.

The Department considered raising the 100 mrem/y all controls fail dose limit in response to an interested party meeting held on December 6, 2007 at the Radiation Protection Program office in Ewing, New Jersey. However, the Department has concerns about leaving high levels of contamination at a site, even with the protections afforded by institutional and engineering controls.

The Technical Requirements for Site Remediation, N.J.A.C. 7:26 detail requirements for the continued monitoring and maintenance of institutional and engineering controls and the include a requirement to certify to the Department every two years that the remedy remains protective of human health and the environment.

To date, more than 2,000 sites State-wide have used institutional and engineering controls to eliminate or mitigate exposure to remaining contaminants. The Department does not have the capacity, with its limited resources, to closely monitor each of these sites. The Department has considered using the NRC language that allows up to 500 mrem/y under certain conditions, but has determined that the resultant risk was too high (from a 5 in 100 to 2 in 10 risk of fatal cancer) to allow a higher than 100 mrem/y all controls fail dose criterion. Considering that the half-lives of

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some of the radionuclides are billions of years, the Department chose not to incorporate the NRC's language.

The proposed amendment to N.J.A.C. 7:28-12.10(d), extending the time period of dose calculations to the time of peak dose, will have an economic impact on licensees only if the licensees have large amounts of contaminated material that will leach into the groundwater and the peak dose occurs after 1000 years. The Department and Commission estimate that there are only one or two NRC licensees in the State that would fall into this category. These licensees are former manufacturing facilities and are in the process of decommissioning.

Proposed amended N.J.A.C. 7:28-12.8(c) requires licensees to adhere to the New Jersey Surface Water Quality standards, N.J.A.C. 7:9B. The proposed amendment will have an economic impact only on those licensees whose activities have resulted in contamination to surface water. The Department knows of only one such facility in the State, which is a former manufacturing facility.

The proposed amendment at N.J.A.C. 7:28-12.12 imposes financial assurance requirements on licensees that are terminating their licenses under restricted release. For licensees or persons responsible for remediating a site that possess only Department-regulated radioactive materials, the proposed financial assurance requirements could have an immediate economic impact on facilities that have decided to terminate under restricted release.

There is no requirement to terminate a license under restricted release. A regulated entity will decide if it is to its advantage to pursue restricted release by weighing the cost of remediating to unrestricted use against the proposed financial assurance requirements for restricted release. If the financial assurance requirements outweigh the costs of cleaning up to unrestricted use, then the licensee will probably not pursue restricted release, but will instead remediate the site for unrestricted use. The Department believes that only a few of the current State-only licensees would

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petition for release under restricted conditions. Licensees with NRC-issued licenses are already subject to the financial assurance requirements in the Federal rules.

Cost to the Public

The Department and the Commission do not anticipate that there will be a negative economic impact on the public at large as a result of the proposed new rules and amendments. There will be a positive economic impact on the public, to the extent that the facilities are required to post financial assurance for decommissioning (see proposed N.J.A.C. 7:28-7:28-12.12(b)2., Subchapters 51, 55, 58, and 60). The public will benefit to the extent that public funds are not needed for remediation of closed facilities.

The Department and the Commission considered the cost to the public from imposing fees on non-profit educational institutions under proposed new Subchapter 64; however, it was determined that if a non-profit educational institution decided to increase tuition because of the Department's fees, it would be a minor increase, considering it would be spread out over all attendees or applicants.

The Department and the Commission considered the cost to the public from the requirement to use dose calibrators more often than the NRC requires their use (proposed new Subchapter 55) and found that the cost would be minimal as described under the Federal Standards analysis below.

The licensing fee for small water utilities that must treat for radionuclides will decrease under the proposed rules; however, this is not expected to have an effect on the water utility cost to the public.

Environmental Impact

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The proposed new rules and amendments, proposed in order that New Jersey can become an Agreement State, are anticipated to have an overall positive impact on the environment, insofar as they continue to ensure that the limits for source, certain special nuclear, byproduct, technologically enhanced naturally occurring and accelerator-produced radioactive materials (both discrete and diffuse), including environmental release limits, will be regulated. Human exposure to radiation causes cancer. Any reduction of radiation allowed in the environment will have a positive effect on the health of humans. A fundamental tenet of radiation protection has been the assertion that populations of non-human biota are protected in situations where exposure levels are protective of humans. (National Council on Radiation Protection Report No. 109, 1991.) Accordingly, by minimizing human exposure, the proposed new rules and amendments will have the incidental benefit of minimizing exposure to the environment.

Moreover, the proposed rules requiring facilities to comply with the Surface Water Quality Standards, and to provide financial assurance to pay for decommissioned sites will have a direct positive impact on the environment by reducing the radioactive material that is released into the environment.

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 proposes the new rules and amendments in order that the State's rules are compatible with the NRC regulations, so that New Jersey can become an

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Agreement State. Except as discussed below, the proposed new rules and amendments do not exceed Federal standards.

The NRC regulations at 10 CFR 20.1401(d) require modeling to 1000 years; whereas, the proposed amendment at N.J.A.C. 7:28-12.10(d) requires modeling to the time of peak dose. The proposed 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 proposed 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 proposed 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

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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 proposed rule is consistent with the Federal rule and no further analysis is required.

Proposed Subchapter 55, medical use of radioactive materials, is incorporates by reference the Federal rules at 10 CFR Part 35; however, the Department and the Commission propose to require 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

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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.

Jobs Impact

The proposed new rules and amendments are not expected to have an impact on employment or jobs in the State.

Agricultural Impact Statement

The proposed new rules and amendments are not expected to have an impact on the agricultural industry in the State.

Regulatory Flexibility Statement

After New Jersey becomes an Agreement State, the Department and the Commission estimate that there will be approximately 700 total licensees that will be affected by the proposed new rules and amendments. Some of these licensees are currently licensed by the NRC only, some

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are licensed by the State only, and some are licensed by both the NRC and the State. Licensees range from small non-community water systems (when water treatment includes removal of naturally occurring radioactive materials from drinking water), to large hospitals, research facilities, and universities. Approximately 30 percent of NRC licensees and 60 percent of Department-only licensees employ fewer than 100 full-time employees and, therefore, are defined as “small businesses” under the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq.

As has been discussed, the majority of these proposed new rules and amendments are already required by the NRC, and NRC licensees are already complying with them. Since many New Jersey radioactive materials licensees are also NRC licensees, most of the State licensees are already in compliance with the proposed regulations. For those licensees, there are no new regulatory, compliance, or recordkeeping requirements, except as discussed above in the Federal Standards analysis, and the fees, discussed below.

As discussed in the Economic Impact, above, small businesses will be required to pay a license fee, as set forth in the proposed new rules and amendments. Most licensees will experience a decrease, or only a slight increase in fees. Some licensees that have both NRC and State licenses under the existing rules will experience more than a 25 percent decrease in fees, since discrete naturally occurring and accelerator-produced radioactive material will be considered byproduct material and will be covered under one license category instead of two. Currently, the NRC has reduced licensing fees for businesses that seek status as a small entity. However, just as with non-profit educational institutions, the NRC gets reimbursed for these costs through OBRA-90. Since the Department has no similar means to recover costs, there is no reduction in licensing fees proposed for small businesses, other than those discussed below. According to the NRC, there were 166 New Jersey licensees that qualified for small entity status, and thus reduced fees. This would

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amount to approximately \$500,000 in unrecovered costs if the State were to offer a similar fee reduction. Many of these licensees are medical offices or diagnostic centers that also possess a Department radioactive materials license. Current Department fees for these facilities range from \$650.00 to \$4,000, while the current reduced NRC fees are \$500.00 to \$2,300. Licensees with both NRC and Department licenses are currently paying \$1,100 to \$6,300. When New Jersey becomes an Agreement State, the proposed new fee for these types of facilities is \$3,600. Therefore, some of NRC's current small entity licensees will see an increase and some will see a decrease in fees.

The Department has evaluated the impact of the fees on non-transient, non-community (NTNC) water systems, many of which are small businesses, and has determined that it would be appropriate to minimize the financial impact to these facilities based on the amount of gallons of water treated per day. The radioactive material associated with these facilities will be small compared to large community water systems, where the costs of treatment and licensing may be passed on to the public. These NTNC facilities have possession-only licenses that allow them to treat groundwater for radionuclides, thus reducing the dose to the general population that is served by the facility. The amount of radionuclides that accumulate on the treatment media is over the Department's and the Commission's exempt quantity limits, but is not enough to endanger the public if the source were not contained. The Department's cost to oversee these licenses is less than is associated with overseeing other facilities. Therefore, the Department proposes reduced licensing fees for NTNC water systems.

Small businesses must also comply with recordkeeping and reporting requirements in the proposed new rules and amendments, such as records of surveys, radiation protection programs, and waste disposal. In order to reduce the record keeping burden to some very small businesses (for example, licensees with lead paint analyzers), the Department instituted an inspection-by-mail

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program. Since many of these businesses have only one employee, taking the time to be present during an inspection reduces the amount of time the employee is available to generate income. The Department is willing to work with businesses on specific licensing conditions so that undue record keeping and reporting is minimized for a small business without compromising the safety of the workers and the general public.

With regard to compliance with the proposed new rules and amendments, small businesses will incur the costs discussed in the Economic Impact, above. These businesses may require the assistance of professionals to assist in decommissioning facilities, and to prepare financial assurances. The cost of hiring these consultants would depend on the amount of material and the extent of contamination. The Department and the Commission do not propose standards for compliance that differ between large and small businesses. Small businesses that use radioactive materials have the same responsibility as large businesses to maintain control over the materials so that public health and safety are maintained. Accordingly, separate standards for small businesses would not be appropriate.

Smart Growth Impact Statement

Executive Order No. 4(2002) requires State agencies that adopt, amend or repeal State regulations to include in the rulemaking document a Smart Growth Impact statement that describes the impact of the proposed rules on the achievement of smart growth and implementation of the State Development and Redevelopment Plan (State Plan).

The proposed new rules and amendments do not relate to the State's official land use and development policies in a way that would either encourage or discourage any development or redevelopment in this State contrary to the guiding principles of the State Plan. As a result, the

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Department and the Commission do not expect the proposed new rules and amendments to have an impact on the State's achievement of Smart Growth or the implementation of the State Plan.

Full text of the proposed repeals of N.J.A.C. 7:28-6, 9, and 11, may be found in the New Jersey Administrative Code at N.J.A.C. 7:28-6, 9, and 11.

Full text of the proposal follows (additions indicated by underline thus; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

7:28-1.1 Purpose and scope

(a) (No change.)

(b) [Unless otherwise provided by statute, or codes, rules or regulations promulgated by the Commission on Radiation Protection, this chapter shall constitute the rules of the Department of Environmental Protection, and shall govern all persons installing, using, handling, transporting or storing sources of radiation.] This chapter applies to persons licensed or registered by the Department to receive, possess, use, transfer, 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.

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(c) The regulations in this chapter establish standards for protection against ionizing radiation resulting from activities conducted under registrations or licenses issued by the Department.

(d) It is the purpose of the regulations in this chapter to control the receipt, possession, use, transfer, and disposal of licensed material, ionizing radiation producing machines, or non-ionizing radiation producing sources by any licensee or registrant in such a manner that the total dose or exposure to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this chapter. However, nothing in this chapter shall be construed as limiting actions that may be necessary to protect health and safety.

7:28-1.4 Definitions

(a) The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise. Additional words and terms applicable to the chapter, incorporated from 10 CFR 20, are located at NJAC 7:28-6. Words and terms applicable to a specific subchapter only, will be found in that subchapter.

[(a)]1. General Terms:

["Absorbed dose" means the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit for absorbed dose is the rad. (See "Rad" under (b) below.)]

...

["ALARA" means "as low as is reasonably achievable," taking into account the state of technology and the economics of improvements in relation to benefits to the public health and

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safety, and other societal and socioeconomic considerations, and in relation to the utilization of radiation in the public interest.]

“Annually” means occurring once per year at intervals of not less than 51 consecutive weeks nor more than 53 consecutive weeks.”

...

["Background radiation" means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source, special nuclear material, or technologically enhanced naturally occurring radioactive material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the State licensee or licensee. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the U.S. Nuclear Regulatory Commission or from naturally occurring or accelerator produced radioactive materials regulated by the State.]

["Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged that no day in any year is omitted from inclusion within a calendar quarter. For purposes of this chapter, no State licensee, licensee, radioactive materials registrant or registrant shall change the method observed by him of determining calendar quarters except at the beginning of a calendar year.]

...

["Controlled area" means any area to which the access, occupancy and activity of those within are subject to control and supervision for the purpose of radiation protection.]

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...

["Dose equivalent" means a numerical quantity that expresses on a common scale for all ionizing radiation, a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose is the Rem. (See "Rem" under (b) below).]

...

["Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation from a machine source or to radioactive material from State licensed and unlicensed sources of radiation, whether in the possession of the State licensee, licensee or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Federal regulations found in Title 10 Code of Federal Regulations, Part 35, section 75, or as a member of the public.]

...

["Person" includes an individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, municipality, any state, or other legal entity; and any legal successor, representative agent, or agency of the foregoing.]

...

["Radiation area" means an area which is accessible to a worker and in which there exists ionizing radiation at such levels that a major portion of the body would receive in any one hour a dose equivalent in excess of five millirems or in any workweek a dose equivalent in excess of 100

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millirems; or levels of nonionizing radiation which exceed the maximum permissible levels of such radiation as specified in the rules and standards established by the Commission.]

...

“Semi-annually” means occurring twice per year at intervals of not less than 25 consecutive weeks, nor more than 27 consecutive weeks.

...

["State license" means a license issued by the Department. See also "License" under (b) below.

"State licensee" means a person who is required to obtain a license from the Department pursuant to this chapter.

"Survey" means evaluation for a specific set of conditions or actual or potential radiation or contamination levels by or under the supervision of a qualified individual.]

...

[(b)]2. Ionizing radiation terms:

["Adult" means an individual 18 or more years of age.

"Airborne-radioactivity area" means an area accessible to workers, in which airborne radioactive materials are present in concentrations such that the values at any time are in excess of the respective values stated in *N.J.A.C. 7:28-6.5(a)* (Average concentrations) Column B, or prorated values if more than one isotope is present; or values if averaged over the hours of occupancy in any week are in excess of 25 percent of the respective foregoing values.]

...

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"Byproduct material" means 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.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Committed dose equivalent" ($H[T,50]$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

"Committed effective dose equivalent" ($H[E,50]$) means the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H[E,50] = \sum w[T]H[T,50]$).

...

"Curie" means that amount of a specific radionuclide which disintegrates at the rate of 37 billion atoms per second.

i. The new International System of Units replaces "curie" with the "becquerel," which means that amount of a specific radionuclide which disintegrates at the rate of one atom per second. One curie equals 3.7×10^{10} becquerel.

"Declared pregnant woman" means a woman who has voluntarily informed the State licensee, radioactive materials registrant or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing, or is no longer pregnant.

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"Deep-dose equivalent" ($H[d]$), which applies to external whole-body exposure, means the dose equivalent at a tissue depth of one cm ($1,000 \text{ mg/cm}^2$).

...

"Diffuse" means a radionuclide that has become concentrated, but not for the purpose of use in commercial, medical, or research activities.

"Domestic sewage" means waste and wastewater from humans or household operations that is discharged to or otherwise enters a treatment works.

"Domestic treatment works" or "DTW" means all publicly owned treatment works as well as any other treatment works processing primarily domestic sewage and pollutants together with any ground water, surface water, storm water or process wastewater that may be present.

["Dose or radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

"Effective dose equivalent" ($H[E]$) means the sum of the products of the dose equivalent to the organ or tissue ($H[T]$) and the weighting factors ($w[T]$) applicable to each of the body organs or tissues that are irradiated ($H[E] = \sum w[T]H[T]$).

"High radiation area" means an area which is accessible to workers and in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.]

...

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["License," except where otherwise specified, means a license issued by the United States Nuclear Regulatory Commission or any state for possession and use of radioactive material. See also "State license" under (a) above.

"Licensee" means a person who is required to obtain a license from the U.S. Nuclear Regulatory Commission or any state other than New Jersey.

"Medical radiographer" means any individual who, under the supervision of a licensed practitioner, uses medical radiographic equipment on human beings for diagnostic or therapeutic purposes.

"Member of the public" means any individual except when that individual is receiving an occupational dose.

"Minor" means an individual less than 18 years of age.

"Monitoring" means a periodic or continuous determination of ionizing radiation levels or of radioactive contamination.]

...

["Public dose" means the dose received by a member of the public from exposure to radiation from a machine source or to radioactive material released by a State licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the patient has received, or from exposure to individuals administered radioactive material and released in accordance with Federal regulations found in 10 CFR 35, section 75.

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"Rad" means the dose corresponding to the absorption of 100 ergs per gram: a measure of the dose of any radiation to body tissues in terms of the energy absorbed per unit mass of the tissue.

i. The new International System of Units replaces the "rad" with the "gray," which means the dose corresponding to the absorption of one joule per kilogram. One rad equals 1×10^{-2} gray.]

....

"Radioactive materials registrant" means a person who is required to register radioactive byproduct material, source material or special nuclear material with the Department pursuant to this chapter.

"Radiographer" means any individual who is in attendance at a site where ionizing radiation-producing machines [sources] are being used and who uses or supervises their use in industrial radiographic operations and who is responsible to the owner for assuring compliance with the requirements of this chapter.

"Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses [sources of] ionizing [radiation including ionizing] radiation-producing machines, [radiographic-exposure devices, sealed sources or] related handling tools, or survey instruments in industrial radiography.

["Radiographic-exposure device" means any instrument containing a sealed source fastened or contained therein which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure.]

"Radiography" means the examination of humans or animals, or of the structure of materials by non-destructive methods, utilizing [sealed sources or] ionizing radiation-producing machines. This term is not intended to apply to techniques such as electron microscopy or x-ray diffraction.

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["Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.]

"Registrant" means a person who is required to register an ionizing radiation-producing machine source of radiation with the Department pursuant to this chapter.

["Rem" means a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of one rad of x-rays. For the purpose of this chapter, any of the following are considered to be equivalent to a dose of one rem:

- i. A dose of one rad due to x, gamma, or beta radiation;
- ii. A dose of 0.1 rad due to neutrons or high-energy protons;
- iii. A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye.

(1) The new International System of Units replaces the "rem" with the "sievert," which means a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of one gray of x-rays. One rem equals 1×10^{-2} sievert.

(2) If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in ii above, one rem of neutron radiation may, for purposes of this chapter, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

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Neutron energy (MeV)	Number of neutrons per square centimeter equivalent to a dose of 1 rem (neutron/cm ²)	Average flux to deliver 100 milli- rem in 40 hours (neutrons/cm ² per sec.)
Thermal	970 x 10 ⁶	670
0.001	720 x 10 ⁶	500
0.005	820 x 10 ⁶	570
0.02	400 x 10 ⁶	280
0.1	120 x 10 ⁶	80
0.5	43 x 10 ⁶	30
1.0	26 x 10 ⁶	18
2.5	29 x 10 ⁶	20
5.0	26 x 10 ⁶	18
7.5	24 x 10 ⁶	17
10	24 x 10 ⁶	17
10 to 30	14 x 10 ⁶	10

"Residual" means a solid waste that consists of the accumulated solids and associated liquids which are by-products of a physical, chemical, biological, or mechanical process or any other process designed to treat wastewater or any other discharges subject to regulation under the New Jersey Water Pollution Control Act, N.J.S.A. 58:10A-1 et seq., as amended. For purposes of this chapter, residual includes, but is not limited to, marketable residual product, sludge and sewage

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sludge. Residual excludes screened vegetative waste and grit and screenings. The terms used in this definition shall have the same meaning as those in N.J.A.C. 7:14A-1.2.

...

"Sanitary sewer system" means any device or system used in the storage and treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature which is owned by a State or municipality. This definition includes sewers, pipes, or other conveyances only if they convey wastewater to a sanitary sewer system providing treatment. A synonym for sanitary sewer system is publicly owned treatment works (POTW).

"Sealed source" means a radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.]

...

"Sewage Sludge" means the solid, semi-solid, or liquid residue generated by the processes of a domestic treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and any material derived from sewage sludge.

...

["Source material" means uranium or thorium, or any combination thereof, in any physical or chemical form, or ores which contain by weight 1/20 of one percent (0.05 percent) or more of uranium, thorium or any combination thereof. Source material does not include special nuclear material.

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"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; U-233 in quantities not exceeding 200 grams; plutonium (Pu) in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all the kinds of special nuclear material in combination shall not exceed "1," that is, unity as illustrated in the following example:

175 grams		50 grams		50 grams	
Contained					
U-235	+	U-233	+	Pu	= 1
350		200		200	

"Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.]

...

["Total effective dose equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).]

...

["Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

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"Unrestricted area" means an area, access to which is neither limited nor controlled by the State licensee or registrant.]

...

["Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (five grays) in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates. Note that at very high doses received at high dose rates, units of absorbed dose (for example, rads and grays) are appropriate, rather than units of dose equivalent (for example, rems and sieverts).]

...

["Weighting factor" ($w[T]$) for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of $w[T]$ are:

Organ Dose Weighting Factors

Organ or Tissue	$w[T]$
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03

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Bone surfaces	0.03
Remainder	0.30 a
Whole Body	1.00 b

a 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

b For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w[T] = 1.0$, has been specified.]

...

[(c)]3. (No change.)

7:28-1.5. Communications

(a) Communications concerning this chapter, or matters relating to radiation protection, may be addressed to the New Jersey Department of Environmental Protection, Radiation Protection and Release Prevention Element, PO Box 415, Trenton, New Jersey 08625-0415. Telephone: (609) 984-5636, Fax: (609) 633-2210. The physical location of the office is 25 Arctic Parkway, Ewing, New Jersey 08638. Applications and forms may be obtained from the website at <http://www.state.nj.us/dep/rpp/index.htm>.

(b) All emergency notification of incidents involving sources of radiation in this State shall be immediately reported to either one of the following agencies:

1. Radiation Protection and Release Prevention Element
New Jersey Department of Environmental Protection

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25 Arctic Parkway

Ewing, NJ 08638

Telephone: (609) 984-5462

Hours: 8:00 A.M. to 5:00 P.M. daily, except Saturday, Sunday, and Holidays

After hours and weekends[: 609 292-7172 or] toll free: 1 (877) 927-6337 (1 (877) WARN-DEP)

2. (No change.)

SUBCHAPTER 2. USE OF SOURCES OF IONIZING RADIATION AND SPECIAL EXEMPTIONS

7:28-2.8 Special Exemptions

The Department, upon application and a showing of hardship or compelling need, with the approval of the Commission, may grant an exemption from any requirement of these rules should it determine that such exemption will not result in any exposure to radiation in excess of the limits permitted by N.J.A.C. 7:28-6, [Dose Limits] Standards for protection against radiation.

7:28-2.13 Violations

(a) The Department may obtain an injunction or other court order to prevent a violation of the provisions of:

1. The Act; or

2. A regulation or order issued pursuant to the Act.

(b) The Department may impose a civil penalty for a violation of:

1. Any provision of this chapter or order issued hereunder;

2. Any term, condition, or limitation of a license issued under this chapter; or

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3. A revocation under N.J.A.C. 7:28-4.17, 51 through 60, or 63.

SUBCHAPTER 3. REGISTRATION OF IONIZING RADIATION-PRODUCING MACHINES
[AND RADIOACTIVE MATERIALS]

7:28-3.1 Registration for possession of ionizing radiation-producing machines [and radioactive by-product material, source material and special nuclear material]

(a) Any person, manufacturer, dealer or State, county or local government shall register with the Department [all radioactive by-product material, source material, special nuclear material and] every ionizing radiation-producing machine possessed within the State of New Jersey except as exempted by N.J.A.C. 7:28-3.2.

(b) Any person, manufacturer, dealer or State, county or local government shall apply for such registration within 30 days after taking possession, custody or control of [radioactive by-product material, source material, special nuclear material and] ionizing radiation-producing machines on forms available from the Department.

(c) (No change.)

7:28-3.2 Exemptions from registration for possession of ionizing radiation-producing machines [and radioactive by-product material, source material and special nuclear material]

(a) - (c) (No change.)

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[(d) Those radioactive materials covered in specific and general state licenses issued by the Department in accordance with N.J.A.C. 7:28-4 are exempt from registration.

(e) Those radioactive materials contained in devices which are covered under general license issued by the United States Nuclear Regulatory Commission or have been granted an exemption from licensing requirements by the United States Nuclear Regulatory Commission are exempt from registration.

(f) Quantities of radioactive material equal to or less than those listed in N.J.A.C. 7:28-3.11 are exempt from registration requirements provided that no individual user of radioactive material shall have more than 10 such quantities of any material or materials at any one time.]

7:28-3.5 [Registration of radioactive by-product material, source material and special nuclear material

(a) Any person having within his possession, custody or control any radioactive by-product material, source material or special nuclear material pursuant to a specific license issued by the United States Nuclear Regulatory Commission shall apply for and obtain a registration for possession, custody or control of the specified type(s) and amount(s) of such material as authorized by the license issued by the Nuclear Regulatory Commission. Application forms for the registration of radioactive material are available from the Department. When submitting an application, the applicant shall attach to the application a copy of the license issued by the Nuclear Regulatory Commission.

(b) A radioactive materials registrant does not have to apply for a new or amended registration for receipt of each shipment of a type of radioactive material for which it has a valid

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current registration provided that the total amount of such type of radioactive material in the radioactive materials registrant's possession, custody or control does not exceed the amount authorized in its registration for such type of material.

(c) Fees in the amounts indicated in N.J.A.C. 7:28-3.13 shall be paid for each initial registration application, each registration amendment and each annual registration renewal.

(d) Any registration issued for radioactive materials pursuant to this subchapter shall be valid for so long as the license issued by the United States Nuclear Regulatory Commission is in full force and effect.] (Reserved.)

7:28-3.6 Transfer of registration for [possession of radioactive by-product material, source material, special nuclear material and] ionizing radiation-producing machines

Registrations for [possession of radioactive by-product material, source material, special nuclear material and] ionizing radiation-producing machines are not transferable.

