ENVIRONMENTAL PROTECTION

AIR QUALITY, ENERGY, AND SUSTAINABILITY

DIVISION OF ENERGY, SECURITY, AND SUSTAINABILITY

COMMISSION ON RADIATION PROTECTION

Radiation Protection Programs

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

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

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

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

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

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

DEP Docket Number: 09-15-09.

Proposal Number: PRN 2015-134.

Submit comments by December 18, 2015, electronically at http://www.nj.gov/dep/rules/comments. Each comment should be identified by the applicable N.J.A.C. citation, with the commenter's name and affiliation following the comment.

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

Alice A. Previte, Esq.

Attention: DEP Docket Number 09-15-09

Office of Legal Affairs

Department of Environmental Protection

401 East State Street, 7th Floor

Mail Code 401-04L

P.O. Box 402

Trenton, New Jersey 08625-0402

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

The agency proposal follows:

Summary

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

The Radiation Protection Act, N.J.S.A. 26:2D-1 et seq., and the Radiologic Technologist Act, N.J.S.A. 26:2D-24 et seq., govern the possession, handling, and use of sources of radiation within the State of New Jersey. The Radiation Protection Act established the Commission and vested in that body the power to promulgate rules and regulations as may be necessary to prohibit and prevent unnecessary radiation. The Radiation Protection Act authorizes the Department to establish and charge fees, through the promulgation of rules, for any of the services it performs under the Radiation Protection Act. Therefore, both the Commission and the Department propose the within amendments, repeals, and new rules.

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

The Department and the Commission propose three general categories of amendments. The first category implements recent amendments to the Radiologic Technologist Act, N.J.S.A. 26:2D-24 et seq. (the Act), which amendments created the new license category of fusion imaging CT technology for licensed nuclear medicine technologists. The proposed amendments establish the educational and licensing requirements and the scope of practice for this new license category, and establish a new fee schedule for examination and licensing. Related to this category are proposed amendments to the existing rules governing the licensing of nuclear medicine technologists to streamline examination requirements and clarify requirements. The second category of amendments relates to the NRC's requirements for Agreement States. Proposed amendments incorporate 10 CFR Part 37, Physical Protection of Category 1 and

Category 2 Quantities of Radioactive Material, by reference into the State's rules, amend the provisions incorporating 10 CFR Part 71, Packaging and Transportation or Radioactive Materials, and provide general provisions applicable to all incorporations of the Federal regulations into the chapter by reference, and that otherwise make the State's rules consistent with the Agreement State rules. The last category is miscellaneous corrections to cross-references, terminology, and the previous incorporations of Federal regulations by reference.

Nuclear Medicine and Fusion Imaging Computed Tomography (CT) Technology

In 2000, the Department and Commission promulgated N.J.A.C. 7:28-24, Nuclear Medicine Technology. The subchapter contains radiation safety requirements for persons performing nuclear medicine procedures, establishes safety requirements for the use of radiopharmaceuticals, establishes the educational standards and licensing requirements for nuclear medicine technologists, and requires certain operating procedures to reduce unnecessary exposure to radiation to the patient, healthcare worker, and the general public during nuclear medicine procedures. The subchapter also establishes fees for nuclear medicine technologist licenses and examinations, the standards for schools that teach nuclear medicine technology, and the process of approving such schools.

In August 2013, the Act was amended to create a new license category that allows a licensed nuclear medicine technologist to obtain an additional license to perform the computed tomography (CT) portion of a fusion imaging procedure, and also perform attenuation correction using CT equipment. (See P.L. 2013 c. 119, August 9, 2013.) A fusion imaging procedure is a medical imaging procedure in which a licensed nuclear medicine technologist performs a nuclear medicine procedure at the same time that a licensed diagnostic radiologic technologist performs

a CT procedure. The data from the two procedures is merged (or fused) to form a single composite image. For the purposes of proposed amended N.J.A.C. 7:28-24, fusion imaging procedures are limited to Positron Emission Tomography/Computed Tomography (PET/CT) and Single-Photon Emission Computed Tomography/Computed Tomography (SPECT/CT). The CT portion of a fusion imaging procedure uses x-rays and not a radioactive material. A licensed nuclear medicine technologist is not, in the absence of another license, authorized to administer x-rays to a person; accordingly, a licensed nuclear medicine technologist is not licensed to perform this portion of the procedure, unless the technologist is also licensed in this new license category called fusion imaging CT technology, or is exempt from the license requirements. Similarly, a person who is authorized to perform the CT portion of the procedure may not perform the nuclear technology portion of the procedure unless he or she is a licensed nuclear medicine technologist, or is exempt from the nuclear medicine technology license requirements.

The Act distinguishes between sources of radiation, such as x-rays, and regulation of radioactive material, such as is used in nuclear medicine. The Department issues licenses to nuclear medicine technologists. (See N.J.S.A. 26:2D-27.1.) The Radiologic Technology Board of Examiners (Board), which is an agency of the Commission, is the entity responsible for licensing professionals who work with sources of x-ray radiation, such as radiologic technologists. (See N.J.S.A. 26:2D-29.) A CT procedure is a radiologic procedure. Therefore, a nuclear medicine technologist who is licensed in fusion imaging CT technology must obtain a license from both the Department and the Board. Under the amended Act at N.J.S.A. 26:2D-24.1 and 24.2, the Board is responsible for promulgating regulations to establish the title of the license, the scope of practice of the license, and the letters that may be used after the licensee's name to denote the title and qualifications. The amended Act instructs the Commission to

establish rules for the licensing of nuclear medicine technologists in this new license category. Therefore, the Commission is proposing the licensed nuclear medicine technologist rules. The Radiation Protection Act at N.J.S.A. 26:2D-9(*l*) authorizes the Department to establish fees in accordance with a fee schedule. Therefore, the Department is proposing the new rules and amendments related to fees, discussed in the Summary and Economic Impact below.