7:28-3.8 [Amendments to registration of radioactive by-product material, source material or special nuclear material

A radioactive materials registrant shall notify the Department in writing within 30 days after any change in the license issued by the Nuclear Regulatory Commission for possession, custody or control of any type of radioactive by-product material, source material or special nuclear material when there is a change in the type and/or quantity of such material or when there is a change in the designated licensed user(s) or radiation safety officer.] (Reserved.)

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7:28-3.10 Denial of an application for registration, and suspension, modification, or revocation of registration of ionizing radiation-producing machines[, radioactive by-product material, source material or special nuclear material]

(a) The Department, in addition to any penalties authorized by the Act, may deny an application for registration or suspend, modify or revoke a registration of ionizing radiation-producing machines[, radioactive by-product material, source material or special nuclear material] by reason of amendments to the Act, adoption of rules, orders issued by the Department pursuant to said Act or if the applicant, [radioactive materials registrant] or registrant:

1. Fails to comply with any provisions of the Act or any rules promulgated pursuant thereto including the timely payment of registration fees;

2. Falsifies or makes misleading statements in the application for registration;

3. Falsifies or makes misleading statements in any documents which were utilized to obtain a registration;

4. Alters registration documents;

5. Falsifies required records;

6. Aids, abets, combines with, or conspires with any person for any purpose which will evade or be in violation of the provisions of the Act or any rules promulgated pursuant thereto;

or

7. Allows a registration to be used by any person for any purpose which will evade or be in violation of the provisions of the Act or any rules promulgated pursuant thereto.

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(b) (No change.)

(c) The Department may terminate a registration upon request submitted by the [radioactive materials registrant or] registrant to the Department in writing.

7:28-3.11 [Table of radioactive materials and quantities exempt from registration

(a) The following radioactive materials, in quantities less than or equal to those specified below, are exempt from registration:

Radioactive Material	Column A Not as a sealed source (microcuries)	Column B As a sealed source (microcuries)
Antimony (Sb 124)	1	10
...		
Zinc 65 (Zn 65)	10	10
Beta and/or Gamma emitting radioactive material not listed above	1	10]

(Reserved.)

[7:28-3.13 Fees for registration of radioactive by-product material, source material and special nuclear material

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(a) Fees for initial registration, annual registration renewal and each registration amendment for possession, custody or control of radioactive by-product material, source material and special nuclear material as provided below shall be paid in full by the radioactive materials registrant.

1. Initial Registration Fee: \$250.00;
2. Annual Registration Renewal: \$165.00;
3. Each Amendment to Registration: \$165.00.

(b) Payment for each initial registration shall be made only by check or money order payable to "Treasurer, State of New Jersey" and shall be submitted with each initial registration application to the Department.

(c) Annual registration renewal fees payable to "Treasurer, State of New Jersey" shall be submitted to the Department annually no later than August 1 of each year.

(d) In the event that registration renewal fees are paid later than 30 days after August 1, a delinquency fee equal to one-half of the annual registration fee will be imposed. Failure to pay a registration renewal fee, including any accrued delinquency fees for longer than 90 days after August 1 shall constitute grounds for suspension or revocation of the registration pursuant to N.J.A.C. 7:28-3.10.

(e) Registration amendment fees shall be submitted with the amended registration.

(f) The initial registration fee, the annual renewal fee and registration amendment fee shall be mailed to:

State of New Jersey
Department of Treasury
Division of Revenue
PO Box 417

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(g) The registration year shall be July 1 of each year to June 30 of the following year.

(h) Fees submitted to the Department are non-refundable.]

SUBCHAPTER 4. LICENSING OF DIFFUSE NATURALLY OCCURRING OR DIFFUSE

ACCELERATOR PRODUCED RADIOACTIVE MATERIALS

7:28-4.1 Scope and general provisions

(a) This subchapter shall apply to persons who 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.

(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 [State] license issued by the Department as provided by N.J.A.C. 7:28-4.7 and 4.8, a general [State] 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) A person who sells, transfers, distributes or arranges for the distribution of a device containing diffuse naturally occurring or diffuse accelerator produced radioactive materials manufactured by another person, but which is sold, transferred or distributed under its own name, shall obtain a [State] license in accordance with this subchapter.

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7:28-4.2 Recognition of licenses for diffuse NARM from other jurisdictions

(a) Any person who possesses a specific license or equivalent licensing document issued by a Federal agency or any other state is granted a general license in this State provided that the provisions of (b)1 through 4 below have been met.

(b) Any person who possesses a specific license or equivalent licensing document issued by a Federal agency or any other state may, pursuant to [such document] the general license in (a) above, transport, receive, possess, or use the radioactive materials specified in such license within this State for a period not in excess of [20] 180 days in any period of 12 consecutive months without obtaining a specific license from the Department provided that

1. (No change.)

2. The licensee notifies the Department in writing at least [two] three days prior to the time that such radioactive material is brought into this State. Such notification shall indicate the location, period, and type of proposed possession and use within this State, and shall be accompanied by a copy of the pertinent licensing document. If in a specific case the [two]three-day period would impose an undue hardship on the user, he may, upon application to the Department, obtain permission to proceed sooner;

3. - 4. (No change.)

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

7:28-4.3 Exemption from requirement for a [State] license for manufacture, production, transfer, distribution or arrangement of distribution, sale, lease, receipt, acquisition, ownership, possession or use of all diffuse naturally occurring or diffuse accelerator produced radioactive materials

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(a) A person shall be exempt from the requirement to obtain a [State] license for the following activities:

1. – 2. (No change.)

3. The person manufactures, produces, receives, possesses, uses, transfers, distributes or arranges for the distribution, sells, leases, owns or acquires products or materials containing diffuse naturally occurring or diffuse accelerator produced radioactive materials in concentrations not in excess of those exempted in N.J.A.C. 7:28-4.3(b);

[4. The person manufactures, receives, possesses, uses, transfers, distributes or arranges for the distribution, sells, leases, owns or acquires luminous timepieces or parts thereof containing radium. However, any person who desires to apply radium to luminous timepieces or parts thereof is not exempt and must obtain a specific State license;]

[5.] 4. (No change in text.)

[6.] 5. (No change in text.)

[7.] 6. (No change in text.)

[8.] 7. The person owns a [sanitary sewer system] domestic treatment works where [residuals are] sewage sludge is present which may contain TENORM from the separation of liquids and solids which is the outcome of normal operations of the [sanitary sewer system] domestic treatment works;

[9.] 8. (No change in text.)

[10.] 9. The person owns property where residual contamination remaining at the site was remediated under the Radiation Protection Act (N.J.S.A. 26:2D-1 et seq.) and/or the other authorities listed in the Soil Remediation Standards at N.J.A.C. 7:28-12.2(a). Such residual

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concentrations may be greater than the limits specified in (a)[6]5 above, but be under restricted conditions imposed by the Department (such as engineering and institutional controls), and meet the dose criteria specified in N.J.A.C. 7:28-12.8[(a)].

(b) The following concentrations of [NARM] diffuse naturally occurring radioactive materials, including TENORM, and diffuse accelerator-produced radioactive materials, when obtained from naturally occurring materials or when produced by an accelerator are exempt from the requirements for a [State] license:

Exempt Concentrations

Element (nuclide)	Column 1	Column 2
	Gas concentration	Liq. & solid
		Concentration
	(uCi/ml)	(uCi/ml) ***[*]
Argon (Ar-37)	1×10^{-3}	--
Arsenic (As-73)	--	5×10^{-3}
(As-74)	--	5×10^{-4}
Barium (Ba-131)	--	2×10^{-3}
Beryllium (Be-7)	--	2×10^{-2}
Bismuth (Bi-206)	--	4×10^{-4}
(Bi-207) *	--	2×10^{-4}
Cadmium (Cd-109)	--	2×10^{-3}
Chromium (Cr-51)	--	2×10^{-2}
Cobalt (Co-56) *	--	1.2×10^{-4}

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(Co-57)	--	5×10^{-3}
(Co-58)	--	1×10^{-3}
Dysprosium (Dy-159) *	--	4×10^{-3}
Fluorine (F-18)	2×10^{-6}	8×10^{-3}
Gallium (Ga-67) *	--	2×10^{-3}
Germanium (Ge-68) *	--	1.2×10^{-3}
(Ge-71)	--	2×10^{-2}
Gold (Au-196)	--	2×10^{-3}
(Au-199)	--	2×10^{-3}
Indium (In-111) *	--	1.2×10^{-3}
(In-113m)	--	1×10^{-2}
Iodine (I-123) *	4×10^{-7}	2×10^{-3}
(I-124) *	8×10^{-9}	4×10^{-5}
Iridium (Ir-190)	--	2×10^{-3}
(Ir-192)	--	4×10^{-4}
Iron (Fe-55)	--	8×10^{-3}
Krypton (Kr-85m)	1×10^{-6}	--
Lead (Pb-201) *	--	2×10^{-3}
(Pb-203)	--	4×10^{-3}
(Pb-210) *	--	2×10^{-7}
Manganese (Mn-52)	--	3×10^{-4}
(Mn-54)	--	1×10^{-3}
Mercury (Hg-197m)	--	2×10^{-3}

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(Hg-197)	--	3×10^{-3}
Neptunium (Np-237) *	--	4×10^{-7}
Palladium (Pd-103)	--	3×10^{-3}
Platinum (Pt-191)	--	1×10^{-3}
(Pt-193m)	--	1×10^{-2}
(Pt-197m)	--	1×10^{-2}
Radium (Ra-226) *	--	1.2×10^{-6}
(Ra-228)	--	4×10^{-11}
Rhenium (Re-183)	--	6×10^{-3}
Rubidium (Rb-81) *	--	1×10^{-2}
(Rb-83) *	--	1.8×10^{-4}
(Rb-84) *	--	1.4×10^{-4}
Ruthenium (Ru-97)	--	4×10^{-4}
Samarium (Sm-153)	--	8×10^{-4}
Scandium (Sc-48)	--	3×10^{-4}
Silver (Ag-105)	--	1×10^{-3}
(Ag-111)	--	4×10^{-4}
Sodium (Na-22) *	--	1.2×10^{-4}
Tantalum (Ta-179) *	--	6×10^{-3}
Technetium (Tc-96)	--	1×10^{-3}
Thallium (Tl-200)	--	4×10^{-3}
(Tl-201)	--	3×10^{-3}
(Tl-202)	--	1×10^{-3}

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** Thorium (Th-228) *	--	4 x 10 ^{<-6>}
(Th-230) *	--	2 x 10 ^{<-6>}
(Th-232) *	--	6 x 10 ^{<-7>}
(Th-234) *	--	1 x 10 ^{<-4>}
Thulium (Tm-170)	--	5 x 10 ^{<-4>}
Tungsten (Wolfram)	--	4 x 10 ^{<-3>}
(W-181)		
** Uranium (U-234) *	--	6 x 10 ^{<-6>}
(U-235) *	--	6 x 10 ^{<-6>}
(U-238) *	--	6 x 10 ^{<-6>}
Vanadium (V-48)	--	3 x 10 ^{<-4>}
Yttrium (Y-88) *	--	2 x 10 ^{<-4>}
(Y-92)	--	6 x 10 ^{<-4>}
Zinc (Zn-69m)	--	7 x 10 ^{<-4>}
Any other beta/gamma emitter with half-life <3 years	1 x 10 ^{<-10>}	1 x 10 ^{<-6>}

* The values for those [NARM] diffuse naturally occurring radioactive materials [nuclides] and diffuse accelerator produced radioactive materials , including TENORM, that are followed by a single asterisk(*) are based upon multiplying 20 times the most restrictive release concentrations specified in 10 CFR 20 Appendix B, Table 2, Columns 1 (air) and 2 (water).

** These concentrations do not apply to source material [as defined by the

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NRC] for thorium and uranium.

*** uCi/g for solids

1. -2. (No change.)

(c) If a person manufactures, produces, transfers, distributes or arranges for the distribution, sells, leases, receives, acquires, owns, possesses or uses [NARM] diffuse naturally occurring radioactive materials or diffuse accelerator produced radioactive materials, including TENORM, in quantities less than those listed in N.J.A.C. 7:28-4.5(c), they are exempt from the requirement for a license.

7:28-4.4 Types of licenses for manufacture, production, transfer, distribution or arrangement for distribution, sale, lease, receipt, acquisition, ownership, possession or use of all diffuse naturally occurring or diffuse accelerator produced radioactive materials

(a) General [State] licenses described in N.J.A.C. 7:28-4.5 are effective without the filing of an application with the Department or the issuance of licensing documents to particular persons.

(b) Specific [State] licenses are issued to named persons upon application filed pursuant to the requirements of this subchapter.

7:28-4.5 General licenses for the transfer, distribution or arrangement for distribution, sale, lease, receipt, acquisition, ownership, possession or use of diffuse naturally occurring or diffuse accelerator produced radioactive materials and certain devices and equipment

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(a) Any person who uses, transfers, distributes or arranges for the distribution, sells, leases, receives, acquires, owns or possesses the following devices and equipment incorporating diffuse naturally occurring or diffuse accelerator produced radioactive material, when manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Department, or a specific license of a Federal agency or any other state, shall be deemed to have a general [State] license:

1. – 3. (No change.)

(b) The devices described in (a) above shall not be transferred, abandoned or disposed of except by transfer to a person duly authorized to receive such device by a specific [State] license issued by the Department, a Federal agency, or any other state.

(c) The following quantities of radioactive substances, when obtained from diffuse naturally occurring materials or [when produced by an] diffuse accelerator produced radioactive materials, are generally licensed provided that no person shall at any one time possess or use more than a total of 10 such quantities:

Radioactive Material	Column A Not as a Sealed Source (microcuries)	Column B As a Sealed Source (microcuries)
Beryllium (Be-7)	50	50
Bismuth 207 (Bi-207)	1	10
Cadmium 109-Silver 109 (Cd 109 + Ag 109)	10	10
Cerium 141 (Ce-141)	1	10
Chromium 51 (Cr-51)	50	50
Cobalt 57 (Co-57)	20	20

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Germanium 68 (Ge-68)	1	10
Iron 55 (Fe-55)	50	50
Manganese 52 (Mn-52)	1	10
Polonium 210 (Po-210)	0.1	1
Radium and daughters	0.1	1
Sodium 22 (Na-22)	10	10
Vanadium 48 (V-48)	1	10
Zinc 65 (Zn-65)	10	10
Beta and/or gamma emitting radioactive material not listed above	1	10

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

(f) Persons who transfer, distribute or arrange for the distribution, sell, lease, receive, acquire, own, possess or use items and quantities of radioactive materials set forth in N.J.A.C. 7:28-4.5(a) and (c) pursuant to a general [State] license shall not:

1. – 4. (No change.)

(g) Persons who receive, acquire, possess or use a device pursuant to a general license specified in N.J.A.C. 7:28-4.5(a):

1. – 2. (No change.)

3. Shall have the device tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at intervals not to exceed six months [except that devices containing only tritium need not be tested for any purpose and devices containing only krypton need not be tested for leakage];

4. – 6. (No change.)

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7. Shall be exempt from the requirements of this subchapter, except the provisions of N.J.A.C. 7:28-4.4(a), 4.9, 4.14, 4.[18]19, [8.2, 8.4, and 13] records of surveys, records of radioactive materials, and reports of theft, loss, or incidents pursuant to the requirements in N.J.A.C. 7:28-6, Standards for protection against radiation.

7:28-4.6 Application for and renewal of specific [State] licenses for manufacture, transfer, distribution or arrangement for distribution, sale, lease, receipt, acquisition, ownership, possession or use of diffuse naturally occurring or diffuse accelerator produced radioactive materials

(a) Upon approval of an initial or renewal application, a specific [State] license may be issued by the Department for a period of [five] ten years commencing on the date the license is issued.

(b) Application for specific [State] licenses and renewals shall be filed with the Department, on forms available from the Department.

(c) All applications shall contain the following signature and certification:

1. "I certify under penalty of law that the information provided in this document is true, accurate and complete. I am aware that there are significant civil and criminal penalties for submitting false, inaccurate or incomplete information, including fines and/or imprisonment."

2. The certification shall be signed by the highest ranking corporate, partnership, or governmental officer or official at the facility or the individual for which or for whom the specific [State] license is requested.

(d) An application for a specific [State] license may include a request for a [State] license authorizing one or more activities.

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[(e)] Subject to the provisions of N.J.A.C. 7:28-4.7 and 4.8, an application for a specific State license for any human use or uses of radioactive material specified in one or more of the Human Use activity Groups I to VI inclusive listed in N.J.A.C. 7:28-4.7(b) may be approved for all of the uses within the group or groups which include the use or uses specified in the application.]

[(f)] (e) Information included in the specific [State] license application will be incorporated in and made a part of the terms and conditions of such license by reference.

[(g)] (f) All applicants for initial and renewal applications for specific [State] licenses shall complete the application in its entirety with no reference to previously filed documents. The Department may accept photocopies of previous relevant applications.

[(h)] (g) No initial or renewal specific [State] licenses shall be issued unless the appropriate annual license fee required by N.J.A.C. 7:28-[4.18]64.4 is paid.

[(i)] (h) Except as provided in N.J.A.C. 7:28-4.[20]19, applications and documents submitted to the Department will be made available for public inspection.(No change.)

[(j)] (i) Upon the request of the Department at any time after the filing of the original or renewal specific [State] license application, and before the expiration of the license, the applicant shall submit further information to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

[(k)] (j) All applications for a [State] license or amendment shall be signed by the applicant or [State] licensee or a person duly authorized to act for and on his behalf.

[(l)] (k) The Department may deny an application for a specific [State] license if the applicant:

1. – 3. (No change.)

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7:28-4.7 General requirements for approval of an application for an initial specific [State] license or renewal of a specific [State] license for use of diffuse naturally occurring or diffuse accelerator produced materials

(a) If the Department determines that an applicant meets the requirements of this subchapter and the Act, it may issue an initial specific [State] license or renew a specific [State] license for non-human use of radioactive materials provided:

1. – 3. (No change.)

[(b) If the Department determines that an applicant meets the requirements of this subchapter and the Act, it may issue an initial specific State license or renew a specific State license for human use of radioactive materials for one or more of the following Human Use Groups of activities:

1. Group I: Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies;

2. Group II: Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies;

3. Group III: Use of generators and reagent kits for the preparation and use of radiopharmaceuticals for certain diagnostic studies;

4. Group IV: Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety;

5. Group V: Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety; and

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6. Group VI: Use of sources and devices containing radionuclides for certain medical uses.

(c) To qualify for an initial specific State license or renewal of a specific State license for human use of radioactive materials for any purpose described in Groups I through VI in (b) above, the applicant must demonstrate qualification by reason of training and experience to use the radioactive material for the purpose requested and in such manner as to protect health, minimize danger to life or property, and prevent unnecessary radiation, by satisfying the training and experience requirements for the appropriate Human Use Group of activities as follows:

1. The training and experience must have been obtained within a five year period preceding the date of the application for an initial or renewal specific State license or must be supplemented by continuing education or experience. The original training and experience should have been received in a formal residency program in an accredited medical institution. Each applicant's training and experience are examined on a case-by-case basis. If an applicant wishes to use radiopharmaceuticals but does not have the training and experience described, the applicant may submit an application listing specific qualifications and these will be considered by the Department.

2. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Human Use Groups I, II, and/or III, an applicant shall have all the training and experience specified in (c)2i, ii and iii below;

- i. Two hundred hours training in basic radioisotope handling techniques applicable to the use of unsealed sources. This training shall consist of lectures, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory (that is, on-the-job

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training in a formalized training program) in the following areas and for the specific hours of class, laboratory or clinical experience:

- (1) Radiation physics and instrumentation (100 hours);
- (2) Radiation protection (30 hours);
- (3) Mathematics pertaining to the use and measurement of radioactivity (20 hours);
- (4) Radiation biology (20 hours); and
- (5) Radiopharmaceutical chemistry (30 hours);

ii. Five hundred hours of experience with the types and quantities of radioactive material for which the application is being made. For authorization of Human Use Group III (generators and reagent kits), this experience shall include personal participation in five elution procedures, including testing of eluate, and in five procedures to prepare radiopharmaceuticals from Human Use Group III reagent kits; and

iii. Five hundred hours of supervised clinical training in an institutional nuclear medicine program. The clinical training shall cover all appropriate types of diagnostic procedures and shall include:

- (1) Supervise examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed;
- (2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data;
- (3) Follow-up of patients when required; and

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(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

3. The requirements specified in (c)2i, ii and iii above may be satisfied concurrently in a three month training program if all three areas are integrated into the program.

4. Certification by the American Board of Nuclear Medicine, or the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology, will be accepted as evidence that an applicant has had adequate training and experience to use Human Use Groups I, II, and III as specified in (c)2i, ii and iii above.

5. An applicant who wishes to be authorized for only one or two specific diagnostic procedures shall have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested. Such requests will be examined on a case-by-case basis by the Department.

6. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups IV and or V, an applicant shall have:

i. Eighty hours training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups or supervised experience in the following areas and for the following specific hours:

(1) Radiation physics and instrumentation (25 hours);

(2) Radiation protection (25 hours);

(3) Mathematics pertaining to the use and measurement of radioactivity (10 hours); and

(4) Radiation biology (20 hours);

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7. To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group VI an applicant shall have:

i. Two hundred hours training in basic radioisotope handling techniques applicable to the use of sealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas and for the following specified hours:

(1) Radiation physics and instrumentation (110 hours);

(2) Radiation protection (40 hours);

(3) Mathematics pertaining to the use and measurements of radioactivity (25 hours); and

(4) Radiation biology (25 hours);

ii. Five hundred hours experience with the types and quantities of radioactive material for which the application is made;

iii. Clinical training in Group VI procedures consisting of active practice in therapeutic radiology with a minimum of three years experience of which at least one year shall have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education; and

iv. Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR), or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the training required in (c)7i and iii above.

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8. In addition to the training required by (c)7 above, an applicant for a specific State license for Human Use Group VI activities shall demonstrate that its proposed equipment, facilities and procedures are adequate to protect health, minimize danger to life or property and prevent unnecessary radiation; and

9. An applicant for a specific State license for Human Use Group VI activities shall satisfy special requirements as may be applicable in N.J.A.C. 7:28-4.8.]

7:28-4.8 Special requirements for approval of an application for an initial specific [State] license or renewal of a specific [State] license for use of diffuse naturally occurring or diffuse accelerator produced radioactive materials

[(a) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of radioactive materials by an institution provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has appointed a medical isotopes committee to evaluate all proposals for research, diagnosis, and therapeutic use of radioactive material within that institution. Membership of the committee shall include one authorized user for each type of use permitted by the specific State license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer;

3. The applicant possesses adequate facilities for the clinical care of patients;

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4. The physician(s) designated on the application as the individual user(s) has considerable pertinent training and experience in the use, handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

5. If the application is for a specific State license to use unspecified quantities of multiple types of radioactive materials, the applicant's staff has had substantial pertinent experience in using a variety of radioactive materials for various human uses.

(b) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of radioactive materials by a physician or dentist provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patient whenever it is advisable; and

3. The applicant has had extensive training and supervised experience in the proposed use, the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients. The applicant shall furnish suitable evidence of such experience with his application. A statement from the institution where the applicant acquired the training and experience, indicating its amount and nature, may be submitted as evidence of such experience.

(c) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for human use of a sealed source of radioactive materials provided:

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1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant or, if the application is made by an institution, the individual user(s) has specialized training in therapeutic use of the radioactive device considered or has experience equivalent to such training; and

3. The individual user is a physician or dentist.]

[(d)] (a) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific [State] license or renewal of a specific [State] license may be issued for use of multiple quantities or types of radioactive material [in research and development] provided:

1. The applicant satisfies the general requirements for approval of specific [State] license applications in N.J.A.C. 7:28-4.7;

2. – 4. (No change.)

[(e)] (b) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific [State] license or renewal of a specific [State] license may be issued for use of multiple quantities or types of radioactive material in processing for distribution to other authorized persons provided:

1. The applicant satisfies the general requirements for approval of specific [State] license application in N.J.A.C. 7:28-4.7;

2. – 3. (No change.)

[(f)] (c) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific [State] license or renewal of a specific [State] license may

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be issued to distribute certain devices to persons generally licensed under N.J.A.C. 7:28-4.5(a) and (e) provided:

1. The applicant satisfies the general requirements for approval of specific [State] license applications in N.J.A.C. 7:28-4.7;

2. The applicant submits sufficient information relating to the design, manufacturer prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:

i. (No change.)

ii. No person possessing, using, transporting or exposed to the device will receive a radiation dose to a major portion of his body in excess of [0.5] 0.1 rem in any one year under ordinary circumstances of use;

iii.-iv. (No change.)

3. (No change.)

[(g) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued for use of a sealed source or sources of radioactive materials in industrial and nonmedical radiography provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

2. The applicant has an adequate program for training radiographers and radiographers' assistants and submits to the Department a schedule or description of such program which specifies the following:

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i. Initial training;

ii. Periodic training;

iii. On-the-job training;

iv. Means to be used by the specific [State] licensee to determine the

radiographer's knowledge and understanding of and ability to comply with the requirements of this subchapter, the specific licensing requirements, and the operation and emergency instructions of the applicant; and

v. Means to be used by the specific State licensee to determine the

radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

3. The applicant has established and submitted to the Department satisfactory written operating and emergency instructions as prescribed by N.J.A.C. 7:28-17;

4. The applicant will have an adequate internal inspection system, or other management control, providing assurance that the requirements of this chapter, the specific State license provisions, and the applicant's operating and emergency instructions are followed by radiographers and radiographers' assistants;

5. The applicant submits a description of its overall organizational structure pertaining to the radiography program, including specified delegation of authority and responsibility for operation of the program; and

6. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Department a description of such procedures, including:

i. Instrumentation to be used;

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ii. Method of performing test (for example, points on equipment from where wipe samples will be taken and method of obtaining the wipe sample); and

iii. Pertinent experience of the person who will perform the test.]

[(h)] (d) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific [State] license or renewal of a specific [State] license will be issued to transfer, possess, or control products or materials containing exempt concentrations of radioactive material specified in N.J.A.C. 7:28-4.3(b) which the transferor has introduced into the product or material provided:

1. The applicant satisfies the general requirements for approval of specific [State] license applications in N.J.A.C. 7:28-4.7;

2. –3. (No change.)

4. Within 30 days subsequent to the end of the reporting period, each specific [State] licensee shall file an annual report with the Department describing kinds and quantities of products transferred, the concentration of radioactive material contained and the quantity of radioactive material transferred during the reporting period which shall be the 12-month period ending June 30 of each calendar year.

[(i) If the Department determines that an applicant meets the requirements of this subchapter and the Act, an initial specific State license or renewal of a specific State license may be issued to distribute certain devices to persons specifically licensed under N.J.A.C. 7:28-4.7 provided:

1. The applicant satisfies the general requirements for approval of specific State license applications in N.J.A.C. 7:28-4.7;

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2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling, proposed uses and potential hazards of the device to provide reasonable assurance that:

- i. The radioactive material contained in the device cannot be easily removed;
- ii. The device can be safely operated by persons having trained in radiological protection; and
- iii. The radioactive material within the device would not be accessible to unauthorized persons; and

3. Each device distributed as authorized by such specific State license is to bear a label containing the following or substantially similar statements:

- i. "Caution: Radioactive Materials";
- ii. The isotope name;
- iii. The isotope quantity and date; and
- iv. The following statement:

"This device contains radioactive material and has been manufactured for distribution as a specifically State licensed device pursuant to

.....

(identify appropriate section of the regulation)

.....

(name of licensing agency and state)

License No. by(name of supplier)

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Disposal of this device shall conform to the requirements listed in N.J.A.C. 7:28-4.5(g)6ii of the Radiation Protection Code. Removal of this label is prohibited."]

7:28-4.9 Terms and conditions of general and specific [State] licenses

(a) Each [State] license issued pursuant to this subchapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to this chapter and orders of the Department.

(b) No [State] license to possess or utilize radioactive material pursuant to this subchapter shall be transferred or assigned.

(c) Each person licensed by the Department pursuant to this subchapter shall confine his or her possession and use of radioactive material to the locations and purposes authorized by such [State] license, and shall not use or permit the use of radioactive materials contrary to the applicable requirements of this chapter. Persons licensed under the provisions of this subchapter may transfer radioactive material within the State only to the persons licensed to receive such material or as otherwise authorized by the Department in writing.

(d) The Department may incorporate in any [State] license at the time of issuance, or thereafter, all such additional requirements and conditions with respect to the [State] licensee's manufacture, distribution or arrangement for the distribution, sale, lease, receipt, possession, use, ownership or transfer of radioactive material as it deems appropriate or necessary in order to assure compliance with this chapter and the Act.

(e) Each [State] licensee authorized under N.J.A.C. 7:28-4.8[(f)] (c) to distribute certain devices to generally licensed persons shall:

1. (No change.)

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2. Furnish to each general licensee to whom such device is transferred a copy of N.J.A.C. 7:28-4.5(a), (e) and (g), 8.[2]3 and 8.[4]5, records of surveys and records of radioactive materials pursuant to the requirements in N.J.A.C. 7:28-6, Standards for protection against radiation.

[(f) Each State licensee authorized under N.J.A.C. 7:28-4.8(i) to distribute certain devices to specifically licensed persons shall:

1. Report to the Department all transfers of such devices to persons in New Jersey specifically licensed under N.J.A.C. 7:28-4.7 and 4.8. Such report shall identify each specific licensee by name and address, the type and number of device(s) transferred, and the quantity and kind of radioactive material contained in each device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to specifically licensed persons.]

7:28-4.10 Expiration of specific [State] license

Except as provided in N.J.A.C. 7:28-4.11, each specific [State] license shall expire at 12:01 A.M. of the day, in the month and year stated in the license.

7:28-4.11 Status of specific [State] licenses pending renewal

In any case in which a specific [State] licensee has filed a complete application in proper form for renewal of a specific [State] license not less than 30 days prior to expiration of the existing

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specific [State] license, such specific [State] license and all its existing conditions shall not expire until the Department has acted upon the application.

7:28-4.12 Amendment of a specific [State] license at request of licensee

(a) Applications for amendment of a specific [State] license shall be filed in accordance with N.J.A.C. 7:28-4.6 and shall specify the amendment desired and the grounds for such amendment.

(b) The Department will evaluate only amendment applications submitted by personnel authorized by the [State] licensee.

(c) The applicant for an amended specific [State] license shall not engage in the activities for which an amendment has been requested until approval has been granted by the Department.

7:28-4.13 Records

All persons licensed pursuant to this subchapter shall keep records in accordance with N.J.A.C. 7:28-[8, Records] 6, Standards for protection against radiation.

7:28-4.14 Inspections

(a) All [State] licensees shall allow the Department or its agents to inspect radioactive material and the facilities and premises where radioactive material is used or stored.

(b) (No change.)

(c) Upon request by the Department, or its agents, [State] licensees shall make available for inspection by the Department records kept pursuant to this chapter.

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7:28-4.15 Tests

(a) At the request of the Department or its agents, each [State] licensee shall perform, or allow the Department to perform if the Department so desires, such tests as the Department deems appropriate or necessary for the administration of this subchapter, including tests of the following:

1. – 4. (No change.)

7:28-4.16 Financial assurance and recordkeeping for decommissioning

(a) Except as set forth in (b) below, this section incorporates by reference 10 CFR 30.35 and the Appendices as referenced in 10 CFR 35.

(b) The following provisions of 10 CFR 30.35 are incorporated by reference with the specified changes:

1. "Unsealed byproduct material" and "byproduct material" shall mean "diffuse NARM."

2. "Commission," "Nuclear Regulatory Commission," "U.S. Nuclear Regulatory Commission," and "NRC," shall mean "Department of Environmental Protection;"

3. 10 CFR 30.35(g), replace "Each person licensed under this part or parts 32 through 36 and 39" with "Each person licensed under this subchapter;"

4. 10 CFR 30.35(g), replace "§30.34(b)," with "N.J.A.C. 7:28-4.9;" and

5. 10 CFR 30.35(g)(3)(iv), replace "10 CFR part 20, subpart E," with "N.J.A.C.

7:28-12."

7:28-4.[16]17 Modification, revocation, suspension, and termination of general and specific [State] licenses

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(a) Each general [State] license shall be subject to modification, suspension or revocation by reason of amendments to the Act, adoption of rules by the Commission or the Department, orders issued by the Department pursuant to authority of the Act, or for violation or failure to observe any of the terms and provisions of the Act, [State] license or any rule of the Commission or the Department, or order of the Department.

(b) Each specific [State] license shall be subject to modification, suspension or revocation by reason of:

1. – 3. (No change.)

4. Conditions revealed by the application for a specific [State] license or statement of fact or any report, records or inspection or other means which would warrant the Department to refuse to grant a specific [State] license on an original application;

5. Violation of or failure to observe any of the terms and provisions of the Act or the [State] license, or any rule of the [Commission or] Department or order of the Department;

6. Falsification or misleading statements in any [State] license application;

7. Alteration of [State] licensing document;

8. (No change.)

9. Failure to make timely payment of [State] licensing fees.

(c) If a specific [State] license is not to be renewed or if a [State] licensee requests a termination of its [State] license, the [State] licensee shall furnish to the Department, prior to the expiration date of the [State] license, close-out surveys, wipe tests and/or soil samples demonstrating that the facility meets the requirements of N.J.A.C. 7:28-12. The facility shall also provide a disposition certificate attesting to the disposal of radioactive material.

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7:28-4.[17]18 Requests for an adjudicatory hearing

(a) When the Department denies an initial application for or renewal of a specific [State] license, or determines to modify, revoke, suspend or terminate a general or specific [State] license, the Department shall send a notice of decision to the applicant or licensee by certified mail return receipt requested. The notice shall advise the applicant or licensee of the right to request a contested case hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the New Jersey Uniform Administrative Procedure Rules, N.J.A.C. 1:1-1 et seq. The notice shall include the following information:

1. – 3. (No change.)

4. The requirements for requesting a stay under N.J.A.C. 7:28-4.[18]19.

(b) - (d) (No change.)

7:28-4.[18]19 Requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested

(a)-(f) (No change.)

[7:28-4.19 Specific State license fee schedule for the manufacture, production, transfer, distribution or arrangement for distribution, sale, lease, receipt, acquisition, ownership, possession or use of naturally occurring or accelerator produced radioactive material

(a) The specific State license fee schedule is as follows:

Category	Annual License Fee
----------	-----------------------

1. Radioactive materials license for Human Use Group

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I:

- | | | |
|------|--|-----------|
| i. | Possession of material only; | \$ 350.00 |
| ii. | Administration of less than 10 doses per
year; | \$ 500.00 |
| iii. | Administration of 10 through 49 doses per
year; | \$ 650.00 |
| iv. | Administration of 50 or more doses per year. | \$ 850.00 |

2. Radioactive materials license for Human Use Group

II:

- | | | |
|------|--|-------------|
| i. | Possession of material only; | \$ 350.00 |
| ii. | Administration of less than 200 doses per
year; | \$ 650.00 |
| iii. | Administration of between 200 and 1,499
doses per year: | \$ 1,300.00 |
| iv. | Administration of 1,500 or more doses per
year. | \$ 2,000.00 |

3. Radioactive materials license for Human Use Group

III:

- | | | |
|------|--|-----------|
| i. | Possession of material only; | \$ 350.00 |
| ii. | Administration of less than 200 doses per
year; | \$ 350.00 |
| iii. | Administration of 200 through 999 doses per
year; | \$ 650.00 |

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- iv. Administration of 1,000 or more doses per \$ 850.00
year.
- 4. Radioactive materials license for Human Use Group
IV:
 - i. Possession of material only; \$ 350.00
 - ii. Administration of less than 10 doses per \$ 500.00
year;
 - iii. Administration of 10 through 49 doses per \$ 650.00
year;
 - iv. Administration of 50 or more doses per year. \$ 850.00
- 5. Radioactive materials license for Human Use Group
V:
 - i. Possession of material only; \$ 350.00
 - ii. Administration of less than 10 doses per \$ 500.00
year;
 - iii. Administration of 10 through 49 doses per \$ 650.00
year;
 - iv. Administration of 50 or more doses per year. \$ 850.00
- 6. Radioactive materials license for Human Use Group
VI:
 - i. Possession of material only; \$ 850.00
 - ii. Administration of less than 10 doses per \$ 1,000.00
year;

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- | | | |
|------|--|-------------|
| iii. | Administration of 10 through 49 doses per

year; | \$ 1,150.00 |
| iv. | Administration of 50 or more doses per year. | \$ 1,300.00 |
| 7. | Radioactive material license for commercial

manufacture, processing and/or distribution of

radioactive materials for Human Use. | \$ 4,950.00 |
| 8. | Radioactive materials license for commercial

manufacture, processing and/or distribution of

radioactive materials. | \$ 4,950.00 |
| 9. | Radioactive materials license for radioactive

materials as sealed sources used for calibration

and quality control purposes with a possession

limit of 10 mCi or less. | \$ 1,000.00 |
| 10. | Radioactive materials license for radioactive

materials, as sealed sources used for calibration

and quality control purposes with a possession

limit greater than 10 mCi. | \$ 1,650.00 |
| 11. | Radioactive materials license for radioactive

materials as sealed sources contained in devices

used for analytical purposes with a possession

limit of one mCi or less. | \$ 850.00 |
| 12. | Radioactive materials license for radioactive

materials, except radium-226, as sealed sources, | |

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contained in devices used for analytical purposes

with a possession limit greater than one mCi but

less than or equal to 300 mCi:

- | | | |
|-----|---|-------------|
| i. | A government body, department, agency,
authority, or any other unit of any state,
Federal, county or local government using
X-ray fluorescence devices for lead paint
Analysis | \$ 200.00 |
| ii. | All others | \$ 1,250.00 |
| 13. | Radioactive materials license for radioactive
materials, except radium-226, as sealed sources,
contained in devices used for analytical purposes
with a possession limit of greater than 300 mCi. | \$ 1,650.00 |
| 14. | Radioactive materials license for radioactive
Radium-226, as sealed sources, contained in
Devices used for analytical purposes with
possession limit greater than one mCi but less
than or equal to 50 mCi. | \$ 1,650.00 |
| 15. | Radioactive materials license for radioactive
Radium-226, as sealed sources, contained in
Devices used for analytical purposes with a
possession limit greater than 50 mCi. | \$ 2,500.00 |
| 16. | Radioactive materials license for radioactive | \$ 3,300.00 |

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materials as sealed sources for Non-Medical

Industrial Radiography.

17. Radioactive materials license for radioactive \$ 2,500.00

materials not as sealed sources with a possession

limit of 500 mCi or less.

18. Radioactive materials license for radioactive \$ 3,300.00

materials not as sealed sources with a possession

limit of greater than 500 mCi.

(b) All State licensees shall pay the fees set forth in (a) above by check payable to "Treasurer, State of New Jersey" prior to August 1 of each year.

1. In the event that the fees are paid after August 1, a delinquency fee equal to one-half of the annual State license fee will be imposed. Failure to pay an annual State license fee including any accrued delinquency fees for longer than 90 days after August 1 shall constitute grounds for suspension or revocation of the State license pursuant to N.J.A.C. 7:28-4.16.

2. The annual State license fee shall be mailed to:

State of New Jersey

Department of Environmental Protection

Bureau of Revenue

428 East State Street

PO Box 420

Trenton, New Jersey 08625-0420

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(c) Facilities for which multiple State license categories apply shall be charged the sum of the fees for each of the applicable categories.

(d) The term "doses per year" when used in (a) above means the number of doses of radioactive materials within a category that are administered during the period July 1 to June 30.

(e) The term "human use group" when used in (a) above includes the use of radioactive material for calibration and quality control procedures as well as the administration of radioactive materials to humans.

(f) Fees submitted to the Department are non-refundable.]

SUBCHAPTER 5. CONTROLLED AREAS FOR REGISTRANTS

7:28-5.1 Areas [which must be controlled] that registrants must control

(a) [Except as provided in (b) below, e]Every area in which there is any reasonable possibility of an occupant receiving an exposure dose from radiation [and radioactive material] more than the dose specified in N.J.A.C. 7:28-6 for radiation levels outside a controlled area shall be set apart as a controlled area by any person having possession, custody or control of any ionizing radiation-producing machine [and/or radioactive material].

[(b) All outgoing or incoming shipments of radioactive material shall be transported in conformance with all pertinent U.S. Department of Transportation regulations.]

7:28-5.2 Limitations on controlled areas for registrants

(No change.)

7:28-5.3. Precautionary procedures

(a) Any person having possession, custody or control of any ionizing radiation-producing machine [and/or radioactive material] shall comply with the following precautionary procedures:

1. Area surveys shall be performed in controlled areas and in adjacent areas to insure that exposure levels to individuals conform to N.J.A.C. 7:28-6. The surveys shall be performed in accordance with N.J.A.C. 7:28-7, Radiation Surveys and Personnel Monitoring for Registrants.

[2. Wipe tests shall be performed in areas where unsealed sources are routinely used to insure compliance with the requirements for radioactive contamination control in N.J.A.C. 7:28-9. The wipe tests shall be performed in accordance with N.J.A.C. 7:28-7.]

[3. Personnel surveys shall be performed and documented to insure compliance with N.J.A.C. 7:28-9.]

[4]2. All individuals entering a controlled area shall wear personnel monitoring equipment pursuant to the requirements for the use of personnel monitoring equipment in N.J.A.C. 7:28-7.4

[5]3. Proper and adequate instruction shall be given to all personnel working in controlled areas in the use of necessary safeguards and procedures, and they shall be supplied with such safety devices as may be required.

[6]4. Adequate instructions or an escort shall be provided to all personnel frequenting or visiting controlled areas as shall be necessary to prevent unnecessary exposure.

[7]5. The area shall be posted in accordance with N.J.A.C. 7:28-10.

[7:28-5.4 Termination of controlled areas

Before an area where radioactive materials had been stored, utilized or generated can be reclassified as an uncontrolled area, surveys shall be performed and documented to ensure

compliance with N.J.A.C. 7:28-6 for radiation levels outside of controlled areas. Wipe tests shall be performed and documented in areas where unsealed sources had been used or generated.]

SUBCHAPTER 6. STANDARDS FOR PROTECTION AGAINST RADIATION

7:28-6.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 20.

(b) The Department does not regulate nuclear reactors, special nuclear materials in quantities sufficient to form a critical mass, high-level waste disposal facilities, or byproduct material defined in Section 11e(2) of the Atomic Energy Act of 1954, 42 U.S.C. §2014, as amended. Insofar as the incorporated rules refer to those facilities and/or materials previously referenced, those references are not incorporated, nor do any cross references include those facilities and/or materials.

(c) The following provisions of 10 CFR Part 20 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. 10 CFR 20.1001, Purpose;

2. 10 CFR 20.1002, Scope;

3. 10 CFR 20.1003, Definitions, the following definitions are not incorporated by reference: "act," "Commission," "Department," and "sanitary sewerage system."

4. 10 CFR 20.1007, Communications;

5. 10 CFR 20.1009, Implementation collection requirements: OMB approval;

6. 10 CFR 20.1401, General Provisions and Scope;

7. 10 CFR 20.1402, Radiological criteria for unrestricted use;

8. 10 CFR 20.1403, Criteria for license termination under restricted conditions;

9. 10 CFR 20.1404, Alternate criteria for license termination;

10. 10 CFR 20.1405, Public notification and public participation;

11. 10 CFR 20.2301, Application for exemptions;

12. 10 CFR 20.2401, Violations; and

13. 10 CFR 20.2402, Criminal penalties.

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

1. "Nuclear Regulatory Commission," "NRC," "Commission," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 20 of the Code of Federal Regulations that are incorporated by reference, mean the New Jersey Department of Environmental Protection, except when specifically noted in this subchapter;

2. 10 CFR 20.1003, in the definition of "ALARA," replace "licensed activity" with "licensed or registered activity," and "and licensed materials" with , " licensed materials, and registered ionizing radiation producing machine sources";

3. 10 CFR 20.1003, in the definition of "background radiation," in the first sentence replace "or special nuclear material)" with special nuclear material, or technologically enhanced naturally occurring radioactive material)," and replace in the last sentence "or special nuclear materials regulated by the Commission" with , " or special nuclear materials regulated by the State or the NRC, or diffuse NARM regulated by the State";

4. 10 CFR 20.1003, in the definition of "controlled area," replace "licensee" with "licensee or registrant";

5. 10 CFR 20.1003, in the definition of "declared pregnant woman," replace "licensee" with " licensee or registrant";

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. 10 CFR 20.1003, in the definition of "licensed material," replace "special nuclear material," with "special nuclear material in quantities not sufficient to form a critical mass, diffuse NARM";

8. 10 CFR 20.1003, in the definition of "occupational dose," replace "licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person," with "licensed and unlicensed, or registered or unregistered sources of radiation, whether in possession of the licensee or registrant or other person";

9. 10 CFR 20.1003, in the definition of "public dose," replace "under the control of a licensee," with "under the control of a licensee or registrant.";

10. 10 CFR 20.1003, in the definition of "survey," replace "or other sources of radiation." with , " other sources of radiation, or radiation from ionizing radiation-producing machines." After the last sentence in the definition of "survey," add "For registrants, the survey must be made under the supervision of a qualified individual.";

11. 10 CFR 20.1003, in the definition of "unrestricted area," replace "licensee" with "licensee or registrant";

12. 10 CFR 20.1006, 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,";

13. 10 CFR 20.1201, replace "licensee" with "licensee or registrant," except in 10 CFR 20.1201(e);

14. 10 CFR 20.1207, replace entire section with "The licensee or registrant shall ensure that the annual occupational dose for minors does not exceed 10 percent of the annual dose limits specified for adult workers in 10 CFR 20.1201.”;

15. 10 CFR 20.1208, replace "licensee" with "licensee or registrant”;

16. 10 CFR 20.1301, replace "licensee" with "licensee or registrant;" and replace "sanitary sewer system" with "domestic treatment works”;

17. 10 CFR 20.1301(a)(1), replace "licensed operation" with "licensed or registered operation”;

18. 10 CFR 20.2001(a)(3), replace "within the limits of § 20.1301; or" with "within the limits of § 20.1301, provided prior permission in writing, in the form of a New Jersey Pollutant Discharge Elimination System permit, is obtained from the Department in accordance with N.J.A.C. 7:14A for discharges to ground or surface waters; or”;

19. 10 CFR 20.2003, replace "sanitary sewerage" with "domestic treatment works”;

20. Replace the text of 10 CFR 20.2201(a)(2) with "Reports must be made to the address and telephone numbers indicated in N.J.A.C. 7:28-1.5”;

21. 10 CFR 20.2201(b)(2)(ii), replace "Administrator of the appropriate NRC Regional Office listed in Appendix D to part 20" with "Supervisor, Radioactive Materials Section of the Department”;

22. Replace the text of 10 CFR 20.2202(d) with “Reports made by licensees in response to the requirements of this section must be made to the address and telephone numbers indicated in N.J.A.C. 7:28-1.5.”;

23. 10 CFR 20.2203(b)(2), replace "Privacy Act Information" with "New Jersey Open Public Records Act, N.J.S.A. 47:1A-1 et seq.";

24. Replace the text of 10 CFR 20.2203(d) with "All licensees, who make reports under paragraph (a) of this section shall submit the report in writing either by mail or by hand delivery to the Supervisor, Radioactive Materials Section of the Department at the addresses indicated in N.J.A.C. 7:28-1.5;"

25. 10 CFR 20.2204, replace "Administrator of the appropriate NRC Regional Office listed in Appendix D to part 20" with "Supervisor, Radioactive Materials Section of the Department";

26. 10 CFR 20.2206(c), replace the second sentence with "The licensee shall submit the report to the Supervisor, Radioactive Materials Section of the Department at the address indicated in N.J.A.C. 7:28-1.5."; and

27. Replace the language at 10 CFR 20.2402 with "Section 26:2D-22 of the Radiation Protection Act of 1958, as amended, provides for criminal sanctions for violation of any provision of the Act.

(e) Requests for adjudicatory hearings shall be made in accordance with NJAC 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at NJAC 7:28-4.18.

SUBCHAPTER 7. RADIATION SURVEYS AND PERSONNEL MONITORING FOR REGISTRANTS

7:28-7.1 Surveys inside controlled areas

(a) The [State licensee or] registrant shall ensure that controlled areas shall be surveyed by, or under the direction of, a qualified individual to determine if the installation is maintained and operations are conducted in compliance with this Chapter.

(b) The [State licensee or] registrant shall ensure that radiation levels shall be determined with the use of suitable instruments and methods.

[(c) The State licensee or registrant shall ensure that surveys shall be made of the air for radioactive content when the average concentrations may exceed $\frac{1}{4}$ the amount specified in N.J.A.C. 7:28-6.5(a), Column B, or prorated values when more than one isotope is present.

(d) The State licensee or registrant shall ensure that installations where unsealed radioactive materials are stored or used shall be periodically surveyed for contamination of surfaces. These surveys shall be conducted in a manner to insure that the levels of surface contamination are below those that could lead to exposures amounting to 10 percent of the limits specified in N.J.A.C. 7:28-6.1(a) and (d).]

[(e)](c) The [State licensee or] registrant shall ensure that the record of a survey shall contain, but shall not be limited to the radiation levels, the time the radiation is produced, the workweek and the fraction of the workweek that any individual may be exposed to the radiation [and when required, the radioactive air concentrations and surface contaminations].

[(f)](d) The [State licensee or] registrant shall ensure that subsequent surveys shall be conducted at such times and as frequently as may be necessary to assure that the controlled areas and operations remain in compliance with this Chapter.

7:28-7.2 Surveys outside controlled areas

Surveys shall be made outside controlled areas at sufficient intervals and locations as may be necessary to insure compliance with [Sections 6.2 (Radiation levels outside controlled areas) and 6.3 (Concentrations in effluents from controlled areas)]Subchapter 6 of this Chapter.

7:28-7.3 Statement in lieu of actual survey

A written statement signed by a qualified individual and including his calculations and analysis of the dose rates in the vicinity of a radiation source may be acceptable in place of the survey required in Section 7.1 (Surveys inside controlled areas) of this Chapter[, except when radioactive-air contamination or surface contamination is involved].

[7:28-7.5 Requirements for bio-assays

Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Department may incorporate license provisions or issue an order requiring the owner to have appropriate bio-assays made and to furnish the Department with copies of such bio-assays.]

SUBCHAPTER 8. RECORDS FOR REGISTRANTS

7:28-8.1 Personnel-monitoring records

(a) Clear and legible records shall be maintained by the owner for calendar quarters on Form RH-26, or on a clear and legible form containing all the information required on RH-26. These records shall show the radiation exposures of all individuals who are required to wear personnel-monitoring equipment according to Section 7.4 (Use of personnel-monitoring equipment) of this Chapter [and any required bio-assays according to Section 7.5 (Requirements for bio-assays) of this Chapter].

(b) Each employee, at his request, shall be supplied by the owner with an annual statement of his radiation exposure record [and any bio-assays].

(c) (No change.)

(d) (No change.)

(e) (No change.)

(f) (No change.)

(g) (No change.)

7:28-8.2 Records of surveys

(a) Records shall be maintained showing the results of such surveys as are required pursuant to Subchapter 7 (Radiation Surveys and Personnel Monitoring for Registrants) of this Chapter.

(b) (No change.)

(c) (No change.)

(d) The owner of any installation covered in Subchapters 14 through 16 of this Chapter shall submit to the Department within 30 days of receipt a copy of each report of radiation surveys made

in compliance with Subchapter 7 (Radiation Surveys and Personnel Monitoring for Registrants) of this Chapter.

[7:28-8.3 Records of radioactive materials

(a) An accurate accounting for all radioactive materials shall be maintained for a radiation installation. Such records shall show radioactive materials received, produced, and disposed, the amounts and form of the radioactive material received or produced and the amount on hand.

(b) Such records shall be retained for at least two years after the final disposition of any radioactive material.

(c) These records or true copy of same shall be made available to the Department on request.

7:28-8.4 Records of sealed source testing

Records of the results of sealed source testing shall be kept at least two years.]

7:28-8.[5]3 Records from discontinued installations

(No change.)

SUBCHAPTER 9. (Reserved.)