Proposed amendments to N.J.A.C. 7:28-24, Nuclear Medicine and Fusion Imaging Computed Tomography (CT) Technology, renamed to refer to the proposed new license, establish the educational and licensing requirements and the scope of practice for this new license category in fusion imaging CT technology. Proposed amendments also eliminate approval standards for schools of nuclear medicine technology that are duplicative of those of the Joint Review Committee on Education Programs in Nuclear Medicine Technology (JRCNMT). The JRCNMT is the only nationally recognized accreditation agency with programmatic accreditation standards. Each of the three nuclear medicine technology schools that are approved by the Department is also accredited by the JRCNMT. By removing the duplicative requirements, the Department's approval process is more streamlined, which will result in faster approval of schools. The proposed amendments, repeals, and new rules also establish a new fee schedule for examination and licensing applications for fusion imaging CT technology.

The proposed amended heading of N.J.A.C. 7:28-24 refers to the new licensing category, fusion imaging CT technology, as do proposed amendments to N.J.A.C. 7:28-24.1, Purpose, scope, and applicability. As discussed above, the amended Act authorizes the new license. The Act states that "a license shall be issued to a nuclear medicine technologist upon obtaining appropriate additional education or training and demonstrating competency, as determined by the [B]oard, by regulation." N.J.S.A. 26:2D-27.1. The nuclear medicine technologists already have

the education and training necessary to perform the nuclear medicine procedure. The "appropriate additional education or training" to which the Act refers relates to operating the CT equipment to perform the CT portion of a fusion imaging procedure. The Commission, through the Board, has determined that some individuals that are not nuclear medicine technologists have appropriate education and training such that they also do not need to be specifically licensed in fusion imaging CT technology in order to operate CT equipment. Licensed physicians hold a plenary license to practice medicine, which includes authorization to operate x-ray equipment such as CT equipment. Licensed diagnostic radiologic technologists have undergone professional educational training in CT equipment. Therefore, neither must hold a separate license to operate CT equipment. These individuals may not, as stated above, perform the nuclear medicine portion of a fusion imaging procedure, unless they are licensed in nuclear medicine technology, or are otherwise exempt from the nuclear medicine technology licensing requirements.

The Commission has identified additional people who need not have a license in order to operate CT equipment. These people use the equipment as part of their education and training, in order to obtain the necessary competence. These are students who are enrolled in and attending a school of medicine or osteopathy, a Department-approved school of nuclear medicine technology, or a Board-approved school of diagnostic radiologic technology. The students are using the equipment as part of their courses of study, and must be strictly supervised in accordance with the relevant rules. Once they are graduated from their programs, they will either be exempt as licensed physicians or diagnostic radiologic technologists, or must obtain appropriate licenses in fusion imaging CT technology before using the equipment on patients. Proposed amendments to N.J.A.C. 7:28-24.1 contain similar exceptions applicable to the existing

license category of nuclear medicine technology, replacing and consolidating the existing exemptions for various medical trainees. However, consistent with the existing rules and in contrast to the proposed rules related to the new fusion imaging CT technology license, a licensed physician is exempt from the nuclear medicine licensing requirements only if he or she is an authorized user (identified on a Department radioactive materials license). Other amendments to the section inform authorized users and owners of nuclear medicine technology equipment that they must comply with all other applicable Federal and State radioactive material regulations, in addition to the provisions in N.J.A.C. 7:28-24.

The proposed new license requires definitions of new terms proposed at amended N.J.A.C. 7:28-24.2, Definitions. The definitions of "fusion imaging CT technology," "fusion imaging procedure," "licensed diagnostic radiologic technologist," "licensed fusion imaging CT technologist" and "operating CT equipment" are new, and identify the new licensing category and the activities that the licensed professional undertakes. The proposed definitions of "Board," "engage," and "indirect supervision" are the same as or comparable to the definitions of the terms in the Radiologic Technology rules at N.J.A.C. 7:28-19, governing radiologic technologists, which is another profession for which the Board issues a license. The existing definition, "direct supervision," is proposed to be amended to replace the specific components of supervision with a general statement that the person be present in the room, and supervise the procedure. This amended definition is also comparable to the definition of the term in the Radiologic Technology rules. A definition of "clinical education center" is proposed, being a place where a person, such as a student of nuclear medicine technology or a licensed nuclear medicine technologist, may obtain practical experience in nuclear medicine technology or fusion imaging CT technology. The proposed definition of "JRCNMT" means the Joint Review

Commission on Educational Programs in Nuclear Medicine Technology, the national body that accredits nuclear medicine technology educational programs. The definition of "initial application" is amended to include a reference to the new licensing category. The definitions of "immediate supervision," "probationary approval," "provisional approval," "supervision" and "temporary license" are proposed to be deleted, as they are not used in the amended subchapter. The definition of "practice of nuclear medicine technology" is deleted as unnecessary, since its provisions are set forth in the scope of practice of nuclear medicine technology at proposed new N.J.A.C. 7:28-24.4. The proposed amended definition of "authorized user" is discussed in the summary of miscellaneous amendments below.

Existing N.J.A.C. 7:28-24.3 contains general provisions applicable to the license for nuclear medicine technologists. Proposed amendments expand the section to apply to the proposed license for fusion imaging CT technology, and amend the provisions applicable to nuclear medicine technologists. The only people who may engage in the practice of fusion imaging CT technology are those who have a license, or who are exempt under N.J.A.C. 7:28-24.1(d). Therefore, unless he or she holds another CT-related license, a licensed fusion imaging CT technologist may not perform CT procedures that are not part of fusion imaging, since this is outside the scope of his or her practice, as set forth in N.J.S.A. 26:2D-27.1 and N.J.A.C. 7:28-24.4.