SUBCHAPTER 10. LABELING, POSTING, AND CONTROLS FOR REGISTRANTS

7:28-10.1 General Requirements

(a) (No change.)

(b) In addition to the language prescribed in the various sections of this Subchapter, any supplementary information which might be appropriate in aiding individuals to minimize exposure to radiation [or to radioactive materials], may be provided on or near such required signs or labels.

[7:28-10.4 Airborne radioactivity areas

(a) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words;

1. CAUTION--AIRBORNE RADIOACTIVITY AREA; or

2. DANGER--AIRBORNE RADIOACTIVITY AREA

7:28-10.5 Areas containing radioactive materials

(a) Each area or room in which radioactive material, other than natural uranium or thorium is used or stored in an amount greater than ten times that listed in Section 10.9 (Labeling, posting and disposal quantities of radioactive material) of this Chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

1. CAUTION--RADIOACTIVE MATERIAL(S); or

2. DANGER--RADIOACTIVE MATERIAL(S)

(b) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity listed in Section 10.9 (Labeling, posting and disposal quantities of

radioactive material) of this Chapter shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

1. CAUTION--RADIOACTIVE MATERIAL(S); or

2. DANGER--RADIOACTIVE MATERIAL(S)]

7:28-10.[6]4 Labeling of equipment [and containers]

[(a) Any equipment or container in which radioactive material, other than natural uranium or thorium, is transported, stored, or used, in an amount greater than that specifically listed in Section 10.9 (Labeling, posting and disposal quantities of radioactive material) of this Chapter shall bear a durable, clearly visible label bearing the radiation caution symbol and the words:

1. CAUTION--RADIOACTIVE MATERIAL; or

2. DANGER--RADIOACTIVE MATERIAL

(b) Each container in which natural uranium or thorium is transported, stored, or used in a quantity greater than 10 times the quantity listed in Section 10.9 (Labeling, posting and disposal quantities of radioactive material) of this Chapter shall bear a durable, clearly visible label bearing the radiation caution symbol and the words:

1. CAUTION--RADIOACTIVE MATERIAL; or

2. DANGER--RADIOACTIVE MATERIAL

(c) Where containers are used for storage, the labels required in this Section shall state also the quantities and kinds of radioactive materials in the containers and the date of measurement of the quantities.]

[(d)] All ionizing radiation-producing machines capable, when operated, of producing a radiation area shall be labeled in a manner which cautions individuals of this fact.

7:28-10.[7]5 Removal of signs and labels

All radiation caution signs and labels which may have been posted at a time when they were required shall be removed when the condition which originally required the posting no longer exists.

7:28-10.[8]6 Exceptions from posting and labeling requirements

(a) Radiation areas and high radiation areas which result from the operation of therapeutic x-ray machines operated at potentials of 60 kv and below or from the operation of diagnostic x-ray machines shall be exempt from the posting requirements of Sections 10.2, 10.3 and 10.[6]4[(d)] of this Chapter provided that the operator of the equipment has taken precautions to insure that no individual other than the patient shall be in the radiation area.

[(b)] Rooms or other areas in hospitals are not required to be posted with radiation caution signs because of the presence of patients containing radioactive material provided that there are personnel in attendance who shall take the precautions necessary to prevent the exposure of any individual other than the patient to radiation or radioactive material in excess of the limits established in this Chapter.

(c) A room or area is not required to be posted with a radiation caution sign because of the presence of a sealed source provided the radiation level 12 inches from the surface of the source container or source housing does not exceed five millirems per hour.

(d) Radiation caution signs are not required to be posted at areas or rooms containing radioactive materials for periods of less than eight hours provided that:

1. The materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any other individual to radiation or radioactive materials in excess of the limits established in these regulations; and

2. Such area or room is subject to the user's control.

(e) Laboratory containers such as beakers, flasks and test tubes need not be labeled if they are being used transiently in laboratory procedures when the user is present.

(f) A container in which radioactive material is transported, stored, or used need not be labeled, if the concentration of the material in the container does not exceed that specified in Section 6.5(a) (Average concentrations) of this Chapter, Column A.

(g) Radioactive materials packaged and labeled in accordance with regulations of the appropriate Federal agency shall be exempt from the labeling and posting requirements of this Section during shipment, provided that the inside containers are labeled in accordance with the provisions of Section 10.6 (Labeling of equipment and containers) of this Chapter.

7:28-10.[9] Quantities of radioactive materials that require labeling and posting

(a) The quantities of radioactive material subject to all labeling and posting regulations in atomic number order are as follows:

Quantities of Licensed or Registered Material Requiring Labeling

(In Atomic Number Order)

Radionuclide	Quantity (uCi)
Hydrogen-3	1,000
Beryllium-7	1,000
Beryllium-10	1
Carbon-11	1,000
Carbon-14	100
Fluorine-18	1,000
Sodium-22	10
Sodium-24	100
Magnesium-28	100
Aluminum-26	10
Silicon-31	1,000
Silicon-32	1
Phosphorus-32	10
Phosphorus-33	100
Sulfur-35	100
Chlorine-36	10

Chlorine-38	1,000
Chlorine-39	1,000
Argon-39	1,000
Argon-41	1,000
Potassium-40	100
Potassium-42	1,000
Potassium-43	1,000
Potassium-44	1,000
Potassium-45	1,000
Calcium-41	100
Calcium-45	100
Calcium-47	100
Scandium-43	1,000
Scandium-44m	100
Scandium-44	100
Scandium-46	10
Scandium-47	100
Scandium-48	100
Scandium-49	1,000
Titanium-44	1
Titanium-45	1,000
Vanadium-47	1,000
Vanadium-48	100

Vanadium-49	1,000
Chromium-48	1,000
Chromium-49	1,000
Chromium-51	1,000
Manganese-51	1,000
Manganese-52m	1,000
Manganese-52	100
Manganese-53	1,000
Manganese-54	100
Manganese-56	1,000
Iron-52	100
Iron-55	100
Iron-59	10
Iron-60	1
Cobalt-55	100
Cobalt-56	10
Cobalt-57	100
Cobalt-58m	1,000
Cobalt-58	100
Cobalt-60m	1,000
Cobalt-60	1
Cobalt-61	1,000
Cobalt-62m	1,000

Nickel-56	100
Nickel-57	100
Nickel-59	100
Nickel-63	100
Nickel-65	1,000
Nickel-66	10
Copper-60	1,000
Copper-61	1,000
Copper-64	1,000
Copper-67	1,000
Zinc-62	100
Zinc-63	1,000
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zinc-71m	1,000
Zinc-72	100
Gallium-65	1,000
Gallium-66	100
Gallium-67	1,000
Gallium-68	1,000
Gallium-70	1,000
Gallium-72	100

Gallium-73	1,000
Germanium-66	1,000
Germanium-67	1,000
Germanium-68	10
Germanium-69	1,000
Germanium-71	1,000
Germanium-75	1,000
Germanium-77	1,000
Germanium-78	1,000
Arsenic-69	1,000
Arsenic-70	1,000
Arsenic-71	100
Arsenic-72	100
Arsenic-73	100
Arsenic-74	100
Arsenic-76	100
Arsenic-77	100
Arsenic-78	1,000
Selenium-70	1,000
Selenium-73m	1,000
Selenium-73	100
Selenium-75	100
Selenium-79	100

Selenium-81m	1,000
Selenium-81	1,000
Selenium-83	1,000
Bromine-74m	1,000
Bromine-74	1,000
Bromine-75	1,000
Bromine-76	100
Bromine-77	1,000
Bromine-80m	1,000
Bromine-80	1,000
Bromine-82	100
Bromine-83	1,000
Bromine-84	1,000
Krypton-74	1,000
Krypton-76	1,000
Krypton-77	1,000
Krypton-79	1,000
Krypton-81	1,000
Krypton-83m	1,000
Krypton-85m	1,000
Krypton-85	1,000
Krypton-87	1,000
Krypton-88	1,000

Rubidium-79	1,000
Rubidium-81m	1,000
Rubidium-81	1,000
Rubidium-82m	1,000
Rubidium-83	100
Rubidium-84	100
Rubidium-86	100
Rubidium-87	100
Rubidium-88	1,000
Rubidium-89	1,000
Strontium-80	100
Strontium-81	1,000
Strontium-83	100
Strontium-85m	1,000
Strontium-85	100
Strontium-87m	1,000
Strontium-89	10
Strontium-90	0.1
Strontium-91	100
Strontium-92	100
Yttrium-86m	1,000
Yttrium-86	100
Yttrium-87	100

Yttrium-88	10
Yttrium-90m	1,000
Yttrium-90	10
Yttrium-91m	1,000
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Yttrium-94	1,000
Yttrium-95	1,000
Zirconium-86	100
Zirconium-88	10
Zirconium-89	100
Zirconium-93	1
Zirconium-95	10
Zirconium-97	100
Niobium-88	1,000
Niobium-89m (66 min)	1,000
Niobium-89 (122 min)	1,000
Niobium-90	100
Niobium-93m	10
Niobium-94	1
Niobium-95m	100
Niobium-95	100

Niobium-96	100
Niobium-97	1,000
Niobium-98	1,000
Molybdenum-90	100
Molybdenum-93m	100
Molybdenum-93	10
Molybdenum-99	100
Molybdenum-101	1,000
Technetium-93m	1,000
Technetium-93	1,000
Technetium-94m	1,000
Technetium-94	1,000
Technetium-96m	1,000
Technetium-96	100
Technetium-97m	100
Technetium-97	1,000
Technetium-98	10
Technetium-99m	1,000
Technetium-99	100
Technetium-101	1,000
Technetium-104	1,000
Ruthenium-94	1,000
Ruthenium-97	1,000

Ruthenium-103	100
Ruthenium-105	1,000
Ruthenium-106	1
Rhodium-99m	1,000
Rhodium-99	100
Rhodium-100	100
Rhodium-101m	1,000
Rhodium-101	10
Rhodium-102m	10
Rhodium-102	10
Rhodium-103m	1,000
Rhodium-105	100
Rhodium-106m	1,000
Rhodium-107	1,000
Palladium-100	100
Palladium-101	1,000
Palladium-103	100
Palladium-107	10
Palladium-109	100
Silver-102	1,000
Silver-103	1,000
Silver-104m	1,000
Silver-104	1,000

Silver-105	100
Silver-106m	100
Silver-106	1,000
Silver-108m	1
Silver-110m	10
Silver-111	100
Silver-112	100
Silver-115	1,000
Cadmium-104	1,000
Cadmium-107	1,000
Cadmium-109	1
Cadmium-113m	0.1
Cadmium-113	100
Cadmium-115m	10
Cadmium-115	100
Cadmium-117m	1,000
Cadmium-117	1,000
Indium-109	1,000
Indium-110 (69.1 min.)	1,000
Indium-110 (4.9 h)	1,000
Indium-111	100
Indium-112	1,000
Indium-113m	1,000

Indium-114m	10
Indium-115m	1,000
Indium-115	100
Indium-116m	1,000
Indium-117m	1,000
Indium-117	1,000
Indium-119m	1,000
Tin-110	100
Tin-111	1,000
Tin-113	100
Tin-117m	100
Tin-119m	100
Tin-121m	100
Tin-121	1,000
Tin-123m	1,000
Tin-123	10
Tin-125	10
Tin-126	10
Tin-127	1,000
Tin-128	1,000
Antimony-115	1,000
Antimony-116m	1,000
Antimony-116	1,000

Antimony-117	1,000
Antimony-118m	1,000
Antimony-119	1,000
Antimony-120 (16 min.)	1,000
Antimony-120 (5.76 d)	100
Antimony-122	100
Antimony-124m	1,000
Antimony-124	10
Antimony-125	100
Antimony-126m	1,000
Antimony-126	100
Antimony-127	100
Antimony-128 (10.4 min.)	1,000
Antimony-128 (9.01 h)	100
Antimony-129	100
Antimony-130	1,000
Antimony-131	1,000
Tellurium-116	1,000
Tellurium-121m	10
Tellurium-121	100
Tellurium-123m	10
Tellurium-123	100
Tellurium-125m	10

Tellurium-127m	10
Tellurium-127	1,000
Tellurium-129m	10
Tellurium-129	1,000
Tellurium-131m	10
Tellurium-131	100
Tellurium-132	10
Tellurium-133m	100
Tellurium-133	1,000
Tellurium-134	1,000
Iodine-120m	1,000
Iodine-120	100
Iodine-121	1,000
Iodine-123	100
Iodine-124	10
Iodine-125	1
Iodine-126	1
Iodine-128	1,000
Iodine-129	1
Iodine-130	10
Iodine-131	1
Iodine-132m	100
Iodine-132	100

Iodine-133	10
Iodine-134	1,000
Iodine-135	100
Xenon-120	1,000
Xenon-121	1,000
Xenon-122	1,000
Xenon-123	1,000
Xenon-125	1,000
Xenon-127	1,000
Xenon-129m	1,000
Xenon-131m	1,000
Xenon-133m	1,000
Xenon-133	1,000
Xenon-135m	1,000
Xenon-135	1,000
Xenon-138	1,000
Cesium-125	1,000
Cesium-127	1,000
Cesium-129	1,000
Cesium-130	1,000
Cesium-131	1,000
Cesium-132	100
Cesium-134m	1,000

Cesium-134	10
Cesium-135m	1,000
Cesium-135	100
Cesium-136	10
Cesium-137	10
Cesium-138	1,000
Barium-126	1,000
Barium-128	100
Barium-131m	1,000
Barium-131	100
Barium-133m	100
Barium-133	100
Barium-135m	100
Barium-139	1,000
Barium-140	100
Barium-141	1,000
Barium-142	1,000
Lanthanum-131	1,000
Lanthanum-132	100
Lanthanum-135	1,000
Lanthanum-137	10
Lanthanum-138	100
Lanthanum-140	100

Lanthanum-141	100
Lanthanum-142	100
Cerium-137m	100
Cerium-137	1,000
Cerium-139	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Praseodymium-136	1,000
Praseodymium-137	1,000
Praseodymium-138m	1,000
Praseodymium-139	1,000
Praseodymium-142m	1,000
Praseodymium-142	100
Praseodymium-143	100
Praseodymium-144	1,000
Praseodymium-145	100
Praseodymium-147	1,000
Neodymium-136	1,000
Neodymium-138	100
Neodymium-139m	1,000
Neodymium-139	1,000
Neodymium-141	1,000

Neodymium-147	100
Neodymium-149	1,000
Neodymium-151	1,000
Promethium-141	1,000
Promethium-143	100
Promethium-144	10
Promethium-145	10
Promethium-146	1
Promethium-147	10
Promethium-148m	10
Promethium-148	10
Promethium-149	100
Promethium-150	1,000
Promethium-151	100
Samarium-141m	1,000
Samarium-141	1,000
Samarium-142	1,000
Samarium-145	100
Samarium-146	1
Samarium-147	100
Samarium-151	10
Samarium-153	100
Samarium-155	1,000

Samarium-156	1,000
Europium-145	100
Europium-146	100
Europium-147	100
Europium-148	10
Europium-149	100
Europium-150 (12.62 h)	100
Europium-150 (34.2 y)	1
Europium-152m	100
Europium-152	1
Europium-154	1
Europium-155	10
Europium-156	100
Europium-157	.100
Europium-158	1,000
Gadolinium-145	1,000
Gadolinium-146	10
Gadolinium-147	100
Gadolinium-148	0.001
Gadolinium-149	100
Gadolinium-151	10
Gadolinium-152	100
Gadolinium-153	10

Gadolinium-159	100
Terbium-147	1,000
Terbium-149	100
Terbium-150	1,000
Terbium-151	100
Terbium-153	1,000
Terbium-154	100
Terbium-155	1,000
Terbium-156m (5.0 h)	1,000
Terbium-156m (24.4 h)	1,000
Terbium-156	100
Terbium-157	10
Terbium-158	1
Terbium-160	10
Terbium-161	100
Dysprosium-155	1,000
Dysprosium-157	1,000
Dysprosium-159	100
Dysprosium-165	1,000
Dysprosium-166	100
Holmium-155	1,000
Holmium-157	1,000
Holmium-159	1,000

Holmium-161	1,000
Holmium-162m	1,000
Holmium-162	1,000
Holmium-164m	1,000
Holmium-164	1,000
Holmium-166m	1
Holmium-166	100
Holmium-167	1,000
Erbium-161	1,000
Erbium-165	1,000
Erbium-169	100
Erbium-171	100
Erbium-172	100
Thulium-162	1,000
Thulium-166	100
Thulium-167	100
Thulium-170	10
Thulium-171	10
Thulium-172	100
Thulium-173	100
Thulium-175	1,000
Ytterbium-162	1,000
Ytterbium-166	100

Ytterbium-167	1,000
Ytterbium-169	100
Ytterbium-175	100
Ytterbium-177	1,000
Ytterbium-178	1,000
Lutetium-169	100
Lutetium-170	100
Lutetium-171	100
Lutetium-172	100
Lutetium-173	10
Lutetium-174m	10
Lutetium-174	10
Lutetium-176m	1,000
Lutetium-176	100
Lutetium-177m	10
Lutetium-177	100
Lutetium-178m	1,000
Lutetium-178	1,000
Lutetium-179	1,000
Hafnium-170	100
Hafnium-172	1
Hafnium-173	1,000
Hafnium-175	100

Hafnium-177m	1,000
Hafnium-178m	0.1
Hafnium-179m	10
Hafnium-180m	1,000
Hafnium-181	10
Hafnium-182m	1,000
Hafnium-182	0.1
Hafnium-183	1,000
Hafnium-184	100
Tantalum-172	1,000
Tantalum-173	1,000
Tantalum-174	1,000
Tantalum-175	1,000
Tantalum-176	100
Tantalum-177	1,000
Tantalum-178	1,000
Tantalum-179	100
Tantalum-180m	1,000
Tantalum-180	100
Tantalum-182m	1,000
Tantalum-182	10
Tantalum-183	100
Tantalum-184	100

Tantalum-185	1,000
Tantalum-186	1,000
Tungsten-176	1,000
Tungsten-177	1,000
Tungsten-178	1,000
Tungsten-179	1,000
Tungsten-181	1,000
Tungsten-185	100
Tungsten-187	100
Tungsten-188	10
Rhenium-177	1,000
Rhenium-178	1,000
Rhenium-181	1,000
Rhenium-182 (12.7 h)	1,000
Rhenium-182 (64.0 h)	100
n2 Rhenium-183	100
Rhenium-184m	10
Rhenium-184	100
Rhenium-186m	10
Rhenium-186	100
Rhenium-187	1,000
Rhenium-188m	1,000
Rhenium-188	100

Rhenium-189	100
Osmium-180	1,000
Osmium-181	1,000
Osmium-182	100
Osmium-185	100
Osmium-189m	1,000
Osmium-191m	1,000
Osmium-191	100
Osmium-193	100
Osmium-194	1
Iridium-182	1,000
Iridium-184	1,000
Iridium-185	1,000
Iridium-186	100
Iridium-187	1,000
Iridium-188	100
Iridium-189	100
Iridium-190m	1,000
Iridium-190	100
Iridium-192 (73.8 d)	1
Iridium-192m (1.4 min.)	10
Iridium-194m	10
Iridium-194	100

Iridium-195m	1,000
Iridium-195	1,000
Platinum-186	1,000
Platinum-188	100
Platinum-189	1,000
Platinum-191	100
Platinum-193m	100
Platinum-193	1,000
Platinum-195m	100
Platinum-197m	1,000
Platinum-197	100
Platinum-199	1,000
Platinum-200	100
Gold-193	1,000
Gold-194	100
Gold-195	10
Gold-198m	100
Gold-198	100
Gold-199	100
Gold-200m	100
Gold-200	1,000
Gold-201	1,000
Mercury-193m	100

Mercury-193	1,000
Mercury-194	1
Mercury-195m	100
Mercury-195	1,000
Mercury-197m	100
Mercury-197	1,000
Mercury-199m	1,000
Mercury-203	100
Thallium-194m	1,000
Thallium-194	1,000
Thallium-195	1,000
Thallium-197	1,000
Thallium-198m	1,000
Thallium-198	1,000
Thallium-199	1,000
Thallium-200	1,000
Thallium-201	1,000
Thallium-202	100
Thallium-204	100
Lead-195m	1,000
Lead-198	1,000
Lead-199	1,000
Lead-200	100

Lead-201	1,000
Lead-202m	1,000
Lead-202	10
Lead-203	1,000
Lead-205	100
Lead-209	1,000
Lead-210	0.01
Lead-211	100
Lead-212	1
Lead-214	100
Bismuth-200	1,000
Bismuth-201	1,000
Bismuth-202	1,000
Bismuth-203	100
Bismuth-205	100
Bismuth-206	100
Bismuth-207	10
Bismuth-210m	0.1
Bismuth-210	1
Bismuth-212	10
Bismuth-213	10
Bismuth-214	100
Polonium-203	1,000

Polonium-205	1,000
Polonium-207	1,000
Polonium-210	0.1
Astatine-207	100
Astatine-211	10
Radon-220	1
Radon-222	1
Francium-222	100
Francium-223	100
Radium-223	0.1
Radium-224	0.1
Radium-225	0.1
Radium-226	0.1
Radium-227	1,000
Radium-228	0.1
Actinium-224	1
Actinium-225	0.01
Actinium-226	0.1
Actinium-227	0.001
Actinium-228	1
Thorium-226	10
Thorium-227	0.01
Thorium-228	0.001

Thorium-229	0.001
Thorium-230	0.001
Thorium-231	100
n1 Thorium-232	.100
Thorium-234	10
Thorium-natural	100
Protactinium-227	10
Protactinium-228	1
Protactinium-230	0.1
Protactinium-231	0.001
Protactinium-232	1
Protactinium-233	100
Protactinium-234	100
Uranium-230	0.01
Uranium-231	100
Uranium-232	0.001
Uranium-233	0.001
n1 Uranium-234	0.001
n1 Uranium-235	0.001
Uranium-236	0.001
Uranium-237	100
1Uranium-238	100
Uranium-239	1,000

Uranium-240	100
Uranium-natural	100
Neptunium-232	100
Neptunium-233	1,000
Neptunium-234	100
Neptunium-235	100
Neptunium-236 (1.15 x 10 ⁵ y)	0.001
Neptunium-236 (22.5 h)	1
Neptunium-237	0.001
Neptunium-238	10
Neptunium-239	100
Neptunium-240	1,000
Plutonium-234	10
Plutonium-235	1,000
Plutonium-236	0.001
Plutonium-237	100
Plutonium-238	0.001
Plutonium-239	0.001
Plutonium-240	0.001
Plutonium-241	0.01
Plutonium-242	0.001
Plutonium-243	1,000
Plutonium-244	0.001

Plutonium-245	100
Americium-237	1,000
Americium-238	100
Americium-239	1,000
Americium-240	100
Americium-241	0.001
Americium-242m	0.001
Americium-242	10
Americium-243	0.001
Americium-244m	100
Americium-244	10
Americium-245	1,000
Americium-246m	1,000
Americium-246	1,000
Curium-238	100
Curium-240	0.1
Curium-241	1
Curium-242	0.01
Curium-243	0.001
Curium-244	0.001
Curium-245	0.001
Curium-246	0.001
Curium-247	0.001

Curium-248	0.001
Curium-249	1,000
Berkelium-245	100
Berkelium-246	100
Berkelium-247	0.001
Berkelium-249	0.1
Berkelium-250	10
Californium-244	100
Californium-246	1
Californium-248	0.01
Californium-249	0.001
Californium-250	0.001
Californium-251	0.001
Californium-252	0.001
Californium-253	0.1
Californium-254	0.001
Einsteinium-250	100
Einsteinium-251	100
Einsteinium-253	0.1
Einsteinium-254m	1
Einsteinium-254	0.01
Fermium-252	1
Fermium-253	1

Fermium-254	10
Fermium-255	1
Fermium-257	0.01
Mendelevium-257	10
Mendelevium-258	0.01

Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition 0.001

Any radionuclide other than alpha emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition 0.01

These quantities do not apply to source materials as defined by the NRC for thorium and uranium.

The value for Re-183 is actually taken from Re-186. The value for Re-183 could not be calculated due to the fact that Re-183 is not listed in 10 CFR 20, Appendix B.

(b) For purposes of N.J.A.C. 7:28-10.5 and 10.6, where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" (that is, "unity").]

SUBCHAPTER 11 (Reserved.)

SUBCHAPTER 12. REMEDIATION STANDARDS FOR RADIOACTIVE MATERIALS

7:28-12.2 Applicability

(a) The standards and/or dose criteria in this subchapter are applicable to:

1. Remediation of radioactive contamination of real property by any technologically enhanced naturally occurring radioactive materials, source, by-product, certain special nuclear material, and diffuse NARM; and

2. [Remediation of radioactive contamination of real property by accelerator-produced radionuclides; and

3.] Any other remediation of radioactive contamination including, without limitation, any remediation pursuant to: the Spill Compensation and Control Act, N.J.S.A. 58:10-23.11 et seq.; the Water Pollution Control Act, N.J.S.A. 58:10A-1 et seq.; the Industrial Site Recovery Act, N.J.S.A. 13:1K-6 et seq.; the Solid Waste Management Act, N.J.S.A. 13:1E-1 et seq.; the Comprehensive Regulated Medical Waste Management Act, N.J.S.A. 13:1E-48.1 et seq.; the Major Hazardous Waste Facilities Siting Act, N.J.S.A. 13:1E-49 et seq.; the Sanitary Landfill Facility Closure and Contingency Fund Act, N.J.S.A. 13:1E-100 et seq.; the Regional Low Level Radioactive Waste Disposal Facility Siting Act, N.J.S.A. 13:1E-177 et seq.; any law or regulation by which the State may compel a person or licensee to perform remediation activities; or N.J.A.C. 7:26C.

(b) (No change.)

(c) The Department shall apply the radiation [soil] remediation standards and dose criteria in this chapter at applicable sites as "Applicable or Relevant and Appropriate Requirements" as defined in the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9601 et seq.

7:28-12.3 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Appropriate period of time" means the length of time [required for the radionuclide to decay seven half-lives] determined by the Department, taking into consideration the radioactive half-life, total activity, concentration, and physical condition of the residual radioactivity, geologic stability of the area, and current and projected future demographics.