Existing N.J.A.C. 7:28-24.3(d) and (e) are deleted. Existing N.J.A.C. 7:24.3(d) limits the activities that a licensed nuclear medicine technologist may perform, such as prescribing radionuclides to a human being, or ordering the administration of therapeutic doses of radionuclides to a human being. These restrictions are contained at proposed new N.J.A.C. 7:28-24.4(c), making them unnecessary in this section. Existing N.J.A.C. 7:28-24.3(e), which

interprets existing subsection (d), is similarly unnecessary. The existing subsection clarifies that despite the restrictions placed on a licensed nuclear medicine technologist, a licensed physician or other person authorized by his or her licensing board may request diagnostic or therapeutic procedures for patients. Such clarification is unnecessary. It is up to the Board of Medical Examiners or other licensing board to determine the scopes of practice of its licensees. Proposed amendments remind licensed nuclear medicine technologists and fusion imaging CT technologists that they must practice their specialties in accordance with N.J.A.C. 7:28 and applicable Federal regulations. Existing N.J.A.C. 7:28-24.3(i) identifies recording requirements for radiopharmaceuticals. Recording requirements are among the provisions incorporated by reference at N.J.A.C. 7:28-55, Medical Use of Byproduct Material; accordingly, N.J.A.C. 7:28-24.3(i) is unnecessary and is proposed to be deleted.

Among the purposes of the Radiation Protection Programs rules at N.J.A.C. 7:28 are to prohibit and prevent the use or presence of unnecessary radiation in such manner as to be, or tend to be, injurious or dangerous to the health of the people. Therefore, the proposed amendments and new rules expressly prohibit the use of ionizing radiation-producing equipment or radioactive materials in such a manner as to expose humans to unnecessary ionizing radiation. The rules also impose safeguards to ensure that students are properly trained. The Commission establishes the standards for schools of nuclear medicine technology, and the Department approves the schools in accordance with those standards. The proposed amendments and new rules prohibit schools of nuclear medicine technology from enrolling students or claiming to be approved by the Department unless the school is actually approved by the Department.

Existing N.J.A.C. 7:28-24.3(k) sets forth a list of activities that are prohibited in the practice of nuclear medicine technology. These include, for example, falsifying an application

for examination or license, making false statements to a representative of the Department or Commission, failure to display an appropriate license on request, and engaging in negligence while practicing nuclear medicine technology. The provisions are recodified as N.J.A.C. 7:28-24.3(p), and proposed amendments make the list applicable to fusion imaging CT technology as well as nuclear medicine technology.

Proposed new N.J.A.C. 7:28-24.4, Scopes of practice, establishes scopes of practice of nuclear medicine technology and fusion imaging CT technology. Some of the provisions of the new section are relocated from the existing rules, such as the limits on the activities that a licensed nuclear medicine technologist may perform, discussed above. The proposed rule requires licensed nuclear medicine technologists and licensed fusion imaging CT technologists to exercise principles of radiation protection when performing nuclear medicine and CT procedures. The activities a licensed nuclear medicine technologist may engage in are set forth in proposed new N.J.A.C. 7:28-24.4(b). Proposed N.J.A.C. 7:28-24.4(b)1 through 5 are the same as in the existing definition of "practice of nuclear medicine technology." The substance of proposed N.J.A.C. 7:28-24.4(b)6 is in existing N.J.A.C. 7:28-24.3(f), proposed to be deleted, which allows licensed nuclear medicine technologists to administer pharmaceuticals under the direction of a licensed physician. The proposed new rule does not expressly require that the administration of pharmaceuticals be under the direction of a physician; however, the rule requires the administration of pharmaceuticals to be in accordance with N.J.A.C. 13:35-6.20 of the rules of the New Jersey State Board of Medical Examiners, which allows a physician to direct a technologist to administer pharmaceuticals under specific circumstances. Proposed N.J.A.C. 7:28-24.4(c) contains the prohibitions in existing N.J.A.C. 7:28-24.3(d).

The scope of practice of fusion imaging CT technology is set forth at proposed new N.J.A.C. 7:28-24.4(d). The practice includes operating CT equipment, positioning patients, setting technique factors, and making x-ray exposures as part of fusion imaging procedures. The practice also includes acquiring and manipulating patient data obtained from fusion image procedures and performing attenuation correction.

As discussed above, in order to be a licensed fusion imaging CT technologist, a person must first be a licensed nuclear medicine technologist. Before a licensed nuclear medicine technologist may take the State examination or a national certifying examination, he or she must gain necessary clinical experience and competency in CT by performing various CT procedures. The national certifying examinations, currently administered by either the American Registry of Radiologic Technologists (ARRT) or the Nuclear Medicine Certification Board (NMTCB), are not limited to fusion CT; consequently, an applicant for the national certifying examinations must gain experience in various CT procedures. Proposed new N.J.A.C. 7:28-24.4(e) permits a licensed nuclear medicine technologist to gain necessary experience and competency by performing CT procedures, but only in a Department-approved clinical education center and only for a limited time, in accordance with an approved educational plan.

The types of procedures and length of time that the licensed nuclear medicine technologist may perform the CT procedures without a license is determined based upon an educational plan that he or she submits to the Board. Both the licensed nuclear medical technologist and the manager or administrator of the clinical education center must sign the plan. The educational plan identifies the clinical prerequisites to be completed, the clinical education center at which the procedures will take place, the types of CT equipment that will be used (for example, PET/CT or SPECT/CT equipment), the names and credentials of the people who will

supervise the procedures, and the period of time that the technologist will be performing procedures under the educational plan. The clinical prerequisites identified in the educational plan are those CT procedures that the technologist must complete in order to be eligible to take the NMTCB, ARRT, or State examination. All procedures performed must be under the direct supervision of a licensed physician, licensed diagnostic radiologic technologist, or a licensed fusion imaging CT technologist. The length of time that the technologist will perform the CT procedures will depend on the number of procedures that the technologist can complete in a period of time. A technologist that is employed at a facility with CT equipment, such as a licensed nuclear medical technologist at a hospital, will likely need less time to complete the necessary procedures than a technologist who is gaining experience other than in his or her usual work location. The length of time also depends on the examination for which the technologist is preparing. To be eligible to take the State examination, N.J.A.C. 7:28-24.6(a)2 requires a technologist to successfully complete at least 20 fusion imaging CT procedures. However, the ARRT requires 125 CT procedures within two years prior to application for examination, and the NMTCB requires 500 hours of CT experience within three years prior to application for examination. (See ARRT Computed Tomography Handbook, July 2014-June 2015 (https://www.arrt.org/pdfs/Disciplines/Handbooks/CT-Handbook.pdf), and NMTCB CT Exam Information, https://www.nmtcb.org/CT/CTexam.php.)