...

"Contaminated site" means a site as defined pursuant to the Technical Requirements for Site Remediation rules at N.J.A.C. 7:26E-1.8.

...

"Engineering controls" means any physical mechanism to contain or stabilize contamination or ensure the effectiveness of a remedial action. Engineering controls under this subchapter may include, without limitation, caps, covers, dikes, trenches, leachate collection systems, radon remediation systems, signs, fences, [and] physical access controls, ground water monitoring systems and ground water containment systems including, without limitation, slurry walls and ground water pumping systems.

...

"Radioactive contamination or radioactive contaminant" means the collective amount of radiation emitted from one or more radionuclides in the soil and in/on building materials and/or equipment at concentrations above natural background levels.

...

"Remediation standards" means the combination of numeric standards that establish a level or concentration, and narrative standards, to which radioactive contaminants must be treated, removed or otherwise cleaned for soil, ground water or surface water, as [provided]established by the Department pursuant to N.J.S.A. 58:10B-12 and this chapter, in order to meet the health risk or environmental standards.

["Residual radionuclides" means the concentration of radionuclides remaining after the remediation is successfully completed, excluding background.] "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's or person responsible for the remediation's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee or person responsible for the remediation, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of US NRC regulations at Title 10 CFR Part 20 or the provisions of N.J.A.C. 7:28-12.15.

...

"Uncontaminated surface soil" means soil whose average natural background radionuclide total concentrations are less than the [limits for residual]remediation standards for radionuclides, and cannot exceed the background established for the site by more than two standard deviations.

...

7:28-12.4 General requirements

(a) Any person or licensee conducting remediation pursuant to this subchapter shall comply with the requirements of N.J.A.C. 7:26E, Technical Requirements for Site Remediation, excluding those sections related to sampling, surveying, and background investigations. Sampling, surveying and laboratory requirements shall be in accordance with N.J.A.C. 7:28-12.5.

(b) The Department shall require a licensee to provide a decommissioning plan that addresses historical site assessment, scoping, characterization, remedial action options and selection, and a final status survey report when, based on the types, quantities, and half-lives of the licensed material, such elements of the decommissioning plan are appropriate.

[(b)](c) Compliance with this subchapter shall not relieve any person or licensee from complying with more stringent cleanup standards or provisions imposed by any other applicable statute, rule or regulation.

(d) Upon Departmental approval of the remedial action workplan or similar plan, the Department may not subsequently require a change to that workplan or similar plan in order to compel a different remediation standard due to the fact that the established remediation standards have changed; however, the Department may compel a different remediation standard if the difference between the new remediation standard and the remediation standard approved by the Department in the workplan or similar plan differs by an order of magnitude.

7:28-12.5 Sampling, surveying and laboratory requirements

(a) Facilities licensed under 10 CFR Part 50 that have Nuclear Regulatory Commission-approved quality assurance plans are exempt from the requirements of this section. Otherwise, in addition to the requirements in N.J.A.C. 7:26E Appendix A IV.1, persons responsible for conducting remediations or licensees shall include the following in the radionuclide analysis reports:

1. – 6. (No change.)

(b) If available, persons responsible for conducting remediations or licensees shall provide:

1. – 5. (No change.)

[(c) For radionuclides, analytical methods contained in the following publications, incorporated herein by reference, or equivalents as approved by the Department, shall be used for determining radionuclide concentrations and/or radiation levels:

1. U.S. Environmental Protection Agency; "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA 600/4-80-32, as amended and

supplemented. This document may be obtained from the USEPA National Air and Radiation Environmental Laboratory, 540 S. Morris Ave., Montgomery, AL 36115-2601;

2. U.S. Department Of Energy; "Environmental Measurements Laboratory--Procedures Manual," HASL-300, 27th Ed., Vol. 1, as amended and supplemented. This document may be obtained from the US Department of Energy, Environmental Measurements Laboratory, 201 Varick St., 5th Floor, New York, NY 10014-4811; and/or

3. U.S. Environmental Protection Agency Eastern Environmental Radiation Facility; "Radiochemistry Procedures Manual," EPA 520/5-84-006, as amended and supplemented. This document may be obtained from the address in (c)1 above.]

[(d)] (c) Any laboratory providing radiological analysis for soil or water shall be certified pursuant to N.J.A.C. 7:18 [for radionuclide analysis in water and, in addition, shall have participated in and passed a soil intercomparison analysis administered by either the International Atomic Energy Agency or the U.S. Department of Energy's Environmental Measurements Laboratory within the year preceding the radiological analysis for the methods of interest].

[(e)] (d) Sampling and surveying for radioactive contamination shall be done in accordance with the protocol specified in that version of the Department of Environmental Protection's Field Sampling Procedure Manual's section on Radiological Assessment, incorporated herein by reference, in effect at the time of sampling and surveying which may be obtained by calling the Bureau of Environmental Radiation at (609) 984-5400 or from the Radiation Protection Program's web site at <http://www.state.nj.us/dep/rpp/index.htm>.

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

(a) Sites shall be remediated so that the incremental radiation dose to any person from any residual radioactive contamination at the site above that due to natural background radionuclide concentration, under either an unrestricted use remedial action, limited restricted use remedial action, or a restricted use remedial action, shall be as specified below:

1. - 2. (No change.)

(b) [3.] Radioactively contaminated ground water shall be remediated to comply with the New Jersey Groundwater Quality Standards rules, N.J.A.C. 7:9C.

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

7:28-12.9 Minimum remediation standards for [radionuclide] TENORM and source material contamination [of soil]

(a) For radioactive contamination [in soils], the requirements of N.J.A.C. 7:28-12.8 shall be considered to be met for a specific radionuclide if:

1. Table 1A - 2B (No change.)

Table 3A Allowed Incremental Derived Concentration Guideline Level of Individual Radionuclides in Soils;
Restricted Use Standards for Radioactive Contamination (pCi/g) (1)

Feet of Uncontaminated		Feet of Vertical Extent of Residual Radionuclides (VE)								
Surface Soil		VE1	VE2	VE	VE4	VE5	VE6	VE7	VE8	VE9
U238(2)	USS 1	82	46	32	24	20	17	15	13	12
	USS 2	83	46	32	25	20	17	15	13	12
	USS 3	83	46	33	25	20	17	15	13	12
	USS 4	83	47	33	25	20	18	15	13	12
	USS 5	85	47	33	25	21	16	14	13	12
U234(2)	USS 1	81	45	31	24	19	16	14	13	11
	USS 2	81	45	31	24	20	17	14	13	11
	USS 3	81	46	32	24	20	17	14	13	11
	USS 4	81	46	32	24	20	17	15	13	11
	USS 5	83	46	32	25	20	17	15	13	12
Ra226(3)	USS 1	7	4	3	3	2	2	2	2	2
	USS 2	7	4	3	3	2	2	2	2	2
	USS 3	7	4	3	3	2	2	2	2	2
	USS 4	7	4	3	3	2	2	2	2	2
	USS 5	7	4	3	3	2	2	2	2	2
U235(2)	USS 1	62	35	25	19	16	13	11	10	9
	USS 2	67	37	25	20	16	13	12	10	9
	USS 3	67	37	26	20	16	14	12	11	10
	USS 4	67	37	26	20	16	14	12	11	10
	USS 5	68	37	26	20	17	14	13	11	10
Ac227	USS 1	17	9	6	5	5	5	5	4	4
	USS 2	[18]17	10	7	7	6	5	5	5	5
	USS 3	[18]17	10	10	8	6	6	6	6	6
	USS 4	[18]17	15	10	8	8	8	8	8	8
	USS 5	[26]17	15	10	10	10	10	10	10	10
Th232	USS 1	[15]13	9	7	5	4	2	3	3	3
	USS 2	[21]13	10	7	5	4	3	3	3	3
	USS 3	[21]13	10	7	5	4	4	4	4	4
	USS 4	[21]13	10	7	5	5	5	5	5	5
	USS 5	[21]13	10	7	6	6	6	6	6	6

Table 3B Allowed Incremental Derived Concentration
Restricted Use Standards for Radioactive Contamination [pCi]Bq/g(1)

Feet of Uncontaminated		Feet of Vertical Extent of Residual (VE)							
Surface Soil (USS)	VE1	VE2	VE3	VE4	VE5	VE6	VE7	VE8	VE9

U238(2)	USS 1	3.03	1.70	1.18	0.90	0.74	0.63	0.54	0.48	0.43
	USS 2	3.08	1.71	1.18	0.92	0.75	0.63	0.55	0.48	0.43
	USS 3	3.09	1.71	1.21	0.92	0.75	0.63	0.55	0.49	0.44
	USS 4	3.09	1.74	1.21	0.92	0.75	0.64	0.56	0.49	0.44
	USS 5	3.14	1.74	1.21	0.93	0.77	0.65	0.56	0.50	0.44
U234(2)	USS 1	2.98	1.66	1.15	0.88	0.72	0.61	0.53	0.47	0.42
	USS2	2.98	1.66	1.15	0.89	0.73	0.61	0.53	0.47	0.42
	USS3	2.98	1.66	1.17	0.90	0.73	0.62	0.54	0.47	0.42
	USS 4	2.98	1.70	1.18	0.90	0.74	0.62	0.54	0.47	0.42
	USS 5	3.05	1.70	1.18	0.91	0.74	0.63	0.54	0.48	0.43
Ra226(1)	USS 1	0.28	0.13	0.11	0.10	0.09	0.09	0.08	0.08	0.08
	USS 2	0.28	0.13	0.11	0.10	0.09	0.09	0.08	0.08	0.08
	USS 3	0.28	0.13	0.11	0.10	0.09	0.09	0.08	0.08	0.08
	USS 4	0.28	0.13	0.11	0.10	0.09	0.09	0.08	0.08	0.08
	USS 5	0.28	0.13	0.11	0.10	0.09	0.09	0.08	0.08	0.08
U235(2)	USS 1	2.30	1.30	0.91	0.70	0.59	0.49	0.42	0.38	0.34
	USS 2	2.47	1.36	0.94	0.73	0.59	0.49	0.43	0.39	0.35
	USS 3	2.48	1.36	0.95	0.73	0.59	0.50	0.44	0.40	0.36
	USS4	2.49	1.38	0.95	0.73	0.60	0.52	0.45	0.41	0.37
	USS 5	2.51	1.38	0.95	0.74	0.62	0.53	0.47	0.42	0.37
Ac227	USS 1	0.62	0.34	0.24	0.18	0.18	0.18	0.17	0.17	0.17
	USS 2	0.6[6]3	0.36	0.24	0.24	0.23	0.20	0.19	0.19	0.19
	USS 3	0.6[6]3	0.36	0.36	0.29	0.23	0.23	0.23	0.23	0.23
	USS 4	0.6[6]3	0.54	0.37	0.29	0.28	0.28	0.28	0.28	0.28
	USS 5	0.[97]63	0.54	0.37	0.36	0.36	0.36	0.36	0.36	0.36
Th232	USS 1	0.[56]48	0.35	0.25	0.19	0.15	0.13	0.11	0.10	0.10
	USS2	0.[77]48	0.39	0.26	0.19	0.15	0.13	0.12	0.12	0.12
	USS3	0.[77]48	0.39	0.26	0.19	0.15	0.14	0.14	0.14	0.14
	USS4	0.[77]48	0.39	0.26	0.19	0.17	0.17	0.17	0.17	0.17
	USS 5	0.[77]48	0.39	0.26	0.22	0.22	0.22	0.22	0.22	0.22

2 –3. (No change.)

(b) (No change.)

7:28-12.10 Minimum remediation standards for accelerator-produced, by-product, and certain special nuclear materials

(a) Remediation standards shall meet the requirements at N.J.A.C. 7:28-12.8.

(b) Computer models acceptable to the Department shall be used to determine the remediation standards.

(c) Modeling parameters used in developing unrestricted and restricted use standards shall be equivalent to those used in the NJDEP's model, RaSoRS, as supplemented or amended, and incorporated herein by reference, which is available on the Radiation Protection Program's website at <http://www.state.nj.us/dep/rpp/index.htm>.

(d) Dose calculations shall be performed out to the time of peak dose or 1000 years, whichever is longer.

(e) Restricted use remediation standards shall meet requirements at N.J.A.C. 7:28-12.11(e) and 12.12.

7:28-12.[10] 11 Petition for alternative remediation standards for radioactive contamination

(a) In lieu of using the minimum remediation standards for radioactive contamination [of soil] 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 [soil] remediation standard for radioactive contamination. Such an alternate [soil cleanup] remediation standard:

1. – 3. (No change.)

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.

(b) The Department shall not consider a petition for an alternative [soil] remediation standard for radionuclides that is supported by increasing, in any manner, the allowed

incremental [background] dose [value] criterion of 15 mrem/yr (0.15 mSv/yr) or the allowed incremental radon in air concentration of three pCi/L (111 Bq/m³), or varying the parameters listed in Tables 6 or 7 below.

(No change to tables.)

(c) The Department shall consider petitions only in cases where site-specific or waste specific factors, and/or site design features are used in performing the dose assessment, which are different than those used by the Department in establishing the [soil concentrations] remediation standards in N.J.A.C. 7:28-12.9 or 12.10. Factors which the Department shall consider in a petition for an alternate [soil] remediation standard include, but are not limited to:

1. – 4. (No change.)

(d) A petition for an alternate [soil] remediation standard shall include an analysis demonstrating how and why the difference in factors such as those in Tables 8 and 9 above and/or indoor and outdoor occupancy times will result in substantially different [soil] remediation standards than those in N.J.A.C. 7:28-12.9.

(e) Regardless of the factors used by the petitioner or licensee, the Department shall not approve alternative standard petitions that include institutional and engineering controls where failure of those controls, not including the failure of a radon remediation system, would result in more than 100 mrem (one mSv) total annual effective dose equivalent.

(f) In the event the Department determines that sufficient evidence exists to support consideration of an alternative [soil] remediation standard, the petitioner or licensee shall submit

a written analysis which demonstrates compliance with the dose limits in N.J.A.C. 7:28-12.9 or 12.10 including:

1. The remedial action informational requirements of N.J.A.C. 7:26E-6; and

2. A dose assessment analysis, including:

i. An estimate of the radiation doses received by a post-remediation on-site resident for an unrestricted use remedial action, or by [a resident or] an employee (of a proposed commercial use facility) for a limited restricted use or restricted use remedial action.

ii. (No change.)

iii. Dose [Groundwater radionuclide concentration] calculations which shall be extended for a period of 1,000 years or to the time of peak dose, whichever is longer;

iv. – vii.(No change.)

(g) Engineering controls or institutional controls may be incorporated as part of a petition for an alternative remediation standard provided that these controls will be durable and implemented for an appropriate period of time to achieve their intended purpose.

(h) Computer models acceptable to the Department may be used by the petitioner or licensee for an alternative [soil] remediation standard to confirm that the requirements of N.J.A.C. 7:28-12.9 or N.J.A.C. 7:28-12.10 have been and will continue to be met.

7:28-12.[11] 12 Requirements pertaining to engineering or institutional controls

(a) All remediation proposals shall designate the intended use(s) of the property. Such intended use(s) shall be restricted as necessary to prevent future exposure, and shall otherwise be consistent with current and projected State and local zoning designations or land uses. For sites

not remediated to the unrestricted use standards in N.J.A.C. 7:28-12.9 or 12.10, the Department shall define the nature and duration of all appropriate engineering or institutional controls necessary to meet the standards in N.J.A.C. 7:28-12.9, 12.10, or 12.[10]11(a), based upon the particular conditions of the site.

(b) In order for any remediation under this subchapter requiring engineering controls or institutional controls to meet the standards in N.J.A.C. 7:28-12.9, 12.10, or 12.[10]11(a), the person responsible for conducting the remediation, or licensee, shall, in addition to meeting the provisions of N.J.S.A. 58:10B-13:

1. (No change.)

2. Provide sufficient financial assurance for the costs of implementing and maintaining the requisite active engineered or institutional controls for an appropriate period of time. Provide sufficient financial assurance for the costs of implementing and maintaining the requisite active engineered or institutional controls for an appropriate period of time. Acceptable financial assurance mechanisms are set forth at 10 CFR 20.1403(c), incorporated herein by reference.

(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. A petition containing the signatures of 25 or more people that live or work within 200 feet of the site, if contamination has not migrated from the site boundary;

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

iii. A written request by a municipal official, such as a Mayor or chairperson of an environmental commission, or a designated local health official.

2. When the Department determines that there is substantial public interest the Department shall notify the person responsible for conducting the remediation or the licensee and post a summary of findings on the Department's web site at www.state.nj.us/dep; and

3. The person responsible for conducting the remediation or the licensee shall develop and implement enhanced public notice based on the expressed needs of the community and may include the following:

i. Publicizing and hosting an information session or public meeting;

ii. Publishing a notice containing basic information about the site in the local paper of record; or

iii. Establishing a local information repository.

4. The notifications required pursuant to this section are not intended to satisfy the public participation requirements applicable to sites subject to the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. 9601, et seq. and the National Contingency Plan, 40 CFR Part 300.

7:28-12.[12] 13

Requirements pertaining to a change in land use

(a) Any subsequent proposed use of a property that is different from the intended use (other than unrestricted use remedial actions) described in the original remediation proposal shall require a prior review and prior approval by the Department. To initiate this review, 90 calendar days prior to a proposed change in land use, the person or licensee proposing such use shall prepare and submit to the Department, at the Bureau of Environmental Radiation, PO Box 415, Trenton, NJ 08625-0415, and to each affected municipality, a brief written description of the new proposed use as compared to the intended use upon which the original remediation was based including all planned soil excavations, and any additional remedial actions to be implemented.

(b) If the Department determines that the proposed new use may cause the dose limitations of N.J.A.C. 7:28-12.8 to be exceeded, the person or licensee requesting the use change shall be required to prepare and submit to the Department's Bureau of Environmental Radiation, PO Box 415, Trenton, NJ 08625-0415, a dose assessment analysis, containing the information required under N.J.A.C. 7:28-12.[10]11(f)2, (g), and (h), to ascertain whether the dose limitation requirements of N.J.A.C. 7:28-12.8 will be met for the proposed new use.

(c) In preparing the dose assessment analysis, the person or licensee may incorporate into the new use plan new remedial measures such as different radionuclide in soil concentrations, or radioactive contamination vertical extents, and/or new engineering or institutional controls, provided that for engineering or institutional controls, the person responsible for conducting the remediation or licensee provides for the cost of implementing and maintaining them as specified in N.J.A.C. 7:28-12.[11]12(c)3.

7:28-12.[13]14 Requirements pertaining to the final status survey

(No change in text.)

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) Owners or licensees with sites that have been used for burial of radioactive materials or where radioactive material has been capped, shall not be allowed to convert these sites to other uses unless the requirements of N.J.A.C. 7:28-12.8 and 12.11 are met.

(c) The owner or licensee of any burial ground or capped material shall notify the Department in writing not less than 30 days in advance of any transfer of title to the property involved.

APPENDIX A

Allowed Incremental Derived Concentration Guideline Levels (pCi/g) for the Gamma and Intake Pathways(1)

Nuclide	Feet of Vertical Extent of Residual								
	VE1	VE	VE3	VE4	VE5	VE6	VE7	VE8	VE9
Ra226 Unrestricted Use Standards	3	2	2	2	2	2	2	2	2
Ra226 Limited Restricted Use Standards	5	5	5	5	5	5	5	4	4

Allowed Incremental Derived Concentration Guideline Levels (pCi/g) for the Gamma and Intake Pathways (1)

Feet of Surface Soil		Feet of Vertical Extent of Residual								
		VE1	VE2	VE3	VE4	VE5	VE6	VE7	VE8	VE9
Ra226 Restricted Standards	USS 1	[22]18	15	10	8	6	5	5	4	4
	USS 2	[28]18	15	10	8	6	5	5	5	5
	USS 3	[28]18	15	10	8	6	6	6	6	6
	USS 4	[28]18	15	10	8	7	7	7	7	7

USS 5 [28]18 15 10 9 9 9 9 9 9

Allowed Incremental Derived Concentration Guideline Levels ([pCi]Bq/g) for the Gamma and Intake Pathways(1)

Nuclide	Feet of Vertical Extent of Residual								VE9
	VE1	VE2	VE3	VE4	VE5	VE6	VE7	VE8	
Ra226									
Unrestricted Use Standards	0.13	0.09	0.09	0.09	0.09	0.09	0.09	0.08	0.08
Ra226									
Limited Restricted Use Standards	0.18	0.18	0.18	0.18	0.18	0.18	0.18	0.15	0.15

Allowed Incremental Derived Concentration Guideline Levels (Bq/g) for the Gamma and

Feet of Uncontaminated Surface Soil		Feet of Vertical Extent of Residual								VE9
		VE1	VE2	VE3	VE4	VE5	VE6	VE7	VE8	
Ra226										
Restricted Standards	USS 1	0.[81]67	0.55	0.37	0.30	0.22	0.18	0.18	0.15	0.15
	USS 2	[1.04] 0.67	0.56	0.37	0.30	0.22	0.18	0.18	0.18	0.18
	USS 3	[1.04]0.67	0.56	0.37	0.30	0.22	0.22	0.22	0.22	0.22
	USS 4	[1.04]0.67	0.56	0.37	0.30	0.23	0.23	0.26	0.26	0.26
	USS 5	[1.04]0.67	0.56	0.37	0.33	0.33	0.33	0.33	0.33	0.33

SUBCHAPTER 13. REPORTS OF THEFTS AND RADIATION INCIDENTS FOR

REGISTRANTS

7:28-13.1 Reports of theft or loss

A [State licensee, radioactive materials registrant or] registrant shall immediately notify the Department by telephone, telefax or telegraph of any theft or loss of any [source of] ionizing radiation-producing [including] machine [sources and any naturally occurring or accelerator produced radioactive material, including TENORM, in such quantities and] under such circumstances that a substantial radiation hazard [and/or contamination hazard] may result.

7:28-13.2. Reportable radiation incidents

(a) A [State licensee, radioactive materials registrant or] registrant shall immediately notify the Department by telephone, telefax or telegraph of any radiation incident which may have caused or threatens to cause the following:

1. (No change.)

[2. The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in N.J.A.C. 7:28-11 Appendix, Table 1, or prorated values if more than one isotope is released;]

[3]2. A loss of one working week or more of the operation of any facilities affected; or

[4]3. Damage to property in excess of \$100,000.

(b) (No change.)

(c) A [State licensee, radioactive materials registrant or] registrant shall notify the Department within 24 hours by telephone, telefax or telegraph of any radiation incident which may have caused or threatens to cause the following:

1. (No change.)

[2. The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limit specified for such materials in N.J.A.C. 7:28-11 Appendix, Table 1, or prorated values if more than one isotope is released;]

[3]2. A loss of one day or more of the operation of any facilities affected; or

[4]3. Damage to property in excess of \$1,000.

(d) (No change.)

(e) A [State licensee, radioactive materials registrant or] registrant shall notify the Department in writing within 30 days of the following:

1. Each exposure of an individual to radiation [or concentrations of radioactive material] in excess of any applicable limit of N.J.A.C. 7:28-6[, or of a State licensee's license];
2. Any incident for which notification is required by subsections (a) and (c) of this Section; or
3. Levels of radiation [or concentrations of radioactivity,] not involving exposure of any individual in excess of any applicable limit of N.J.A.C. 7:28-6 outside a controlled area in excess of 10 times the limits of N.J.A.C. 7:28-6[.2], Standards for Protection Against Radiation [and 11 or of a State licensee's license].

(f) The reports set forth in subsection (e) of this Section shall describe the extent of exposure of individuals to radiation [or to radioactive materials], the levels of radiation [and concentrations of radioactive materials involved], the cause of the exposure[, and/or levels, [or concentrations] and corrective steps taken or planned to assure against a recurrence.

(g) In each case where (e)1 above requires a report to the Department of exposure of an individual, the owner shall:

1. (No change.)
2. Concurrently give written notification to the individual of the nature and extent of the exposure. Such notice shall contain the following statement: "This report is furnished to you under the provisions of [Subchapter]N.J.A.C. 7:28-13, [(Reports of Thefts and Radiation Incidents for Registrants)] of the New Jersey Administrative Code]. You should preserve this report for future reference."

SUBCHAPTER 17. INDUSTRIAL AND NONMEDICAL X-RAY RADIOGRAPHY

7:28-17.1 Scope

(a) This subchapter establishes radiation-safety requirements for persons utilizing [sealed sources, radiographic-exposure devices or] ionizing radiation-producing machines for industrial and nonmedical radiography.

(b) – (d) (No change.)

7:28-17.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise[.]:

...

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a [license or] registration issued by the Department pursuant to N.J.A.C. 7:28-3 [or 7:28-4].

7:28-17.3 Registration [and licensing] requirements

(a) (No change.)

[(b) All owners of sealed sources or radiographic-exposure devices shall comply with N.J.A.C. 7:28-3 and 7:28-4.]

7:28-17.4 Equipment control

(a) [The permissible levels of radiation from radiographic-exposure devices and storage containers shall be as follows:

1. Radiographic-exposure devices measuring less than four inches from the sealed source storage position to any external surface of the device shall not produce a radiation level in excess of 50 milliroentgens per hour at least six inches from any point on the external surface of the device.

2. Radiographic-exposure devices measuring a minimum of four inches from the sealed source storage position to any external surface of the device and all storage containers for sealed sources or for radiographic-exposure devices shall not produce radiation levels in excess of 200 milliroentgens per hour at any point on the external surface and 10 milliroentgens per hour at one meter from any point on the external surface.

3. The radiation levels specified in one and two above are with the sealed source in the shielded or "off" position.] (Reserved.)

(b) (No change.)

(c) [Each radiographic-exposure device and each storage container shall be provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of a sealed source or its change from a shielded to an unshielded position.] All ionizing radiation-producing machines[, radiographic-exposure devices and storage containers] shall be kept locked at all times except when under the direct surveillance of a radiographer or of a radiographer's assistant or as provided in N.J.A.C. 7:28-17.6(a).

(d) [Locked radiographic-exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.] (Reserved.)

(e) (No change.)

(f) [The replacement of any sealed source fastened to or contained in a radiographic-exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized by the Department, a Federal agency or any Agreement State.] (Reserved.)

(g) [Sealed sources are to be leak tested under the following conditions and requirements:

1. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the six months prior to the transfer, the sealed source shall not be put into use until tested.

2. The leak test shall be capable of detecting the presence of 0.005 microcuries of removable contamination on the sealed source. A test made at the nearest accessible point to the sealed source storage position may be an acceptable leak test.

3. Leak tests shall be carried out only by individuals and by procedures both of which require prior approval by the Department. Approval will be based upon a description of the following:

i. Instrumentation to be used;

ii. Method of performing test including points on equipment to be tested;

and

iii. Pertinent experience of person who will perform the test.

4. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Department.] (Reserved.)

(h) [Requirements regarding any leaking sealed source shall be as follows:

1. Any test conducted pursuant to (g) above which reveals the presence of 0.005 microcuries or more of removable radioactive material shall be considered evidence that a sealed source is leaking.

2. The owner shall immediately withdraw any leaking sealed source above from use and shall cause it to be decontaminated and repaired in accordance with (f) or to be disposed of in accordance with N.J.A.C. 7:28-11.

3. Within five working days after obtaining results of the test performed pursuant to (g) above, a report shall be filed with the Department, describing the equipment involved, the test results, and the corrective action taken.] (Reserved.)

(i) [A sealed source which is not fastened to or contained in a radiographic-exposure device shall have permanently attached to it a durable tag at least one inch square, bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger--Radioactive Material--Do Not Handle--Notify Civil Authorities if Found."] (Reserved.)

(j) [Each owner shall conduct an ongoing inventory and keep a written record of each sealed source that is received, possessed, and used. This record shall include the date of receipt of each sealed source, the identity and quantity of the radioactive material contained within each sealed source, the date and to whom each sealed source is assigned and of the location at which each sealed source is to be used, the date that each sealed source is returned for storage at the owner's facility, the date that the source is returned for replacement, and the date of calibration.] (Reserved.)

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

1. A description, or make and model number of the ionizing radiation-producing machine[, or of the radiographic-exposure device or storage container in which the sealed source is located];

2. - 3. (No change.)

(l) Each owner conducting industrial radiography at a temporary job site shall make the following records available at the site for inspection by the Department:

1. [A copy of the owner's current license to possess or use radioactive materials issued by the Department pursuant to N.J.A.C. 7:28-4.] (Reserved.)

2. A copy of the owner's current registration of a [radioactive material or] ionizing radiation-producing machine issued by the Department pursuant to N.J.A.C. 7:28-3;

3. [A copy of the owner's current license to possess or use radioactive materials issued by the United States Nuclear Regulatory Commission;] (Reserved.)

4. - 8. (No change.);

9. [A copy of the record of leak test results made pursuant to (g)4 above.]

7:28-17.5 Personal radiation safety requirements for radiographers

(a) The owner shall not permit any person to act as a radiographer until such person:

1. - 2. (No change.)

3. Has demonstrated competence to use the ionizing radiation-producing machines[, radiographic-exposure devices, sealed sources, related handling tools] and survey instruments which will be employed in his assignment.

(b) The outline of the course for radiographer's training is as follows:

1. Fundamentals of radiation safety:

i. – iii. (No change.)

iv. Levels of radiation from ionizing radiation-producing machines [and radioactive materials];

v. (No change.)

2. (No change.);

3. Radiographic equipment to be used:

i. (No change);

ii. [Radiographic-exposure devices] (Reserved.);

iii. – iv. (No change.)

4. – 5. (No change.)

(c) The owner shall not permit any person to act as a radiographer's assistant until such person:

1. (No change.)

2. Has demonstrated competence to use under the personal supervision of the radiographer the ionizing radiation-producing machines[, radiographic-exposure devices, sealed sources, related handling tools] and radiation-survey instruments which will be employed in his assignment; and

3. (No change.)

(d) The owner shall prepare written operating and emergency procedures which shall include instructions in at least the following:

1. The handling and the use of ionizing radiation-producing machines[, sealed sources and radiographic-exposure devices] to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in N.J.A.C. 7:28-6;

2. – 3. (No change.)

4. Methods and occasions for locking and securing ionizing radiation-producing machines[, radiographic-exposure devices, storage containers and sealed sources];

5. (No change.)

6. [Transporting sealed sources to field locations, including packing of radiographic-exposure devices and storage containers in the vehicles, posting of vehicles, and control of the sealed sources during transportation](Reserved.);

7. – 9. (No change.)

(e) (No change.)

7:28-17.6 Precautionary procedures in radiographic operations

(a) – (c) (No change.)

(d) In addition to the requirements of N.J.A.C. 7:28-7, no radiographic operation shall be conducted unless the owner ensures that radiation surveys are made and recorded as follows:

1. (No change.)

2. [A physical radiation survey shall be made after each radiographic exposure employing a sealed source to determine that the sealed source has been returned to its shielded condition.] (Reserved.)

3. [After radiographic operations employing a sealed source or sources have been completed, a physical radiation survey shall be made to determine that each sealed source is in its shielded condition prior to securing the radiographic-exposure device and storage container as specified in N.J.A.C. 7:28-17.4(a) and (c).] (Reserved.)

4. Clear and legible records shall be kept of the surveys that are required by (d)1 [and 3] above and maintained for inspection by the Department.

7:28-17.8 Shielded room radiography

(a) No person shall operate or permit the operation of any ionizing radiation-producing machine[, radiographic-exposure device, or sealed source] used in shielded room radiography unless the equipment, installation, and personnel meet the requirements of N.J.A.C. 7:28-17.1 through 7:28-17.6 and 7:28-17.8.

(b) No person shall operate or permit any person to operate an ionizing radiation-producing machine[, radiographic-exposure device, or sealed source] used in shielded room radiography until such operator has completed the following requirements:

1. – 3. (No change.)

(c) Each owner shall supply appropriate personnel monitoring equipment and shall require that it be used by every individual who operates, makes "set-ups," or performs maintenance on an ionizing radiation-producing machine[, radiographic-exposure device, or sealed source] used in shielded room radiography.

(d) (No change.)

(e) No person shall enter an enclosed room in which shielded room radiography is performed until after a physical radiation survey is conducted to determine whether the ionizing radiation producing machine is off [or the radiographic-exposure device or the sealed source is in the shielded or "off" position]. A record shall be maintained of the date and exposure rate measured for each physical radiation survey and shall be made available for inspection by the Department.

(f) – (g) (No change.)

(h) All ionizing radiation-producing machines[, radiographic-exposure devices, and sealed sources] used in shielded room radiography and all objects exposed thereto shall be confined within an installation or structure designed or intended for radiography and in which radiography is regularly performed in accordance with the following requirements:

1. – 6. (No change.)

SUBCHAPTER 18. MAJOR NUCLEAR FACILITIES

7:28-18.1 Scope

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

(c) The intent of this Section is to insure that individuals outside of these facilities receive no radiation exposures from environmental or direct radiation that are in excess of the limits of [Sections 6.1 (Exposure of individuals in controlled areas) and 6.2 (Radiation levels outside controlled areas)] Subchapter 6 of this Chapter.

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

7:28-48.2 Definitions

...

"Radiation area" means an area which is accessible to a worker and in which there exists levels of nonionizing radiation that exceed the maximum permissible levels of such radiation as specified in the rules of the Commission.

...

SUBCHAPTER 49. (Reserved.)

SUBCHAPTER 50. NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS:
INSPECTION AND INVESTIGATIONS

7:28-50.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 19.

(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. 10 CFR 19.5, Communications.
2. 10 CFR 19.8, Information collection requirements: OMB approval

(c) The following provisions of 10 CFR Part 19 are incorporated by reference with the specified changes:

1. At 10 CFR 19.2, Scope, delete references to 10 CFR Parts 50, 60, 63, 72 and 76.

2. At 10 CFR 19.3, Definitions, "Commission" shall mean the New Jersey Department of Environmental Protection;

3. "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 19 of the Code of Federal Regulations that are incorporated by reference, mean the New Jersey Department of Environmental Protection, except when specifically noted in this subchapter;

4. 10 CFR 19.4, 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,";

5. 10 CFR 19.11(a)(1), replace "Part 20" with "N.J.A.C. 7:28-6";

6. 10 CFR 19.13(b), replace "§ 20.2106 of 10 CFR Part 20" with "N.J.A.C. 7:28-6";

7. 10 CFR 19.13(c)(1)(i), replace "§ 20.2106" with "N.J.A.C. 7:28-6";

8. 10 CFR 19.13(c)(1)(i), replace "§ 20.1502" with "N.J.A.C. 7:28-6";

9. 10 CFR 19.13(d), replace "§§ 20.2202, 20.2203, 20.2204, or 20.2206 of this Chapter" with "N.J.A.C. 7:28-6";

10. 10 CFR 19.17(a), replace all references to "Executive Director for Operations" with "Chief, Bureau of Environmental Radiation of the Department";

11. 10 CFR 19.17(a) and (b), replace all references to “Administrator of the appropriate Regional Office” with “Supervisor, Radioactive Materials Section”;

12. 10 CFR 19.18(b), replace “Office of the General Counsel” with “Office of the Attorney General of New Jersey”;

13. 10 CFR 19.20, delete references to 10 CFR Parts 50, 60, 63, 72 and 76;

14. 10 CFR 19.32, add “Allegations of discrimination are to be reported to the Division on Civil Rights, Department of Law and Public Safety, 140 East Front Street, P.O. Box 089, Trenton, New Jersey, 08625-089.”

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the Department via the Department’s website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC’s Form 3, “Notice to Employees,” and the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation.”

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 51. RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING
OF BYPRODUCT MATERIAL

7:28-51.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 30.

(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. 10 CFR 30.4, Definitions, the following definitions are not incorporated by reference: “act,” “byproduct material,” “curie,” “decommission,” “department “ and “Department of Energy,” “effective dose equivalent,” “government agency,” “license,” “medical use,” “person,” “source material” and “special nuclear material.”

2. 10 CFR 30.6, Communications;

3. 10 CFR 30.8, Information collection requirements: OMB approval;

4. 10 CFR 30.21(c), Radioactive drug: Capsules containing carbon-14 urea for “in vivo” diagnostic use for humans;

5. 10 CFR 30.34(d), (e)(1) and (e)(3), Terms and conditions of licenses;

6. 10 CFR 30.41(a)(6), Transfer of byproduct material; and

7. 10 CFR 30.55, Tritium reports.

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

1. 10 CFR 30.4, Definitions, "Commission" shall mean the New Jersey Department of Environmental Protection;
2. "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 30 of the Code of Federal Regulations that are incorporated by reference, mean the New Jersey Department of Environmental Protection, except when specifically noted in this subchapter;
3. 10 CFR 30.5, 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. 10 CFR 30.9(b), replace all references to "Administrator of the appropriate Regional Office" with "Supervisor, Radioactive Materials Section";
5. 10 CFR 30.10(b), replace "10 CFR part 2, subpart B" with "N.J.S.A. 26:2D-13";
6. 10 CFR 30.12, replace "when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law" with "when the Department and the Commission on Radiation Protection determine that the exemption of the prime contractor or subcontractor is in accordance with N.J.A.C. 7:28-2.8";
7. 10 CFR 30.14(c), add "the Department" after "holding a specific license issued by";
8. 10 CFR 30.14(c), "Commission" shall mean the U.S. Nuclear Regulatory Commission;
9. 10 CFR 30.15(a), delete "20 and" and add "and N.J.A.C. 7:28-6" after "of this Chapter";

10. 10 CFR 30.16, delete “20 and” and add “and N.J.A.C. 7:28-6” after “of this Chapter”;
11. 10 CFR 30.19(a), delete “20 and” and add “and N.J.A.C. 7:28-6” after “of this Chapter”;
12. 10 CFR 30.20(a), delete “20 and” and add “and N.J.A.C. 7:28-6” after “of this Chapter”;
13. 10 CFR 30.32(a), replace the first sentence with “Application for specific licenses and renewals from the State shall be filed with Department on forms available from the Department”;
14. 10 CFR 30.32(e), replace all references to 10 CFR Part 170 with N.J.A.C. 7:28-64.
15. 10 CFR 30.33(a)(5), replace “Director Office of Federal and State Materials and Environmental Management Program,” with “Manager, Bureau of Environmental Radiation.”
16. 10 CFR 30.35(c)(5), replace “10 CFR Part 20, Appendix G” with “N.J.A.C. 7:28-6”;
17. 10 CFR 30.35(c)(5), replace “10 CFR Part 20” with “N.J.A.C. 7:28-12”;
18. 10 CFR 30.35(g)(3)(i), replace “10 CFR 20.1003” with “N.J.A.C. 7:28-6”;
19. 10 CFR 30.35(g)(3)(iii), replace “10 CFR 20.2108” with “N.J.A.C. 7:28-6”;
20. 10 CFR 30.35(g)(3)(iv), replace “10 CFR Part 20, subpart E” with “N.J.A.C. 7:28-12”;
21. 10 CFR 30.35(g)(3)(iv), replace “10 CFR 20.2002” with “N.J.A.C. 7:28-6”;

22. 10 CFR 30.36(j)(2), replace “10 CFR Part 20, subpart E” with “N.J.A.C. 7:28-12”
23. 10 CFR 30.36(k)(3)(i), replace “10 CFR Part 20, Subpart E” with “N.J.A.C. 7:28-12”
24. 10 CFR 30.36(k)(3)(ii), replace “10 CFR Part 20, subpart E” with “N.J.A.C. 7:28-12”;
25. 10 CFR 30.37(a), replace the wording of (a) with “Application for renewal of a specific State license shall be filed with the Department on forms available from the Department.”;
26. 10 CFR 30.38, Change the title of the section from “Application for amendment of licenses” to “Amendment of licenses.” Replace “Applications for amendment of a license shall be filed on Form NRC-313 in accordance with 30.32” with “Requests to amend a license shall be submitted in letter form to the Department”;
27. 10 CFR 30.50(b)(1)(ii), replace “appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20” with “N.J.A.C. 7:28-6.1”;
28. 10 CFR 30.50(b)(4)(i), replace “appendix B of §§ 20.1001-20.2401 of 10 CFR Part 20” with “N.J.A.C. 7:28-6.1”;
29. 10 C.F.R 30.50(c)(2), replace “appropriate NRC Regional office listed in appendix D to part 20 of this Chapter” with “Department”;
30. 10 CFR 30.51(d), replace “appropriate NRC Regional Office” with “Department”;
31. 10 CFR 30.51(d)(1), replace “§§ 20.2002 (including burials authorized before January 28, 1981), 20.2003, 20.2004, 20.2005” with “N.J.A.C. 7:28-6”;

32. 10 CFR 30.51(d)(2), replace “§ 20.2103(b)(4)” with N.J.A.C. 7:28-6”;

33. 10 CFR 30.51(e)(1), replace “§§ 20.2002 (including burials authorized before January 28, 1981), 20.2003, 20.2004, 20.2005” with “N.J.A.C. 7:28-6”;

34. 10 CFR 30.51(e)(2), replace “§ 20.2103(b)(4)” with N.J.A.C. 7:28-6”; and

35. 10 CFR 30, Appendix B to Part 30—Quantities of Licensed Material Requiring Labeling, end Note, replace “§ 20.303” with “N.J.A.C. 7:28-6.”

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the Department via the Department’s website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC’s Form 3, “Notice to Employees” and the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation.”

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 52. GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

7:28-52.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 31.

(b) The following provisions of 10 CFR Part 31 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. 10 CFR Part 31.4, Information collection requirements: OMB approval

(c) The following provisions of 10 CFR Part 31 are incorporated by reference with the specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 31 of the Code of Federal Regulations that are incorporated by reference, means the Department, except when specifically noted in this subchapter;

2. 10 CFR 31.2, delete "20," and add "and N.J.A.C. 7:28-6" after "of this chapter";

3. 10 CFR 31.5(c)(5), replace "§ 20.1402" with "N.J.A.C. 7:28-12";

4. 10 CFR 31.5(c)(9)(i), replace "20.2201, and 20.2202" with "and N.J.A.C. 7:28-6";

5. 10 CFR 31.5(c)(10), replace "§§ 20.2201, and 20.2202 of this chapter" with "N.J.A.C. 7:28-6";

6. 10 CFR 31.5(c)(10), delete "20," and add "and N.J.A.C. 7:28-6" after "of this chapter";

7. 10 CFR 31.5(c)(13)(ii), after "fee required by" replace "Section 170.31" with "N.J.A.C. 7:28-64";

8. 10 CFR 31.5(c)(13)(iv), the terms “NRC” and “Commission” mean the U.S. Nuclear Regulatory Commission;

9. 10 CFR 31.5(c)(14), replace “Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001” with “Department”;

10. 10 CFR 31.7(b), delete “20,” and add “N.J.A.C. 7:28-6” after “of this chapter”;

11. 10 CFR 31.7(b), replace “§§ 20.2201, and 20.2202” with “N.J.A.C. 7:28-6”;

12. 10 CFR 31.8(c), delete “20,” and add ,” as well as N.J.A.C. 7:28-6” after the second “of this chapter”;

13. 10 CFR 31.10(b)(1), replace “§ 20.2001” with “N.J.A.C. 7:28-6”;

14. 10 CFR 31.10(b)(3), delete “20,” and add “and N.J.A.C. 7:28-6,”;

15. 10 CFR 31.10(b)(3), replace “§§ 20.2001, 20.2201, and 20.2202 of this chapter” with “N.J.A.C. 7:28-6”;

16. 10 CFR 31.11(c)(5), replace “§ 20.2001” with “N.J.A.C. 7:28-6”;

17. 10 CFR 31.11(e), add "radioactive materials" prior to "registrant";

18. 10 CFR 31.11(f), delete “20,” and add “and N.J.A.C. 7:28-6” after “of this chapter” and

19. 10 CFR 31.11(f), replace “§§ 20.2001, 20.2201, and 20.2202” with “N.J.A.C. 7:28-6.”

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees,” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the

Department via the Department's website at www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license for radioactive materials from both the Department and the NRC shall post both the NRC's Form 3, "Notice to Employees," and the Department's Form RPP-14, "Notice to Employees, Standards for Protection Against Radiation."

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

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

7:28-53.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 32.

(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. 10 CFR 32.8, Information collection requirements: OMB approval;
2. 10 CFR 32.11, Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.

3. 10 CFR 32.12, Same: Records and material transfer reports.
4. 10 CFR 32.14, Certain items containing byproduct material; requirements for license to apply or initially transfer;
5. 10 CFR 32.15, Same: Quality assurance, prohibition of transfer, and labeling;
6. 10 CFR 32.16, Certain items containing byproduct material: Records and reports of transfer;
7. 10 CFR 32.18, Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license;
8. 10 CFR 32.19, Same: Conditions of licenses;
9. 10 CFR 32.20, Same: Records and material transfer reports;
10. 10 CFR 32.21, Radioactive drug: Manufacture, preparation or transfer for commercial distribution of capsules containing carbon-14 urea each for “in vivo” diagnostic use for humans to persons exempt from licensing; Requirements for a license;
11. 10 CFR 32.21a, Same: Conditions of license;
12. 10 CFR 32.22, Self-luminous products containing tritium, krypton-85 or promethium 147: Requirements for license to manufacture, process, produce, or initially transfer;
13. 10 CFR 32.23, Same: Safety criteria;
14. 10 CFR 32.25, Conditions of licenses issued under Part 32.22: Quality control, labeling, and reports of transfer;
15. 10 CFR 32.26, Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer;
16. 10 CFR 32.27, Same: Safety criteria;
17. 10 CFR 32.28, Same: Table of organ doses;

18. 10 CFR 32.29, Conditions of licenses issued under 32.26: Quality control, labeling, and reports of transfer;

19. 10 CFR 32.40, Schedule A-Prototype tests for automobile lock illuminators and

20. 10 CFR 32.210, Registration of product information.

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

1. 10 CFR 32.52(a), replace “Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001,” with “New Jersey Department of Environmental Protection, Radioactive Materials Section, P.O. Box 415, Trenton, New Jersey 08625-0415”;

2. 10 CFR 32.56, replace “Director of Nuclear Material Safety and Safeguards,” with “Department”;

3. “Commission,” “Nuclear Regulatory Commission,” “NRC,” and “U.S. Nuclear Regulatory Commission,” as used in the provisions of Part 32 of the Code of Federal Regulations that are incorporated by reference, mean the Department, except when specifically noted in this subchapter;

4. 10 CFR 32.2, in the definition of “nationally tracked source,” replace “part 20 of this Chapter” with “10 CFR part 20 as incorporated by reference in N.J.A.C. 7:28-6”;

5. 10 CFR 32.51(a)(2)(ii), replace “§ 20.1201(a) of this chapter” with “N.J.A.C. 7:28-6”;

6. 10 CFR 32.51(a)(4), replace “§ 20.1901 of this chapter” with “N.J.A.C. 7:28-6”;

7. 10 CFR 32.51(a)(5), replace “§ 20.1901 of this chapter” with “N.J.A.C. 7:28-6”;
8. 10 CFR 32.51(c), replace “§ 20.1201(a) of this chapter” with “N.J.A.C. 7:28-6”;
9. 10 CFR 32.51a(a)(2), add “and” between “31.2,” and “30.51”;
10. 10 CFR 32.51a(a)(2), delete “20.2201, and 20.2202” and add “and N.J.A.C. 7:28-6” after “of this chapter”;
11. 10 CFR 32.51a(b)(1), add “and” between “31.2” and “30.51” in both locations;
12. 10 CFR 32.51a(b)(1), delete “20.2201, and 20.2202” from both locations and add “and N.J.A.C. 7:28-6” after “of this chapter” in both locations;
13. 10 CFR 32.54(a), replace “§ 20.1901 of this chapter” with “N.J.A.C. 7:28-6”;
14. 10 CFR 32.61(d), replace “§ 20.1901(a) of this chapter” with “N.J.A.C. 7:28-6”;
15. 10 CFR 32.71(c)(2), replace “§ 20.1901(a) of this chapter” with “N.J.A.C. 7:28-6” and
16. 10 CFR 32.71(e), replace “§ 20.2001” with “N.J.A.C. 7:29-6.”
- (d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the Department via the Department’s website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC's Form 3, "Notice to Employees," and the Department's Form RPP-14, "Notice to Employees, Standards for Protection Against Radiation."

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 54: SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR

BYPRODUCT MATERIAL

7:28-54.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 33.

(b) The following provisions of 10 CFR Part 33 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. 10 CFR 33.8, Information collection requirements: OMB approval.

(c) The following provisions of 10 CFR Part 33 are incorporated by reference with the specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 33 of the Code of Federal Regulations that are incorporated by reference, mean the Department.

2. 10 CFR 33.12, replace with "Application for specific licenses from the State and renewals shall be filed with Department on forms available from the Department."

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, "Notice to Employees," shall mean the Department's Form RPP-14, "Notice to Employees, Standards for Protection Against Radiation," available from the Department via the Department's website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC's Form 3, "Notice to Employees," and the Department's Form RPP-14, "Notice to Employees, Standards for Protection Against Radiation."

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 55. MEDICAL USE OF BYPRODUCT MATERIAL

7:28-55.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 35.

(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. 10 CFR 35.8, Information collection requirements: OMB approval

2. 10 CFR 35.63(b)(2)(i);

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

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 35 of the Code of Federal Regulations, that are incorporated by reference, means the Department, except when specifically noted in this subchapter.

2. 10 CFR 35.1, delete "20," and add "and N.J.A.C. 7:28-6" after "of this chapter";

3. 10 CFR 35.12(b)(1), replace "Filing an original and one copy of NRC Form 313, "Application for Material License," with "Filing an original application for a specific license from the State with the Department on forms available from the Department,";

4. 10 C.F.R 35.12(c), delete the wording "amendment or";

5. 10 CFR 35.12(c)(1), delete the wording "and one copy" and "either";

6. 10 CFR 35.12(c)(1)(i), delete the wording "NRC Form 313, 'Application for Material License,;' or" and replace with "an initial application or renewal application form available from the Department";

7. 10 CFR 35.12(c)(1)(ii), delete wording “or renewal”;
8. 10 CFR 35.12(d), create new wording for (d) to state “A request for an amendment must be made by submitting a letter requesting the amendment with relevant supporting documentation as required by 35.610, 35.642, 35.643, and 35.645, as applicable”;
9. 10 CFR 35.12(d), change existing citation to 35.12(e);
10. 10 CFR 35.12(e), change existing citation to 35.12(f);
11. 10 CFR 35.18(a)(1), delete the wording “NRC Form 313 'Application for Material License,' and replace with “an original application for a specific license from the State”;
12. 10 CFR 35.24(a), replace “§ 20.1101 of this chapter” with “N.J.A.C. 7:28-6”;
13. 10 CFR 35.61(a), replace “10 CFR Part 20” with “N.J.A.C. 7:28-6”;
14. 10 CFR 35.70(a), replace “Part 20 of this chapter” with “N.J.A.C. 7:28-6”;
15. 10 CFR 35.80(a)(4), replace “Part 20 of this chapter” with “N.J.A.C. 7:28-6”;
16. 10 CFR 35.310(a)(2)(i), replace “§ 20.1301(a)(1) of this chapter” with “N.J.A.C. 7:28-6”;
17. 10 CFR 35.310(a)(2)(ii), replace “§ 20.1301(c) of this chapter” with “N.J.A.C. 7:28-6”;
18. 10 CFR 35.410(a)(4)(i), replace “§ 20.1301(a)(1) of this chapter” with “N.J.A.C. 7:28-6”;
19. 10 CFR 35.410(a)(4)(ii), replace “§ 20.1301(c) of this chapter” with “N.J.A.C. 7:28-6”;
20. 10 CFR 35.652(a), replace “§ 20.1501 of this chapter” with “N.J.A.C. 7:28-6”;
21. 10 CFR 35.3045(c), replace “NRC Operations Center” with “Department”;

22. 10 CFR 35.3047(c), replace “NRC Operations Center” with “Department”;

23. 10 CFR 35.3047(d), replace “appropriate NRC Regional Office listed in § 30.6 of this chapter” with “Department”; and

24. 10 CFR 35.3067, replace “appropriate NRC Regional Office listed in § 30.6 of this chapter” with “Department” and delete “, with a copy to the Director, Office of Nuclear Material Safety and Safeguards.”