Existing N.J.A.C. 7:28-24.4 is recodified as N.J.A.C. 7:28-24.5, with an updated cross-reference. Examination for licensure of fusion imaging CT technologists, N.J.A.C. 7:28-24.6, is new. Stakeholders at the December 2013 meeting with the Department assisted in drafting the educational and practical requirements of this section. During the December 2013 meeting, several stakeholders suggested that the Department develop its own requirements and administer

a State licensing examination for fusion imaging CT technologists, since the requirements of the national certifying examination by ARRT and NMTCB include more than fusion imaging CT procedures and test on more than the scope of practice of fusion imaging CT technology. The Department and Commission agree with this suggestion and propose to administer a State-specific examination, as set forth in this section. Such an examination is not yet available. The Board will recognize the results of either the national certifying examination, or the State-specific examination (when one is available) when issuing a license in fusion imaging CT technology. (See proposed N.J.A.C. 7:28-24.8.) Once a State examination is available, notice will be placed on the Department's website and will be sent to the State's licensed nuclear medicine technologists, and an examination application will be made available. The various examinations are discussed further in the Economic Impact below.

The Radiologic Technologist Act at N.J.S.A. 26:2D-31.a requires each applicant for a license to use equipment emitting ionizing radiation on a human being for diagnostic or therapeutic purposes to pass a license examination designated and approved by the Board in that specialty. Proposed new N.J.A.C. 7:28-24.6 governs the examination for licensure of fusion imaging CT technologists. In order to qualify to take the State examination, an applicant must apply to the Board, be of good moral character, pay the appropriate fee, and be licensed in nuclear medicine technology. The applicant must also submit satisfactory evidence that the applicant has fulfilled the educational requirements of N.J.A.C. 7:28-24.6(a)1 and 2. The didactic requirement can be met through traditional classroom style learning or by on-line courses, provided that the educational activity is recognized by the Board. The applicant must have performed at least 20 fusion imaging CT procedures, which include at least two different fusion imaging procedures. Proposed N.J.A.C. 7:28-24.6(b), (c), and (f) establish when the

Board may deny an application for examination, when an applicant may retake a failed examination, and when examinations shall be offered. Proposed new (d) and (e) limit the number of times an applicant may retake an examination without first taking a remedial course or repeating the didactic and practical requirements of N.J.A.C. 7:28-24.6(a). These provisions are comparable to N.J.A.C. 7:28-19.6(e) and (f), which limit the number of times an applicant may take the radiologic technology license examination before the applicant must complete remedial instruction.

N.J.A.C. 7:28-24.5, Nuclear medicine technologist licenses, is proposed to be recodified as N.J.A.C. 7:28-24.7. Existing N.J.A.C. 7:28-24.5(a)1, which requires passage of a nuclear medicine technology licensing examination within three years prior to the date of application, duplicates the requirements of existing paragraph (a)2; accordingly, it is proposed to be deleted. The remaining paragraphs are recodified, and cross-references are updated.

Proposed new N.J.A.C. 7:28-24.8, Fusion imaging CT technologist licenses, establishes the criteria the Board is to follow when issuing a fusion imaging CT technologist license as provided in the amended Act at N.J.S.A. 26:2D-27.1. As the amended Act requires at N.J.S.A. 26:2D-27.1, an applicant seeking licensure to operate hybrid fusing imaging technology must first be licensed by the Department as a licensed nuclear medicine technologist. In order to be eligible for a fusion imaging CT technology license, the applicant be of good moral character, and must show that he or she holds a current certification in CT from either the ARRT or NMTCB or has passed the ARRT or NMTCB or an equivalent examination as determined by the Board within five years prior the date of license application, or holds a current license or practice document in fusion imaging CT technology from another state (provided that the issuing state's requirements are equivalent to those of the Board). If the applicant passed one of the approved

examinations more than five years prior to applying for a license, the applicant must show that he or she has competently engaged in the practice of fusion imaging technology for at least 500 hours during the three years prior to the application. In this way, experienced practitioners of CT may obtain a license without retaking an examination, provided the applicant meets the requirements of the section. As with the nuclear medicine technology license (proposed N.J.A.C. 7:28-24.7(b)), a license may be denied if the applicant has committed an act or omission specified at N.J.A.C. 7:28-24.12(b).

Existing N.J.A.C. 7:28-24.6(a) and (b) allow the Department to issue temporary licenses. The Department stopped issuing temporary licenses in 2010. Prior to 2010, temporary licenses were issued to only new graduates of schools of nuclear medicine technology in order that they could be employed while waiting for their examination results. Due to computer based testing by the ARRT and NMTCB, graduates are able to take the examination shortly after graduation and are informed of the examination results almost immediately after taking the examination; the Department finds that a temporary license is no longer needed. The Department also finds that it is in the best interest of patient safety to not issue temporary licenses, inasmuch as the holders of the licenses may not have passed the licensing examination. During the years since it stopped issuing temporary licenses, the Department has not received any complaints regarding the lack of temporary licenses. Therefore, the Department proposes to delete the temporary licensing provisions at N.J.A.C. 7:28-24.6 (proposed for recodification as N.J.A.C. 7:28-24.9), and amend the section heading. Other proposed amendments to the recodified section add fusion imaging CT technologist to the types of conditional or restricted licenses that the Board may issue.

Existing N.J.A.C. 7:28-24.7, License expiration and license renewal, is proposed to be recodified as N.J.A.C. 7:28-24.10 and amended to update cross-references and add fusion

imaging CT technologist to the licenses to which the section applies. As discussed above, an application for a license may be denied if the applicant has committed any act or omission as specified in N.J.A.C. 7:28-24.12. Proposed new N.J.A.C. 7:28-24.10(e) provides that a renewal license may be denied on the same grounds.

The Act at N.J.S.A. 26:2D-33 allows a radiologic technologist who has been licensed and who has temporarily ceased activities as a radiologic technologist for not more than five years to apply to renew his or her license. The radiologic technology rules at N.J.A.C. 7:28-19.9 codify this provision. The nuclear medicine technologist rules have a similar provision at existing N.J.A.C. 7:28-24.7(e), which allows a nuclear medicine technologist to renew an expired license, provided the license has not been expired for more than three years. In order that the three technologist licenses in the Radiation Protection Program rules (radiologic technologist, nuclear medicine technologists, and fusion imaging CT technologist) are treated similarly, proposed amended N.J.A.C. 7:28-24.10(f) allows nuclear medicine technologists and fusion imaging CT technologists to renew expired licenses, provided the license has not been expired for more than five years. If the nuclear medicine technologist or fusion imaging CT technologist license has been expired for more than five years, proposed new N.J.A.C. 7:28-24.11(g) and (h) provide instructions for obtaining a new license.

Existing N.J.A.C. 7:28-24.8, Fees, is proposed to be recodified as N.J.A.C. 7:28-24.11, and amended. The amendments add new fees for an examination, license, or license renewal for fusion imaging CT technology. A discussion of the basis for the fees is in the Economic Impact below. The proposed amendments also expand the means by which the applicants and licensees may pay the fees. The existing rule allows for only check or money order. Under the proposed rule, fees can be paid by check or money order, or by any other method acceptable to the

Department. Applications and renewal forms identify the acceptable methods. At the time of this proposal, the Department accepts payment for license renewal through its on-line business portal. As more fees become payable via the on-line business portal, the associated application or renewal form will be modified to include the on-line payment option. The existing rule provides that fees are not refundable. The amended rule specifies that the fees are also not transferrable. For example, a person who applies for a license and is found ineligible because he or she needs to take and pass an examination cannot transfer the license fee to cover part of the cost of the examination, nor can the person apply the payment to another person's license fee.

Proposed amended N.J.A.C. 7:28-24.12, Examination application or license application denial, license revocation and suspension, and sanction, is recodified from existing N.J.A.C. 7:28-24.9. The amended heading of the section reflects the proposed rule provision that allows sanctions to be issued in the event of a violation of the Radiation Protection Act or the rules. Proposed new N.J.A.C. 7:28-24.12(b) gives the Board the same authority over applicants and licensed fusion imaging CT technologists that it has over radiologic technologists at N.J.A.C. 7:28-19.5. Since the Board is the licensing agency for both the fusion imaging CT technologists and the radiologic technologists, the proposed amendments are intended to ensure that all applications to the Board and licenses issued by the Board are handled consistently. Proposed N.J.A.C. 7:28-24.12(b) includes 13 items that could result in either the denial of an application or a license sanction. If the Board determines, in accordance with N.J.S.A. 26:2D-34.b, that a licensee has violated any of the 13 items, he or she is subject to sanction, and his or her license could be suspended or revoked pursuant to N.J.S.A. 26:2D-34.a and 36. Proposed N.J.A.C. 7:28-24.12(c) establishes a rebuttable presumption that a person who has committed an act of unethical conduct or has been convicted of a crime involving moral turpitude is not of good

moral character. Good moral character is a Board requirement for examination, initial and continued licensing, or license renewal eligibility in all categories of licensure. A person may rebut the presumption by demonstrating to the satisfaction of the Board that he or she is of good moral character.

Existing N.J.A.C. 7:28-24.10, School of nuclear medicine technology; standards for approval, and N.J.A.C. 7:28-11, School of nuclear medicine technology; process for approval; provisional approval; probationary approval; withdraw of approval and other general provisions, are proposed to be repealed. In their place are proposed new N.J.A.C. 7:28-24.13, School of nuclear medicine technology; standards, and N.J.A.C. 7:28-24.14, School of nuclear medicine technology; process for approval and termination. Proposed new N.J.A.C. 7:28-24.13, School of nuclear medicine technology; standards, establishes the standards that a school must meet in order to be approved. The approval process is contained at proposed N.J.A.C. 7:28-24.14. A review of the existing rules revealed that the Department's standards and the standards of JRCNMT significantly overlapped. The proposed new section eliminates the overlap by requiring a school of nuclear medicine technology to be accredited by the JRCNMT (or an equivalent accreditation agency). All existing New Jersey-approved schools are already accredited by the JRCNMT, so no school will lose its approval as a result of this new requirement. The Department contacted the New Jersey-approved schools of nuclear medicine technology, and each was in favor of mandatory JRCNMT or equivalent accreditation.

In addition to maintaining JRCNMT accreditation, the school must develop a curriculum that complies with the JRCNMT standards, or standards that the Department determines are equivalent. In this way, the Department can ensure that all schools of nuclear medicine technology in the State provide comparable education and training. In addition, the proposed

rule requires that students be supervised when they perform procedures. In their clinical rotations, students may not substitute for licensed technologists. Proposed N.J.A.C. 7:28-24.1(c) exempts students from licensing requirements, but that is not a basis for allowing unlicensed individuals to replace licensed technologists.

Schools and their clinical education centers must be Department-approved, and schools must maintain an appropriate pass rate for students taking the certifying examination. In order that the Department can verify that a school is maintaining the pass rate, documentation is required. The school must also provide the Department with the names of enrolling students and students who satisfactorily complete the training. If there is a change to the school's accreditation, or other change that could adversely affect the school's ability to provide appropriate instruction, the school must notify the Department. The school must also provide its students with appropriate radiation monitoring devices, to ensure that the students are not exposed to radiation in excess of the Federal Standards for Protection against Radiation, incorporated by reference into the Department's rules at N.J.A.C. 7:28-6.1. The school must demonstrate that it is in compliance with the requirements of N.J.A.C. 7:28-24, and permit the Department to conduct inspections, review records, and talk to school personnel, in order that the Department is able to monitor a school's compliance with the requirements of the subchapter.