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the Department via the Department’s website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC’s Form 3, “Notice to Employees” and the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation.”

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 56. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR

IRRADIATORS

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 36.

(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:

1. 10 CFR 36.8, Information collection requirements: OMB approval

(c) The following provisions of 10 CFR Part 36 are incorporated by reference with the specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 36 of the Code of Federal Regulations that are incorporated by reference, means the Department, except when specifically noted in this subchapter.

2. 10 CFR 36.1(a), delete "20," and add "N.J.A.C. 7:28-6" after "of this chapter";

3. 10 CFR 36.11, replace "Form NRC 313, 'Application for Material License,'" with "forms available from the Department," delete "and one copy," and replace "appropriate NRC Regional Office listed in appendix D to part 20 of this chapter" with "Department";

4. 10 CFR 36.17, replace "Commission" with "Department, with approval of the Commission on Radiation Protection," and replace "by law and will not endanger life or property or the common defense and security and are otherwise in the public interest" with "in accordance with the provisions of N.J.A.C. 7:28-2.8";

5. 10 CFR 36.23(g), replace “10 CFR 20.1902” in both locations with “N.J.A.C. 7:28-6”;

6. 10 CFR 36.55(a), replace “10 CFR 20.1501(c)” with “N.J.A.C. 7:28-6”;

7. 10 CFR 36.57(d), replace “10 CFR part 20, table 2, column 2 or table 3 of appendix B” with “as incorporated by reference in N.J.A.C. 7:28-6 ” and

8. 10 CFR 36.59(c), replace “table 2, column 2, appendix B to part 20” with “as incorporated by reference in N.J.A.C. 7:28-6.”

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the Department via the Department’s website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC’s Form 3, “Notice to Employees” and the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation.”

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 57. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL
LOGGING

7:28-57.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10
CFR Part 39.

(b) The following provisions of 10 CFR Part 39 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. 10 CFR 39.8, Information collection requirements: OMB approval

(c) The following provisions of 10 CFR Part 39 are incorporated by reference with the
specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear
Regulatory Commission," as used in the provisions of Part 39 of the Code of Federal Regulations
that are incorporated by reference, means the Department, except when specifically noted in this
subchapter.

2. 10 CFR 39.1(a), delete "20," and add "and N.J.A.C. 7:28-6" after "of this
chapter";

3. 10 CFR 39.11, replace "Form NRC 313, "Application for Material License."
with "forms available from the Department" and replace "appropriate NRC Regional Office
listed in appendix D of part 20 of this chapter" with "Department";

4. 10 CFR 39.15(a)(5)(iii)(B), replace "§ 20.1901(a)" with "N.J.A.C. 7:28-6";

5. 10 CFR 39.31(a)(1), replace "§ 20.1901(a)" with "N.J.A.C. 7:28-6";

6. 10 CFR 39.31(a)(2), replace “§ 20.1901(a)” with “N.J.A.C. 7:28-6”;
 7. 10 CFR 39.33(a), replace “part 20 of this chapter” with “N.J.A.C. 7:28-6”;
 8. 10 CFR 39.35(d)(2), replace “appropriate NRC Regional Office listed in appendix D of part 20 of this chapter” with “Department”;
 9. 10 CFR 39.61(a)(2)(i), delete “20,” and add “and N.J.A.C. 7:28-6” after “of this chapter”;
 10. 10 CFR 39.61(b)(1), delete “parts 19 and 20 of this chapter” and add “part 19 of this chapter and N.J.A.C. 7:28-6”;
 11. 10 CFR 39.63(h), replace “§ 20.1906 of this chapter” with “N.J.A.C. 7:28-6”;
 12. 10 CFR 39.71(b), replace “§ 20.1003 of this chapter” with “N.J.A.C. 7:28-6”;
 13. 10 CFR 39.73(a), replace “19, 20, and 39” with “N.J.A.C. 7:28-6, 50 and 57”;
 14. 10 CFR 39.75(d), replace § 71.5” with “N.J.A.C. 7:28-61”;
 15. 10 CFR 39.75(e), add “, or NRC” after “Agreement State”;
 16. 10 CFR 39.77(a), replace “NRC Regional Office by telephone” with “Department by telephone as per N.J.A.C. 7:28-1.5”;
 17. 10 CFR 39.77 (b), replace “§§ 20.2201-20.2202, § 20.2203 and §30.50” with “N.J.A.C. 7:28-6 and N.J.A.C. 7:28-51”; and
 18. 10 CFR 39.91, add "with the approval of the Commission on Radiation Protection," after "initiative," and replace “and will not endanger life or property or the common defense and security and are otherwise in the public interest” with “in accordance with the provisions of N.J.A.C. 7:28-2.8.”
- (f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 58. DOMESTIC LICENSING OF SOURCE MATERIAL

7:28-58.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 40.

(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. 10 CFR 40.2a, Coverage of inactive tailings sites;
2. 10 CFR 40.4, Definitions. The following definitions in 10 CFR 40.4 are not incorporated by reference: "Commission," "decommission," and "license."
3. 10 CFR 40.5, Communications;
4. 10 CFR 40.8, Information collection requirements: OMB approval;
5. 10 CFR 40.12(b), Carriers;
6. 10 CFR 40.20(b) and (c), Types of licenses;
7. 10 CFR 40.23, General license for carriers of transient shipments of natural uranium other than in the form of ore or ore residue;

8. 10 CFR 40.26, General license for possession and storage of byproduct material as defined in this part;
9. 10 CFR 40.27, General license for custody and long-term care of residual radioactive material disposal sites;
10. 10 CFR 40.28, General license for custody and long-term care of uranium or thorium byproduct materials disposal sites;
11. 10 CFR 40.31(c), (f) through (h), (j), (k), (l), Application for specific licenses;
12. 10 CFR Part 40.32(d), (e), (g), General requirements for issuance of specific licenses;
13. 10 CFR 40.33, Issuance of a license for a uranium enrichment facility;
14. 10 CFR 40.35(f), Conditions of specific licenses issued pursuant to §40.34
15. 10 CFR 40.38, Ineligibility of certain applicants;
16. 10 CFR 40.41(d), (e)(1), (e)(3), and (g), Terms and conditions of licenses;
17. 10 CFR 40.51(b)(6), Transfer of source or byproduct material;
18. 10 CFR 40.64, Reports;
19. 10 CFR 40.65, Effluent monitoring reporting requirements;
20. 10 CFR 40.66, Requirements for advance notice of export shipments of natural uranium;
21. 10 CFR 40.67, Requirement for advance notice for importation of natural uranium from countries that are not party to the Convention on the Physical Protection of Nuclear Material and

22. 10 CFR 40 Appendix A, Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material from Ores Processed Primarily for Their Source Material Content.

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

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 40 of the Code of Federal Regulations that are incorporated by reference, means the Department, except when specifically noted in this subchapter.

2. "Registrant" as used in the provisions of Part 40 of the Code of Federal Regulations that are incorporated by reference, means a "radioactive materials registrant" except when specifically noted.

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. 10 CFR 40.9(b), replace "Administrator of the appropriate Regional Office" with "Department";

5. 10 CFR 40.14(a), replace "Commission" with "Department, with approval of the Commission on Radiation Protection," and replace "by law and will not endanger life or property or the common defense and security and are otherwise in the public interest" with "in accordance with the provisions of N.J.A.C. 7:28-2.8";

6. 10 CFR 40.21, delete "or byproduct material";

7. 10 CFR 40.22(b), replace "parts 19, 20, and 21, of this chapter" with "part 21 of this chapter and N.J.A.C. 7:28-6 and N.J.A.C. 7:28-50" ;

8. 10 CFR 40.25(c)(1), replace "NRC Form 244, "Registration Certificate--Use of Depleted Uranium Under General License" with "forms available from the Department";

9. 10 CFR 40.25(c)(2), replace "Director, Division of Industrial and Medical Nuclear Safety, with a copy to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D of part 20 of this chapter" with "Department";

10. 10 CFR 40.25(d)(4), replace "Director, Division of Industrial and Medical Nuclear Safety, with a copy to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D of part 20 of this chapter" with "Department";

11. 10 CFR 40.25(e), delete " parts 19, 20, and 21, of this chapter" with "part 21 of this chapter and N.J.A.C. 7:28-6 and N.J.A.C. 7:28-50" ;

12. 10 CFR 40.31(a), replace "NRC Form 313, 'Application for Material License,' in accordance with the instructions in § 40.5 of this chapter" with "forms available from the Department";

13. 10 CFR 40.31(e), replace "§ 170.31" with "N.J.A.C. 7:28-64";

14. 10 CFR 40.34(a)(2), replace "§ 20.1201(a)" with "N.J.A.C. 7:28-6";

15. 10 CFR 40.25(c)(1), (c)(2), and (d)(3), add "or Department equivalent" after "Registration Certificate-Use of Depleted Uranium Under General License,";

16. 10 CFR 40.35(d)(1) and (d)(2), add "or Department equivalent" after "Registration Certificate-Use of Depleted Uranium Under General License,";

17. 10 CFR 40.35(e)(1), replace "Director, Office of Nuclear Material Safety and Safeguards" with "Department";

18. 10 CFR 40.31(c), replace "regulations contained in parts 2 and 9 of this chapter" with "the Open Public Records Act (N.J.S.A. 47:1A-1 et seq.)";

19. 10 CFR 40.31(e), replace "part 170" with "Subchapter 64" and "§ 170.31" with "Subchapter 64";

20. 10 CFR 40.36(e)(2), replace "part 30" with "Subchapter 51";

21. 10 CFR 40.36(f)(3)(i), replace "10 CFR 20.1003" with "N.J.A.C. 7:28-6";

22. 10 CFR 40.36(f)(3)(iii), replace "10 CFR 20.2108" with "N.J.A.C. 7:28-6";

23. 10 CFR 40.36(f)(3)(iv), replace "10 CFR part 20, subpart E" with "N.J.A.C. 7:28-12" and replace "10 CFR 20.2002" with "N.J.A.C. 7:28-6";

24. 10 CFR 40.41(c), replace "part 71" with "N.J.A.C. 7:28-61";

25. 10 CFR 40.41(f)(1), replace "appropriate NRC Regional Administrator" with "Department";

26. 10 CFR 40.42(j)(2), replace "10 CFR part 20, subpart E" with "N.J.A.C. 7:28-12";

27. 10 CFR 40.42(k)(3)(i), replace "10 CFR part 20, subpart E" with "N.J.A.C. 7:28-12";

28. 10 CFR 40.42(k)(3)(ii), replace "10 CFR part 20, subpart E" with "N.J.A.C. 7:28-12";

29. 10 CFR 40.43(a), add "or Department equivalent" after "NRC Form 313";

30. 10 CFR 40.44, add "or Department equivalent" after "NRC Form 313";

31. 10 CFR 40.60(b)(1)(ii), replace “appendix B of §§ 20.1001-20.2401 of 10 CFR part 20” with “N.J.A.C. 7:28-6”;

32. 10 CFR 40.60(b)(4)(i), replace “appendix B of §§ 20.1001-20.2401 of 10 CFR part 20” with “N.J.A.C. 7:28-6”;

33. 10 CFR 40.60(c)(2), replace “NRC’s Document Control Desk” with “Department” and replace “appropriate NRC regional office listed in appendix D to part 20 of this chapter” with “Department”;

34. 10 CFR 40.61(d)(1), replace “§ 20.2002, (including burials authorized before January 28, 1981), 20.2003, 20.2004, 20.2005” with “N.J.A.C. 7:28-6”;

35. 10 CFR 40.61(d)(2), replace “§20.2103(b)(4)” with “N.J.A.C. 7:28-6”;

36. 10 CFR 40.61(e)(1), replace “§ 20.2002, 20.2003, 20.2004, 20.2005” with “N.J.A.C. 7:28-6”; and

37. 10 CFR 40.61(e)(2), replace “§ 20.2103(b)(4)” with “N.J.A.C. 7:28-6.”

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the Department via the Department’s website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC’s Form 3, “Notice to Employees” and the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation.”

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 59. Licensing Requirements for Land Disposal of Radioactive Waste

7:28-59.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 61.

(b) The following provisions of 10 CFR Part 61 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. 10 CFR 61.4, Communications;
2. 10 CFR 61.8, Information collection requirements: OMB approval;
3. 10 CFR 61.16, Other information; and
4. 10 CFR 61.23(i), (j), Standards for issuance of a license.

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

1. “Nuclear Regulatory Commission,” “NRC,” and “U.S. Nuclear Regulatory Commission,” as used in the provisions of Part 61 of the Code of Federal Regulations, that are incorporated by reference, means the Department, except when specifically noted in this subchapter.

2. 10 CFR 61.1(a), replace “part 20 of this chapter” with “N.J.A.C. 7:28-6”;
3. 10 CFR 61.1(b), replace “part 150 of this chapter” with “N.J.A.C. 7:28-62”;

4. 10 CFR 61.1(b)(2), replace “part 40 of this chapter” with “N.J.A.C. 7:28-58”;
5. 10 CFR 61.1(b)(3), replace “part 20 of this chapter” with “N.J.A.C. 7:28-6”;
6. 10 CFR 61.5, 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,";
7. 10 CFR 61.6, replace "Commission" with "Department, with approval of the Commission on Radiation Protection," and replace "by law and will not endanger life or property or the common defense and security and are otherwise in the public interest" with "in accordance with the provisions of N.J.A.C. 7:28-2.8";
8. 10 CFR 61.7(c)(4), replace "Department" with "Department of Energy";
9. 10 CFR 61.12(k), replace “part 20 of this chapter” with “N.J.A.C. 7:28-6”;
10. 10 CFR 61.13(c), replace “part 20 of this chapter” with “N.J.A.C. 7:28-6”;
11. 10 CFR 61.20(c), replace “part 170 of this chapter” with “N.J.A.C. 7:28-64”
12. 10 CFR 61.23(d), replace “part 20 of this chapter” with “N.J.A.C. 7:28-6”;
13. 10 CFR 61.24(k)(1), replace “NRC Regional Administrator” with Supervisor of the Radioactive Materials Section”;
14. 10 CFR 61.43, replace “part 20 of this chapter” with “N.J.A.C. 7:28-6”;
15. 10 CFR 61.52(a)(6), replace “§§ 20.1301 and 20.1302 of this chapter” with “N.J.A.C. 7:28-6”;
16. 10 CFR 61.71, 10 CFR 61.72(a), 10 CFR 61.73(a), 10 CFR 61.73(b), and 10 CFR 61.73(c), replace “Director” with “Manager of the Bureau of Environmental Radiation”;
17. 10 CFR 61.80(i)(1), delete “to the Director, Office of Federal and State Materials and Environmental Management Programs," and replace “with a copy to the

appropriate NRC Regional Office shown in appendix D to part 20 of this chapter” with “to the Department”;

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

19. 10 CFR 61.80(j), replace “§70.52 of this chapter” with “N.J.A.C. 7:28-60”;
and

20. 10 CFR 61.80(k), replace “§§30.41, 40.51, and 70.42 of this chapter” with “N.J.A.C. 7:28-51, 58, and 60” and

21. 10 CFR 61.80(l)(1)(i), replace “in 10 CFR part 20, appendix G” with “as is incorporated by reference in N.J.A.C. 7:28-6”.

(d) For those facilities whose radioactive materials are licensed solely by the Department, NRC Form 3, “Notice to Employees” shall mean the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation,” available from the Department via the Department’s website at: www.nj.gov/dep/rpp/rms/rmsdown.htm, or by requesting a copy by telephone during business hours at (609) 984-5462.

(e) Those facilities which possess a license from the Department and the NRC for radioactive materials shall post both the NRC’s Form 3, “Notice to Employees” and the Department’s Form RPP-14, “Notice to Employees, Standards for Protection Against Radiation.”

(f) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(g) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 60. DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

7:28-60.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 70.

(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. 10 CFR 70.1(c) through (e), Purpose;
2. 10 CFR 70.4, definition of "Commission";
3. 10 CFR 70.5, Communications;
4. 10 CFR 70.8, Information collection requirements: OMB approval;
5. 10 CFR 70.13, Department of Defense;
6. 10 CFR 70.14, Foreign military aircraft;
7. 10 CFR 70.20a, General license to possess special nuclear material for transport;
8. 10 CFR 70.20b, General license for carriers of transient shipments of formula quantities of strategic special nuclear material, special nuclear material of moderate strategic significance, special nuclear material of low strategic significance, and irradiated reactor fuel;
9. 10 CFR 70.21(a)1, (c), and (f) through (h), Filing;
10. 10 CFR 70.22(b), (c), and (f) through (n), Contents of application;

11. 10 CFR 70.23(a)(6) through (12), and (b), Requirements for the approval of applications;

12. 10 CFR 70.23a, Hearing required for uranium enrichment facility;

13. 10 CFR 70.24, Criticality accident requirements;

14. 10 CFR 70.25(a), Financial assurance and recordkeeping for decommissioning;

15. 10 CFR 70.31(c) through (e), Issuance of licenses;

16. 10 CFR 70.32(a)(1), (4) through (7), (b)(1), (3), (4), and (c) through (k),

Conditions of licenses;

17. 10 CFR 70.37, Disclaimer of warranties;

18. 10 CFR 70.40, Ineligibility of certain applicants;

19. 10 CFR 70.42(b)(6), Transfer of special nuclear material;

20. 10 CFR 70.44, Creditor regulations;

21. 10 CFR 70.51(c), Records requirements;

22. 10 CFR 70.52, Reports of accidental criticality;

23. 10 CFR 70.55(c), Inspections;

24. 10 CFR 70.56(d), Tests;

25. 10 CFR 70.59, Effluent monitoring reporting requirements;

26. 10 CFR 70.60, Applicability;

27. 10 CFR 70.61, Performance requirements;

28. 10 CFR 70.62, Safety program and integrated safety analysis;

29. 10 CFR 70.64, Requirements for new facilities or new processes at existing facilities;

- 30. 10 CFR 70.65, Additional content of applications;
- 31. 10 CFR 70.66, Additional requirements for approval of license application;
- 32. 10 CFR 70.72, Facility changes and change process;
- 33. 10 CFR 70.74, Additional reporting requirements;
- 34. 10 CFR 70.76, Backfitting; and
- 35. 10 CFR 70.82, Suspension and operation in war or national emergency.

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

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 70 of the Code of Federal Regulations that are incorporated by reference, mean the Department.

2. 10 CFR 70.4, in definition of "person," replace "Department" with "Department of Energy";

3. 10 CFR 70.11, replace "Department" with "Department of Energy";

4. 10 CFR 70.17(a), replace "Commission" with "Department, with approval of the Commission on Radiation Protection," and replace "by law and will not endanger life or property or the common defense and security and are otherwise in the public interest" with "in compliance with N.J.A.C. 7:28-2.8";

5. 10 CFR 70.19(c), delete ,” 20,” and add “and N.J.A.C. 7:28-6”;

6. 10 CFR 70.21(d), replace "regulations contained in part 2 of this chapter" with "Open Public Records Act (N.J.S.A. 47:1A-1 et seq.)";

7. 10 CFR 70.25(g)(3)(i), replace “10 CFR 20.1003” with “N.J.A.C. 7:28-6”;

8. 10 CFR 70.25(g)(3)(iii), replace “10 CFR 20.2108” with “N.J.A.C. 7:28-6,”
replace “10 CFR part 20, subpart E” with “N.J.A.C. 7:28-12” and replace “10 CFR 20.2002”
with “N.J.A.C. 7:28-6”;
9. 10 CFR 70.25(g)(3)(iv) replace “10 CFR part 20, subpart E” with “N.J.A.C.
7:28-12” and replace “10 CFR 20.2002” with “N.J.A.C. 7:28-6”;
10. 10 CFR 70.38(j)(2), replace “10 CFR part 20, subpart E” with “N.J.A.C.
7:28-12”;
11. 10 CFR 70.38(k)(3)(i), replace “10 CFR part 20, subpart E” with “N.J.A.C.
7:28-12”;
12. 10 CFR 70.38(k)(3)(ii), replace “10 CFR part 20, subpart E” with “N.J.A.C.
7:28-12”;
13. 10 CFR 70.42(b)(1), replace "Department" with "Department of Energy";
14. 10 CFR 70.50(b)(1)(ii), replace “Appendix B of §§20.1001-20.2401 of 10
CFR part 20” with “N.J.A.C. 7:28-6”;
15. 10 CFR 70.50(b)(4)(i), replace “appendix B of §§20.2001-20.2401 of 10 CFR
part 20” with “N.J.A.C. 7:28-6”;
16. 10 CFR 70.50(c)(2), delete “to the NRC’s Document Control Desk,” and
replace “with a copy to the appropriate NRC regional office listed in appendix D to part 20 of
this chapter” with “to the Department”;
17. 10 CFR 70.51(a)(1), replace “10 CFR 20.2002, (including burials authorized
before January 28, 1981), 20.2003, 20.2004, 20.2005” with “N.J.A.C. 7:28-6”;
18. 10 CFR 70.51(a)(2), replace “10 CFR 20.2103(b)(4)” with “N.J.A.C. 7:28-6”;

19. 10 CFR 70.51(b)(1), replace “10 CFR 20.2002, (including burials authorized before January 28, 1981), 20.2003, 20.2004, 20.2005” with “N.J.A.C. 7:28-6”;

20. 10 CFR 70.51(b)(2), replace “10 CFR 20.2103(b)(4)” with “N.J.A.C. 7:28-6”; and

21. 10 CFR 70.56, replace "(b) facilities wherein special nuclear material is utilized, produced or stored," with "and."

(d) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(e) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 61. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

7:28-61.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 71.

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

1. 10 CFR 71.6, Information collection requirements: OMB approval;
2. 10 CFR 71.10, Public inspection of application;

3. 10 CFR 71.14(b), Exemptions for low-level materials;
4. 10 CFR 71.19, Previously approved package;
5. 10 CFR 71.31, Contents of application;
6. 10 CFR 71.33, Package description;
7. 10 CFR 71.35, Package evaluation;
8. 10 CFR 71.37, Quality assurance;
9. 10 CFR 71.38, Renewal of a certificate of compliance or quality assurance

program approval;

10. 10 CFR 71.39, Requirement for additional information;
11. 10 CFR 71.41, Demonstration of compliance;
12. 10 CFR 71.43, General standards for all packages;
13. 10 CFR 71.45, Lifting and tie-down standards for all packages;
14. 10 CFR 71.51, Additional requirements for Type B packages;
15. 10 CFR 71.55, General requirements for fissile material packages;
16. 10 CFR 71.59, Standards for arrays of fissile material packages;
17. 10 CFR 71.61, Special requirements for Type B packages containing more

than $10^5 A_2$;

18. 10 CFR 71.63, Special requirement for plutonium shipments;
19. 10 CFR 71.64, Special requirements for plutonium air shipments;
20. 10 CFR 71.65, Additional requirements;
21. 10 CFR 71.71, Normal conditions of transport;
22. 10 CFR 71.73, Hypothetical accident conditions;
23. 10 CFR 71.74, Accident conditions for air transport of plutonium;

24. 10 CFR 71.75, Qualification of special form radioactive material;
25. 10 CFR 71.77, Qualification of LSA-III Material;
26. 10 CFR 71.101(c)(2), (d) through (e), Quality assurance requirements;
27. 10 CFR 71.107, Package design control;
28. 10 CFR 71.109, Procurement document control;
29. 10 CFR 71.111, Instructions, procedures and drawings;
30. 10 CFR 71.113, Document control;
31. 10 CFR 71.115, Control of purchased material, equipment and services;
32. 10 CFR 71.117, Identification and control of materials, parts and components;
33. 10 CFR 71.119, Control of special processes;
34. 10 CFR 71.121, Internal inspection;
35. 10 CFR 71.123, Test control and;
36. 10 CFR 71.125, Control of measuring and test equipment.

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

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 71 of the Code of Federal Regulations that are incorporated by reference, means the Department, except at:
 - i) 10 CFR 71.0(a)2 and (d)1;
 - ii) 10 CFR 71.4, definitions for "Certificate Holder," "Certificate of Compliance(CoC)" and "Package (3) Type B Package";
 - iii) 10 CFR 71.85(c), Preliminary determinations;
 - iv) 10 CFR 71.88(a)4, Air transport of plutonium;

- v) 10 CFR 71.93(c), Inspections and tests;
- vi) 10 CFR 71.95(a)(1) and (a)(2);
- vii) 10 CFR 71.97(c)(1), (c)(3)(iii), and (f), Advance notification of shipment of irradiated reactor fuel and nuclear waste; and
- viii) 10 CFR 71.101(f), Quality assurance requirements;
2. 10 CFR 71.0(b), replace “parts of this chapter (e.g., 10 CFR parts 20, 21, 30, 40, 70 and 73),” with “State Regulations (e.g. N.J.A.C. 7:28-6, 51, 58, and 60)” and add “U.S. Nuclear Regulatory Commission (NRC)” into the list of other agencies;
3. 10 CFR 71.1(a), replace rule text with “Except where otherwise specified, all communications and reports concerning the regulations in this part and applications filed under them should be sent to the Department as specified in N.J.A.C. 7:28-1.5.”;
4. 10 CFR 71.2, 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,";
5. 10 CFR 71.5(b), replace "Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555-0001" with "the Department in accordance with N.J.A.C. 7:28-1.5”;
6. 10 CFR 71.7(b), replace "Administrator of the appropriate Regional Office" with "Department”;
7. 10 CFR 71.9(c), replace “Commission licensee, certificate holder, applicant for a Commission license or a CoC” with “Department licensee, NRC certificate holder, applicant for a Department license or NRC CoC”;

8. 10 CFR 71.9(e)(1), replace “Each licensee, certificate holder, and applicant for a license or CoC must prominently post the current revision of NRC Form 3, ‘Notice to Employees,’ referenced in §19.11(c) of this chapter” with “Each licensee, certificate holder, and applicant for a license or CoC must prominently post the current revision of Department Form RPP-14, ‘Notice to Employees, Standards for Protection Against Radiation,’ referenced in Subchapter 50”;

9. 10 CFR 71.9(e)2, replace with "Copies of Department Form RPP 14 may be obtained from the Department in accordance with N.J.A.C. 7:28-1.5.";

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";

11. 10 CFR 71.13, replace “10 CFR part 35” with “N.J.A.C. 7:28-55”;

12. 10 CFR 71.47(b)(4), replace “10 CFR 20.1502” with “N.J.A.C. 7:28-6”;

13. 10 CFR 71.89, replace "10 CFR 20.1906" with "N.J.A.C. 7:28-6";

14. 10 CFR 71.95(c), replace “§ 71.1(a)” with “N.J.A.C.7:28-1.5” and replace “to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards” with “to the Department”;

15. 10 CFR 71.101(c)1, replace “§ 71.1(a)” with “N.J.A.C.7:28-1.5” and replace “to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards” with “to the Department”; and

16. 10 CFR 71.101(f), replace “NRC, in accordance with § 71.1” with “Department, in accordance with N.J.A.C.7:28-1.5.”