Proposed new N.J.A.C. 7:28-24.14, School of nuclear medicine technology; process for approval and termination, establishes how a school applies for Department approval. The rule is intended to streamline the approval process for schools of nuclear medicine, compared with the process in the existing rule. The contents of an application are identified in proposed N.J.A.C. 7:28-24.14(a). Among the requirements is a copy of the school's accreditation letter. Requiring a school to be accredited by the JRCNMT (or equivalent accreditation agency)

will significantly reduce the amount of information that a school must submit to the Department. The school shall submit an application, a copy of the school's accreditation, and copies of policies indicating compliance with the standards in proposed N.J.A.C. 7:28-24.13(b). In addition, if the school has been operating and has had graduates take either the ARRT or NMTCB certifying examinations, the school must submit the annual reports from the certifying agencies showing its graduates' examination performance for the past three years, if the reports are available. A school that has operated for less than three years will submit records for the years it has graduated students. As set forth in proposed N.J.A.C. 7:28-24.14(e), a school that is already approved before the operative date of the proposed amendments will be deemed approved, and need not submit a new application.

In order that there is no question regarding the Department's authority to inspect the school, the school must include a written statement allowing the Department access to the school. If an application is complete and complies with the requirements of the subchapter, the Department will approve the application. Thereafter, if any of the information contained in the application changes, the school must tell the Department. This is comparable to the requirement at proposed N.J.A.C. 7:28-24.13(g) and (h), requiring a school to notify the Department if there is any change to the school's accreditation status or school operation. These changes could affect whether the school remains in compliance with the subchapter, and could affect the school's approval. To maintain its approval, the school must continue to comply with the subchapter; otherwise, the Department may terminate the approval. If the Department terminates a school's approval, or denies a school's application, the Department will notify the school, and advise it of the reasons for the termination or denial.

N.J.A.C. 7:28-24.12 is proposed to be recodified as N.J.A.C. 7:28-24.15, and amended to update cross-references.

Proposed new N.J.A.C. 7:28-24.16, Adjudicatory hearings, establishes the procedure for a person or school to follow to request an adjudicatory hearing, in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1. As in the rules governing Radiologic Technologists, N.J.A.C. 7:28-19, a school or person must submit a request for an adjudicatory hearing within 20 days after receipt of the Department's or Board's findings or administrative order. Existing N.J.A.C. 7:28-24.9(b), which is proposed to be deleted, contains administrative hearing provisions applicable to individuals whose nuclear medicine technologist license has been revoked or suspended. The proposed new rule applies not only to nuclear medical technologists, but also to schools, applicants for a license in either nuclear medicine technology or fusion imaging CT technology, or licensees in either specialty.

Proposed new N.J.A.C. 7:28-24.17, Severability, provides that if any part of the proposed subchapter is determined to be invalid, the remaining parts of the subchapter will remain in force.

Agreement State

New Jersey has assumed responsibility for regulation of radioactive materials that are governed under the Atomic Energy Act of 1954, 42 U.S.C. §§ 2011 et seq. (AEA), through an agreement with the Nuclear Regulatory Commission (NRC). This is known as becoming an Agreement State. The AEA requires that an Agreement State's regulations be compatible with the NRC's regulations, and that the state's regulations be adequate to protect the public health

and safety, with respect to such materials. (See 42 U.S.C. § 2021(d).) In order that New Jersey's rules are "adequate and compatible" with the Federal regulations, the Department's rules incorporate by reference substantial portions of the Federal regulations. The Department and the Commission propose new general provisions at N.J.A.C. 7:28-1.6 to govern the incorporation of the NRC's regulations into the Department's rules. The proposed amendment to N.J.A.C. 7:28-61.1 incorporates by reference the portions of 10 CFR Part 71, Packaging and Transportation of Radioactive Material, that are not automatically incorporated by reference in accordance with proposed N.J.A.C. 7:28-1.6. Proposed new N.J.A.C. 7:28-65, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Materials, incorporates 10 CFR Part 37, which the NRC promulgated regarding the physical protection of category 1 and category 2 quantities of radioactive material. (See 78 Fed. R. 16922, March 18, 2013.) Amendments throughout the chapter either correct errors in the existing incorporations by reference, or update cross-references that include new Subchapter 65.

General provisions

The Department and the Commission propose new general provisions at N.J.A.C. 7:28-1.6 to govern the incorporation of the NRC's regulations by reference. The existing rules indicate in each Agreement State subchapter whether individual Federal regulations are excluded from incorporation by reference, and whether the language of the Federal regulation is incorporated with or without changes. For example, existing N.J.A.C. 7:28-52.1 incorporates by reference 10 CFR Part 31, General Domestic Licenses for Byproduct Material. At N.J.A.C. 7:28-52.1(c)1, references to "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission" are replaced with "Department," in order that the

Federal regulations governing Agreement States make sense within the framework of N.J.A.C. 7:28. N.J.A.C. 7:28-52.1(b) excludes from incorporation by reference 10 CFR 31.4, Information collection requirements: OMB approval, and 10 CFR 31.22, Violations. Similarly, the existing rules incorporating the Federal regulations by reference exclude provisions that remain solely within the jurisdiction of the NRC, such as nuclear power plants.

Rather than carving out individual provisions of the Federal regulations that remain within the jurisdiction of the NRC, proposed N.J.A.C. 7:28-1.6 provides that none of the provisions solely within the jurisdiction of the NRC are incorporated by reference. These can be identified through the NRC's "Regulation Toolbox: Review Summary Sheets for Regulation Adoption for New Agreement States/Programs (10 CFR __)" at http://nrc-stp.ornl.gov/regsumsheets_newregs.html, where the NRC lists each Part of CFR title 10 that relates to the Agreement State program. For each Part, the NRC provides a Review Summary Sheet, on which there is a table that identifies the NRC regulation citation, the title of the section, and the "compatibility category" of the section. If the "compatibility category" is identified as "NRC," then the section remains within the jurisdiction of the NRC, and it is not incorporated into N.J.A.C. 7:28. In its Frequently Asked Questions for the Regulatory Toolbox, the NRC states that such a designation means the regulation relates to "Areas of Exclusive NRC Regulatory Authority," which are program elements that address areas of regulation that cannot be relinquished to Agreement States and should not be adopted by Agreement States. See Frequently Asked Questions, http://nrc-stp.ornl.gov/regulationtoolbox/faqs.pdf. For example, in the Review Summary Sheet for 10 CFR Part 70, Domestic Licensing of Special Nuclear Material, 10 CFR 70.1(c), (d), and (e) are identified as "NRC," and should not be incorporated by reference into New Jersey's rules. Accordingly, proposed N.J.A.C. 7:28-1.6(h) does not

incorporate such categories by reference. Table 1 below provides an example of the information contained on the Review Summary Sheet for 10 CFR Part 70.