(d) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(e) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 62. EXEMPTIONS AND CONTINUED NRC REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER 42 U.S.C. §2021

SECTION 274

7:28-62.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 150.

(b) The following provisions of 10 CFR Part 150 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. 10 CFR 150.3, Definition of "Commission";
2. 10 CFR 150.4, Communications;
3. 10 CFR 150.7, Persons in offshore waters not exempt;
4. 10 CFR 150.8, Information collection requirements: OMB approval;
5. 10 CFR 150.10, Persons exempt;
6. 10 CFR 150.14, Commission regulatory authority for physical protection;
7. 10 CFR 150.15, Persons not exempt;

8. 10 CFR Part 150.15a, Continued Commission authority pertaining to byproduct material;
9. 10 CFR Part 150.16, Submission to Commission of nuclear material transfer reports;
10. 10 CFR Part 150.17, Submission to Commission of source material reports;
11. 10 CFR Part 150.17a, Compliance with requirements of US/IAEA safeguards agreement;
12. 10 CFR Part 150.19, Submission to Commission of tritium reports;
13. 10 CFR Part 150.21, Transportation of special nuclear material by aircraft;
14. 10 CFR 150.31, Requirements for Agreement State regulation of byproduct material; and
15. 10 CFR 150.32, Funds for reclamation or maintenance of byproduct material.

(c) The following provisions of 10 CFR Part 150 are incorporated by reference with the specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 150 of the Code of Federal Regulations that are incorporated by reference, mean the Department.

2. 10 CFR 150.20(b), references to specific sections of 10 CFR part 30, refer to N.J.A.C. 7:28-51, sections of 10 CFR part 40, refer to N.J.A.C. 7:28-58, and sections of 10 CFR part 70, refer to N.J.A.C. 7:28-60. Replace "parts 19, 20, and 71" with "N.J.A.C. 7:28-6, 50, and 61", and replace "part 34" with N.J.A.C. 7:28-63".

(d) The incorporation by reference of 10 CFR 150.20(b) shall not include the ability to issue general licenses to operate in areas of exclusive Federal jurisdiction and offshore waters,

but only to Agreement State and NRC licensees that wish to operate within New Jersey's jurisdiction in accordance with N.J.A.C. 7:28-50.1(d).

(e) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(f) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 63. LICENSES FOR INDUSTRIAL RADIOGRAPHY USING SEALED SOURCES AND RADIATION SAFETY REQUIREMENTS FOR SUCH INDUSTRIAL RADIOGRAPHIC OPERATIONS

7:28-63.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 34.

(b) The following provisions of 10 CFR Part 34 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. 10 CFR 34.8, Information collection requirements: OMB approval.

(c) The following provisions of 10 CFR Part 34 are incorporated by reference with the specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the provisions of Part 34 of the Code of Federal Regulations that are incorporated by reference, mean the Department, except in 10 CFR 34.41(c), and 34.27(a) and (c)(1);

2. 10 CFR 34.1, replace "parts 19, 20, 21, 30, 71, 150, 170, and 171" with "10 CFR Part 21 and N.J.A.C. 7:28-6, 50, 51, 61, 62 and 64";

3. 10 CFR 34.11, replace "on NRC Form 313, "Application for Material License," in accordance with the provisions of § 30.32 of this chapter," with an original application for a specific State license";

4. 10 CFR 34.13(a), replace "§ 30.33 of this chapter" with "N.J.A.C. 7:28-51";

5. 10 CFR 34.25(a), replace "10 CFR part 20" with "N.J.A.C. 7:28-6";

6. 10 CFR 34.27(d), replace "Director of Nuclear Material Safety and Safeguards" with "Manager, Bureau of Environmental Radiation";

7. 10 CFR 34.27(d), replace "Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of 10 CFR part 20 of this chapter 'Standards for Protection Against Radiation' with "Manager, Bureau of Environmental Radiation";

8. 10 CFR 34.33(a)(1), replace "§ 20.1601(a)(1) of this chapter" with "N.J.A.C. 7:28-6";

9. 10 CFR 34.35(b), replace "10 CFR part 71" with "N.J.A.C. 7:28-61";

10. 10 CFR 34.42(c)(1), replace "10 CFR part 20 of this chapter" and "10 CFR part 20" with "N.J.A.C. 7:28-6" in both instances;

11. 10 CFR 34.42(c)(4), replace "§ 20.2203 of this chapter" with "N.J.A.C. 7:28-6";

12. 10 CFR 34.43(a)(1), replace “Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a)” with “Manager, Bureau of Environmental Radiation, by an appropriate method listed in N.J.AC. 7:28-51”;

13. 10 CFR 34.43(b)(1), replace “in §§30.7, 30.9, and 30.10” with “N.J.A.C. 7:28-51”, replace “10 CFR parts 19 and 20” with “N.J.A.C.7:28-6 and 50”, and replace “10 CFR 71” with “N.J.A.C. 7:28-61”;

14. 10 CFR 34.43(c)(1), replace “in §§30.7, 30.9, and 30.10” with “N.J.A.C. 7:28-51”, replace “10 CFR parts 19 and 20” with “N.J.A.C.7:28-6 and 50”, and replace “10 CFR part 71” with “N.J.A.C. 7:28-61”;

15. 10 CFR 34.45(a)(1), replace “10 CFR part 20” with “N.J.A.C. 7:28-6”;

16. 10 CFR 34.51, replace “10 CFR part 20” with “N.J.A.C. 7:28-6”;

17. 10 CFR 34.53, replace “§ 20.1902” with “N.J.A.C. 7:28-6” and replace “§ 20.1903” with “N.J.A.C. 7:28-6”;

18. 10 CFR 34.89(b)(2), replace “ 19, 20,” with “and N.J.A.C. 7:28-6, 50, and 63”;

19. 10 CFR 34.89(b)(11), replace “§ 71.5” with “N.J.A.C. 7:28-61”

20. 10 CFR 34.89(b)(12), and replace “§ 150.20” with “N.J.A.C. 7:28-62”;

21. 10 CFR 34.101(a), replace “§ 30.50 and under other sections of this chapter, such as § 21.21, each licensee shall send a written report to the NRC's Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety, by an appropriate method listed in § 30.6(a) of this chapter” with “N.J.A.C. 7:28-51 and under other sections of this subchapter or Federal rule such as 10 CFR § 21.21, each licensee shall send a written report

to the Manager, Bureau of Environmental Radiation, by an appropriate method listed in N.J.A.C. 7:28-51”;

22. 10 CFR 34.101(b), replace “10 CFR 20.2203” with “N.J.A.C. 7:28-6”;

23. 10 CFR 34.101(c), replace “appropriate NRC regional office listed in § 30.6(a)(2) of this chapter” with “Department”; and

22. 10 CFR 34.111, replace "Commission" with "Department, with approval of the Commission on Radiation Protection," and replace "by law and will not endanger life or property or the common defense and security and are otherwise in the public interest" with "in accordance with the provisions of N.J.A.C. 7:28-2.8";

(d) Reports that are to be submitted to the Department pursuant to this subchapter shall be submitted to the address at N.J.A.C. 7:28-1.5.

(f) Requests for adjudicatory hearings shall be made in accordance with N.J.A.C. 7:28-4.17, and requirements governing requests for stay of the effective date of the Department decision for which an adjudicatory hearing is requested are set forth at N.J.A.C. 7:28-4.18.

SUBCHAPTER 64. RADIOACTIVE MATERIALS LICENSE FEES

7:28-64.1 Purpose and Applicability

(a) This subchapter establishes fees for registration and licensing of radioactive materials. Annual license fees for radioactive materials are set forth in Tables 1 and 2 at N.J.A.C. 7:28-64.2.

(b) Fees will be effective on the (the operative date of the rules).

(c) Fees for NRC licenses that are transferred to New Jersey will be prorated to (July of the year following the operative date of these rules), when the Department will again issue invoices for annual fees.

7:28-64.2 Schedule of fees

(a) Except as set forth in (b) and (c) below, this section incorporates by reference the table in 10 CFR 171.16 entitled "Schedule of materials annual fees and fees for government agencies licensed by NRC."

(b) The Department does not regulate nuclear reactors, special nuclear materials in quantities sufficient to form a critical mass, high-level waste disposal facilities, or byproduct material defined in Section 11e(2) of the Atomic Energy Act of 1954, 42 U.S.C. § 2014, as amended.

(c) Insofar as the incorporated rules refer to the facilities and/or materials in (b) above, they do not apply. The following provisions of the table identified in (a) above are incorporated by reference with the specified changes:

1. Delete column 2, labeled "Annual fees";
2. Delete row labeled 2.A.(5);
3. Row labeled 3.A, replace "parts 30 and 33 of this chapter" with "N.J.A.C.

7:28-51 and 54";

4. Row labeled 3.C., replace "§§ 32.72 and/or 32.74 of this chapter" with "N.J.A.C. 7:28-53.

5. Row labeled 3.C., delete "This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under 171.11(a)(1). The licenses are covered by fee under Category 3.D.";

6. Row labeled 3.J., replace "Subpart B of part 32 of this chapter" with "N.J.A.C. 7:28-53," and replace "part 31 of this chapter" with "N.J.A.C. 7:28-52";

7. Row labeled 3.K, replace " Subpart B of part 32 of this chapter" with "N.J.A.C. 7:28-53," and replace "part 31 of this chapter" with "N.J.A.C. 7:28-52";

8. Row labeled 3.L., replace "parts 30 and 33 of this chapter" with "N.J.A.C. 7:28-51 and 54";

9. Row labeled 3.M., replace "part 30 of this chapter" with "N.J.A.C. 7:28-51";

10. Row labeled 3.O., replace "part 40 of this chapter" with "N.J.A.C. 7:28-58";

11. Row labeled 3.R., replace "10 CFR 31.12" with "N.J.A.C. 7:28-52";

12. Row labeled 3.R.2., replace "10 CFR 31.12(a)(4), or (5)" with "N.J.A.C. 7:28-52";

13. Row labeled 7.A., replace "parts 30, 35, 40, and 70 of this chapter" with "N.J.A.C. 7:28-51, 55, 58, and 60";

14. Row labeled 7.B., replace "parts 30, 33, 35, 40, and 70" with "N.J.A.C. 7:28-51, 54, 55, 58, and 60";

15. Row labeled 7.C., replace "parts 30, 35, 40, and 70 of this chapter " with "N.J.A.C. 7:28-51, 55, 58, and 60";

16. Row labeled 14.A., replace "parts 30, 40, 70, 72, and 76 of this chapter" with "N.J.A.C. 7:28-51, 58, and 60";

(d) Fees for source, byproduct, and certain special nuclear materials are established in Table 1, Schedule of Source, Special Nuclear, and Byproduct Material Annual Fees, and are matched to the NRC categories, incorporated by reference in (a) and (b) above.

(e) Other specified fees, including fees for diffuse NARM, are established in Table 2, Schedule of Radioactive Materials Annual Fees.

(f) If, by amendment or otherwise, a license changes to another fee category, the fee for the new category will take effect on the anniversary date of the license.

(g) The fee for any category for which a fee is not provided at Table 1 below shall be calculated in accordance with N.J.A.C. 7:28-64.3(c) and 64.4(e).

Table 1

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

<u>FEE CATEGORY</u>	<u>LICENSE TYPE</u>	<u>ANNUAL FEE (\$)</u>
<u>1.</u>	<u>Special Nuclear Material</u>	
<u>A.</u>	<u>(Reserved.)</u>	
<u>B.</u>	<u>(Reserved.)</u>	
<u>C.</u>	<u>(Reserved.)</u>	
<u>D</u>	<u>All other special nuclear material</u> <u>except a) licenses</u> <u>authorizing special nuclear material</u> <u>in unsealed form in combination</u> <u>that would constitute a critical</u>	<u>4,275</u>

facility.

<u>C.</u>	All other source material licenses	<u>9,825</u>
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<u>3.</u>	<u>Byproduct material</u>	
<u>A.</u>	<u>Licenses of broad scope for possession and use of byproduct material issued under subchapters 51 and 54 for processing or manufacturing of items containing byproduct material for commercial distribution.</u>	<u>21,600</u>
<u>B.</u>	<u>Other licenses for possession and use of byproduct material issued under subchapter 51 for processing or manufacturing of items containing byproduct material for commercial distribution. This category also includes licenses for repair, assembly, and disassembly of products containing radium-226.</u>	<u>6,225</u>
<u>C.</u>	<u>Licenses issued under subchapter 53 authorizing the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits and/or sources and</u>	<u>8,850</u>

	<u>devices containing byproduct</u>	
	<u>material. This category also includes</u>	
	<u>the possession and use of source</u>	
	<u>material for shielding authorized</u>	
	<u>under subchapter 58 of this chapter</u>	
	<u>when included on the same license.</u>	
<u>D.</u>	<u>(Reserved.)</u>	
<u>E.</u>	<u>Licenses for possession and use of</u>	<u>3,000</u>
	<u>byproduct material in sealed sources</u>	
	<u>for irradiation of materials in which</u>	
	<u>the source is not removed from its</u>	
	<u>shield (self-shielded units).</u>	
<u>F.</u>	<u>Licenses for possession and use of</u>	<u>5,850</u>
	<u>less than 10,000 curies of byproduct</u>	
	<u>material in sealed sources for</u>	
	<u>irradiation of materials in which the</u>	
	<u>source is exposed for irradiation</u>	
	<u>purposes. This category also includes</u>	
	<u>underwater irradiators for irradiation</u>	
	<u>of materials in which the source is</u>	
	<u>not exposed for irradiation purposes.</u>	
<u>G.</u>	<u>Licenses for possession and use of</u>	<u>23,100</u>
	<u>10,000 curies or more of byproduct</u>	

material in sealed sources for
irradiation of materials in which the
source is exposed for irradiation
purposes. This category also includes
underwater irradiators for irradiation
of materials in which the source is
not exposed for irradiation purposes.

H. (Reserved.)

I. (Reserved.)

J. Licenses issued under subchapter 53 1,800
of this chapter to distribute items
containing byproduct material that
require sealed source and/or device
review to persons generally licensed
under subchapter 52 of this chapter,
except specific licenses authorizing
redistribution of items that have been
authorized for distribution to persons
generally licensed under subchapter
52 of this chapter.

K. Licenses issued under subchapter 53 1,350
of this chapter to distribute items
containing byproduct material or

quantities of byproduct material that
do not require sealed source and/or
device review to persons generally
licensed under subchapter 52 of this
chapter, except specific licenses
authorizing redistribution of items
that have been authorized for
distribution to persons generally
licensed under subchapter 52 of this
chapter.

<u>L.</u>	<u>Licenses of broad scope for</u> <u>possession and use of byproduct</u> <u>material issued under subchapters 51</u> <u>and 54 of this chapter for research</u> <u>and development that do not</u> <u>authorize commercial distribution.</u>	<u>11,000</u>
<u>M.</u>	<u>Other licenses for possession and use</u> <u>of byproduct material issued under</u> <u>subchapter 51 of this chapter for</u> <u>research and development that do not</u> <u>authorize commercial distribution.</u>	<u>4,200</u>
<u>N.</u>	<u>Licenses that authorize services for</u> <u>other licensees, except: Licenses that</u>	<u>6,225</u>

authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.

<u>Q.</u>	<u>Licenses for possession and use of byproduct material issued under subchapter 63 of this chapter for industrial radiography operations.</u> <u>This category also includes the possession and use of source material for shielding authorized under subchapter 58 of this chapter when authorized on the same license.</u>	<u>10,575</u>
<u>P.</u>	<u>All other specific byproduct material licenses, except those in Categories 4.A through 9.D.</u>	<u>2,025</u>
<u>Q.</u>	<u>(Reserved.)</u>	
<u>R.</u>	<u>Possession of items or products containing radium-226 identified in subchapter 52 which exceed the number of items or limits specified in that section: (Persons who possess radium sources that are used for operational purposes in another fee</u>	

	<u>category are not also subject to the</u>	
	<u>fees in this category. This exception</u>	
	<u>does not apply if the radium sources</u>	
	<u>are possessed for storage only.)</u>	
<u>1.</u>	<u>Possession of quantities exceeding</u>	<u>1,575</u>
	<u>the number of items or limits in 10</u>	
	<u>subchapter 52, but less than or equal</u>	
	<u>to 10 times the number of items or</u>	
	<u>limits specified.</u>	
<u>2.</u>	<u>Possession of quantities exceeding 10</u>	<u>2,025</u>
	<u>times the number of items or limits</u>	
	<u>specified in Subchapter 52.</u>	
<u>S.</u>	<u>Licenses for production of</u>	<u>8,100</u>
	<u>accelerator-produced radionuclides.</u>	
<u>4.</u>	<u>Waste Processing</u>	
<u>A.</u>	<u>(Reserved.)</u>	
<u>B.</u>	<u>(Reserved.)</u>	
<u>C.</u>	<u>(Reserved.)</u>	
<u>5.</u>	<u>Well Logging</u>	
<u>A.</u>	<u>Licenses for possession and use of</u>	<u>3,225</u>
	<u>byproduct material, source material,</u>	
	<u>and/or special nuclear material for</u>	
	<u>well logging, well surveys, and tracer</u>	

tracer studies.

6. Nuclear Laundry

7. Medical

authorized on the same license.

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

8. (Reserved.)

9. (Reserved.)

10. (Reserved.)

11. (Reserved.)

12. (Reserved.)

13. (Reserved.)

14. **Decommissioning/Reclamation**

A. Byproduct, source, or special nuclear Full Cost
material licenses and other approvals
authorizing decommissioning,
decontamination, reclamation, or site
restoration activities under
subchapters 51, 58, and 60 of this
chapter.

B. Site-specific decommissioning Full Cost
activities associated with unlicensed
sites, whether or not the sites have
been previously licensed.

15. (Reserved.)

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|-------------------|---------------------------|--|---------------------------------|
| <u>16.</u> | <u>Reciprocity</u> | <u>Reciprocal recognition of an out-of-</u> | <u>50 percent of annual fee</u> |
| | | <u>state license for a period of less than</u> | <u>of applicable category</u> |
| | | <u>180 days.</u> | |
| <u>17.</u> | <u>(Reserved.)</u> | | |
| <u>18.</u> | <u>(Reserved.)</u> | | |

Table 2

Schedule of Radioactive Materials Annual Fees

<u>FEE CATEGORY</u>	<u>LICENSE TYPE</u>	<u>ANNUAL FEE (\$)</u>
<u>1.</u>	<u>Water Treatment</u>	
	<u>Facilities as defined in</u>	
	<u>N.J.A.C. 7:10-3.6</u>	
<u>A.</u>	<u>Very Small Community</u>	<u>\$300</u>
	<u>Water Systems</u>	
<u>B.</u>	<u>Small Community Water</u>	<u>\$875</u>
	<u>Systems</u>	
<u>C.</u>	<u>Medium Community Water</u>	<u>\$1250</u>
	<u>Systems</u>	
<u>D.</u>	<u>Large Community Water</u>	<u>\$2500</u>
	<u>Systems</u>	
<u>E.</u>	<u>Non-Transient Non-</u>	<u>\$200</u>
	<u>Community Water Systems</u>	

	<u>treating equal to or less than</u>	
	<u>1000 gallons per day</u>	
<u>F.</u>	<u>Non-Transient Non-</u>	<u>\$500</u>
	<u>Community Water Systems</u>	
	<u>treating more than 1000</u>	
	<u>gallons per day</u>	
<u>2.</u>	<u>Amendments</u>	
<u>A.</u>	<u>Request to amend a license</u>	<u>\$0</u>
	<u>requiring no license review</u>	
	<u>including, but not limited</u>	
	<u>to, facility name change or</u>	
	<u>removal of a previously</u>	
	<u>authorized user.</u>	
<u>B.</u>	<u>Request to amend a license</u>	<u>\$200</u>
	<u>requiring review including,</u>	
	<u>but not limited to, addition</u>	
	<u>of isotopes, procedure</u>	
	<u>changes, new authorized</u>	
	<u>users, or a new radiation</u>	
	<u>safety officer.</u>	
<u>C.</u>	<u>Request to amend a license</u>	<u>\$400</u>
	<u>requiring review and a site</u>	
	<u>visit, but not limited to,</u>	

facility move or addition of
a process.

3. Inspections

<u>A.</u>	<u>Routine</u>	<u>\$0</u>
<u>B.</u>	<u>Non-routine reinspection</u>	<u>Full Cost</u>
<u>C.</u>	<u>Pre-licensing</u>	<u>\$400</u>
<u>D.</u>	<u>Reciprocity</u>	<u>\$400</u>
<u>E.</u>	<u>Inspection as a result of an</u> <u>incident</u>	<u>Full Cost</u>

4. Additional Use Sites

<u>A.</u>	<u>(Non-contiguous)</u> <u>Non-profit educational</u> <u>institutions</u>	<u>25% of appropriate fee</u>
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<u>B.</u>	<u>Medical Private Practices</u>	<u>50% of appropriate fee</u>
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<u>5.</u>	<u>Generally Licensed</u>	<u>\$350</u>
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Devices

<u>6.</u>	<u>Diffuse NARM License</u>	<u>\$2500</u>
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7:28-64.3 Application Fee

(a) An initial application for a license shall be accompanied by payment in the full amount of the fee specified in Tables 1 and 2 at N.J.A.C. 7:28-64.2.

(b) The Department may not process the application prior to the receipt of the required fee. The application fee is not refundable except in those cases where the Department determines that a license is not required.

(c) A license covering more than one of the categories in Tables 1 and 2 at N.J.A.C. 7:28-64.2 shall be accompanied by the prescribed fee for each category applicable to the license.

(d) The application fee for a category of NRC license that is not included in Table 1 at N.J.A.C. 7:28-64.2 shall be calculated as follows: NJ Fee = 0.75 (NRC Annual fee + 0.1 NRC application fee). NRC fees are established in 10 CFR Parts 170 and 171. The Department incorporates by reference the fee provisions of 10 CFR Parts 170 and 171, for purposes of calculating fees pursuant to this subsection.

7:28-64.4 Annual Fee

(a) The annual fee is not refundable except in those cases where the Department determines that the fee is not required.

(b) Fees are payable 30 days after the date of the invoice.

(c) A license covering more than one of the categories in Tables 1 and 2 at N.J.A.C. 7:28-64.2 shall be invoiced for the prescribed fee for each category applicable to the license.

(d) The annual fee for a category of NRC license that is not included in Tables 1 and 2 at N.J.A.C. 7:28-64.2 shall be calculated as follows: NJ Fee = 0.75 (NRC Annual fee + 0.1 NRC application fee). NRC fees are established in 10 CFR Part 170 and 171. The Department incorporates by reference the fee provisions of 10 CFR Parts 170 and 171, for purposes of calculating fees pursuant to this subsection.

(e) No refund of a fee will be provided if a license is terminated.

7:28-64.5 Inspections

(a) The Department shall make periodic inspections of licensees.

(b) If the Department finds a violation that could have implications regarding worker or public dose limits at Subchapter 6 during an inspection, the licensee must pay all Department costs associated with subsequent reinspection of the licensee. The costs shall be the actual costs incurred by the Department and include, but not limited to, labor, transportation, per diem, materials, legal fees, and monitoring costs.

7:28-64.6 Reciprocity fees

(a) A licensee submitting an application for reciprocal recognition of a materials license issued by another Agreement State or the NRC for a period of 180 days or less during a calendar year must pay one-half of the fee specified under Tables 1 and 2 at N.J.A.C. 7:28-64.2 .

(b) The Department will not process the application for reciprocity prior to the receipt of the required fee.

7:28-64.7 Fees for Licensees with Additional Use Sites

(a) The Department will consider sites that are not contiguous or adjacent as additional use sites for non-profit educational institutions provided that:

1. The sites are operated by the same person;
2. The sites are in the same license category or categories;
3. The applicant for a license provides for one radiation safety officer, and if applicable, one radiation safety committee, as responsible for all sites; and
4. The Department is reasonably satisfied from the information provided in the application that the applicant will adequately control radioactive material at all sites listed in the application.

(b) Each additional use site as defined (a) above shall be charged 25 percent of the applicable fee for each applicable category.

(c) The Department will consider sites that are not contiguous or adjacent as additional use sites for private medical practices, provided that:

1. The sites are operated by the same person;
2. The sites are in the same license category or categories;
3. The applicant for a license provides for one radiation safety officer, and if applicable, one radiation safety committee, as responsible for all sites;
4. The Department is reasonably satisfied from the information provided in the application that the applicant will adequately control radioactive material at all sites listed in the application; and
5. There shall be no more than three additional use sites per license.

(d) Each additional use site as defined (c) above shall be charged 50 percent of the applicable fee for each applicable category.

7:28-64.8 Fees for license amendments

An application for 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.

7:28-64.9 Failure to pay prescribed fees

(a) The Department will not process any application unless the licensee pays, on or before the due date, the fee prescribed by this subchapter.

(b) If the Department finds that a licensee has not paid a renewal fee prescribed by this section by the due date, the Department will take the appropriate enforcement action.

7:28-64.10 Annual adjustment of fees

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

(b) The inflation factor shall be the past year percent change for the United States city average, all items, all urban consumers.

(c) If the inflation factor for a 12 month period is negative, the fees will remain unchanged from the previous year.

(d) The adjusted fees shall be reflected through a Notice of Administrative Change, published in the New Jersey Register; however, the adjusted fees shall be effective on July 1, whether or not a Notice of Administrative Change has been published.