Table 1: Exerpt from the Regulation Toolbox: Review Summary Sheet for Regulation Adoption for New Agreement States/Programs (10 CFR Part 70)

NRC Regulation Section	**Section Title**	**Compatibility Category**
§ 70.1(a) and (b)	Purpose	D
§ 70.1(c), (d), and (e)	Purpose	NRC

Compatibility categories “A,” “B,” and “C” must be incorporated by Agreement States in order that the state’s rules are compatible with the Federal regulations. Sections identified as compatibility category “D” do not need to be adopted by Agreement States for compatibility, but New Jersey does incorporate some such sections by reference. Accordingly, the proposed rule does not categorically exclude sections identified as category D from incorporation by reference. Sections identified as compatibility category “H&S,” which stands for “Health and Safety,” are also not required to be incorporated by reference to maintain compatibility with the Federal regulations; however, New Jersey does incorporate the essential elements of these provisions into its rules by reference in order to maintain an adequate program. Sections identified as category H&S have a particular health and safety role in the regulation of material within the

state, and (according to NRC) "embody the essential objectives of the NRC program elements because of particular health and safety considerations." See Frequently Asked Questions.

Proposed N.J.A.C. 7:28-1.6 also excludes from incorporation by reference any section of the Federal regulations entitled "violations," "communications," and "information collection requirements." The existing rules exclude these sections individually from incorporation by reference. See, for example, N.J.A.C. 7:28-52.1(b)1 and 2. Violations are addressed in the State's rules at N.J.A.C. 7:28-2.13, and in the Radiation Protection Act at N.J.S.A. 26:2C-22, which provides for criminal sanctions for violations. Therefore, it is not necessary to incorporate the Federal violations provisions. Wherever the Federal regulations refer to "criminal penalties," the rules incorporated by reference will refer to the criminal sanction provisions of the Radiation Protection Act. As for Federal provisions entitled "communications," once a Federal regulation is incorporated by reference into the State's rules, it is unnecessary for a regulated entity to communicate with the NRC. The Department provides contact information at proposed amended N.J.A.C. 7:28-1.5, Communications, and replaces references in the incorporated regulations to Federal contact information with State contact information. The provisions of the NRC rules that relate to "information collection requirements" are specific to the Federal agency, and do not apply to the State's program. The NRC has identified these sections of the Federal regulations as compatibility category D, meaning they are not necessary for a state's rules to be compatible with the Federal regulations. These sections are also not incorporated by reference into the State's rules.

Rather than identify in each Agreement State subchapter a list of substituted terms or citations, as in N.J.A.C. 7:28-52.1(c), the proposed rule contains a table of the most common substitutions necessary when the Federal regulations are incorporated into the Radiation

Protection Programs rules. Each time the identified terms appear in the Federal regulations, the incorporation by reference includes the corresponding substitution. For example, whenever the NRC regulations use "part 20 of this chapter," the incorporation by reference substitutes "N.J.A.C. 7:28-6," which is the subchapter that incorporates 10 CFR Part 20 by reference. References to the Atomic Energy Act are replaced with the Radiation Protection Act, and contact information in the Federal regulations is replaced with New Jersey-specific contact information. If all or a portion of a Federal regulation is incorporated without the substitutions identified in proposed N.J.A.C. 7:28-1.6, the Department will state that in the rule, such as in proposed new N.J.A.C. 7:28-65.1(c)1 and 3, discussed further below.

The proposed amendments to N.J.A.C. 7:28-1.5(b)1 update the name of the relevant Department program to which emergency notification of incidents involving sources of radiation shall be provided, and delete unnecessary punctuation.

Packaging and Transportation of Radioactive Materials

The NRC recently amended 10 CFR Part 71, Packaging and Transportation of Radioactive Materials. The NRC regulates the transportation of radioactive material under 10 CFR Part 71. Periodically, the International Atomic Energy Agency (IAEA) revises its regulations related to transportation of radioactive material. The NRC evaluated changes in the 2009 edition of the IAEA's "Regulations for the Safe Transport of Radioactive Material" (TS-R-1) and identified a number of areas in 10 CFR Part 71 that needed to be revised to maintain compatibility with the IAEA's regulations. The NRC published its revised regulations on June 12, 2015 (80 F.Reg. 33987). Existing N.J.A.C. 7:28-61.1(a) incorporates 10 CFR Part 71 by

reference, including any supplements or amendments to the NRC regulation. Therefore, the June 12, 2015, amendments are incorporated into the chapter.

The operation of proposed new N.J.A.C. 7:28-1.6 modifies the incorporation by reference in order that the Federal regulations fit within New Jersey's Agreement State rules. However, the Department and Commission propose one amendment to N.J.A.C. 7:28-61.1 to modify the incorporation by reference. Ordinarily, proposed N.J.A.C. 7:28-1.6 would replace "NRC" with "Department" in an incorporated rule; however, at 10 CFR Part 71.106, "NRC" should not be replaced with "Department," because the provision refers to NRC-approved quality assurance programs for shipments of licensed materials. The NRC has not delegated this approval to Agreement States, but continues to issue the approvals itself. Proposed amended N.J.A.C. 7:28-61.1(c)1 identifies this exception.

Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

Proposed new N.J.A.C. 7:28-65, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material, incorporates by reference 10 CFR Part 37, of the same heading. Until the NRC's rules are incorporated into the Department's rules, the Department implements the requirements through license conditions that reference NRC's Order Imposing Increased Control (EA-05-090) and NRC's Orders Imposing Fingerprinting (EA-07-305). In the absence of incorporated rules, these Department license conditions govern. Differences between the Orders and 10 CFR Part 37 are discussed in the Economic Impact below.

The summary below of 10 CFR Part 37, proposed to be incorporated into the Department's rules by reference, is adapted from the summary of the Federal regulations that the NRC published in the Federal Register (78 Fed. R. 17007, Mar. 19, 2013). The NRC's summary

is modified to conform to changes that the Department and Commission propose in order that the rules make sense in the context of the State's Radiation Protection Programs.

The Federal regulations at 10 CFR Part 37 establish security requirements for use and transportation of category 1 and category 2 quantities of radioactive material. The requirements establish the objectives and minimum requirements that licensees must meet to protect against theft or diversion of this material. Licensees that possess these materials are typically hospitals, industrial radiographers, blood irradiators, broad scope users (such as a larger research or medical facility for training, research and development, medical studies or therapy), and pool irradiators. These requirements are intended to increase the protection of the public against the unauthorized use of category 1 or category 2 quantities of radioactive material by reducing the risk of the theft or diversion of the material.

The NRC refers to category 1 and category 2 quantities of radioactive material as "risk-significant radioactive material." Category 1 and category 2 quantities refer specifically to 16 radioactive materials (14 single radionuclides and 2 combinations). These materials are: americium-241; americium-241/beryllium; californium-252; curium-244; cobalt-60; cesium-137; gadolinium-153; iridium-192; plutonium-238; plutonium-239/beryllium; promethium-147; radium-226; selenium-75; strontium-90 (yttrium-90); thulium-170; and ytterbium-169. Irradiated fuel and mixed oxide fuel are not included even though they may contain category 1 or category 2 quantities of radioactive material; these materials are covered by other Federal regulations. The thresholds for category 1 and category 2 quantities of radioactive material are provided in the Appendix to 10 CFR Part 37, also incorporated by reference. Terabecquerels is the official unit to be used for determining whether a radioactive material is a category 1 or category 2 quantity.

Because many licensees refer to quantities of material in curies instead of Becquerels, the table provides the curie value at three significant figures for convenience.

The materials and thresholds in the rules are based on the International Atomic Energy Agency (IAEA) Code of Conduct. The IAEA published these results in a document titled "Code of Conduct on the Safety and Security of Radioactive Sources." A link to this document can be found on the NRC's Web site at http://www.nrc.gov/security/byproduct/enhanced-security.html. The NRC and the international community, led by the IAEA, revised the IAEA Code of Conduct in 2003, to establish common international guidance for safety and security measures for radioactive sources. In a separate effort, the U.S. Department of Energy (DOE) and the NRC reviewed the chemical, physical, and radiological characteristics of each radioactive material that is licensed in the United States, for its attractiveness to a terrorist. This effort identified 16 radioactive materials that could pose a serious threat to people and the environment if used malevolently. This effort further identified the different quantities or "thresholds" of materials that could be useful to a terrorist. The results of the DOE/NRC effort closely matched the Code of Conduct Category 2 quantities. The NRC adopted the IAEA Code of Conduct Category 1 and Category 2 threshold quantities to provide consistency between domestic and international efforts for security of radioactive materials that are deemed to be attractive targets for malevolent use.

Any licensee that possesses category 1 or category 2 quantities of radioactive materials at a facility must determine whether it needs to have an access authorization program. Only those licensees that permit unescorted access to an aggregated category 1 or category 2 quantity of radioactive material are required to establish and implement an access authorization program. "Escorted access" and "unescorted access" are defined terms. Escorted access requires an

approved individual to accompany and maintain direct continuous visual surveillance of an individual who is not approved for unescorted access; unescorted access does not. If the material can be accessed by the breach of a single physical barrier, the licensee needs to implement an access authorization program. In addition, any applicant for a license or license amendment to possess category 1 or category 2 quantities of radioactive material at a facility is required to establish an access authorization program before obtaining the radioactive material, if it will be aggregating the material at or above the category 2 threshold. The main objective of the access authorization program is to ensure that individuals who have unescorted access to category 1 or category 2 quantities of radioactive material are trustworthy and reliable and do not constitute an unreasonable risk to the public health and safety or security.

As part of the protection of category 1 or category 2 quantities of materials, fingerprinting and background checks are required. Individuals subject to a licensee's access authorization program include anyone permitted to have unescorted access to category 1 or category 2 quantities of radioactive material. Unescorted access is defined as solitary access to category 1 or category 2 quantities of radioactive material or the devices that contain the material. The reviewing official, the individual in charge of the background check program, is also included in the program to ensure that this individual is subjected to the same background check and degree of trustworthiness and reliability.

The access authorization program may also include individuals that have access to information on the protection of the materials, such as vehicle drivers and accompanying individuals for road shipments of category 1 quantities of radioactive material, movement control center personnel for shipments of category 1 quantities of radioactive material, and any individual whose assigned duties provide access to shipment information on category 1

quantities of radioactive material. Licensees may have a separate program for access to the protection information, or may include the program with the authorization program for unescorted access to the material.

Those individuals who have unescorted access to certain quantities of byproduct material could pose a threat to the public health and safety or the common defense and security because they could divert or steal risk-significant radioactive material, or could aid others in the commission of such acts. The Radiation Source Protection and Security Task Force encouraged the NRC to require fingerprinting and Federal criminal history checks of any individual with access to category 1 or category 2 quantities of radioactive material. Certain categories of individuals are relieved from the background investigation aspect of the access authorization program. Licensees do have the option to escort an individual and not make a trustworthiness and reliability determination. The escorts need to be approved for unescorted access.

The key components of an access authorization program are the reviewing official, a background investigation, use of procedures, and an opportunity for an individual to correct and complete the information on which the decision to grant unescorted access is based. The reviewing official is the individual who makes the trustworthiness and reliability determinations for the licensee; the reviewing official determines who can be allowed unescorted access authorization. It is important that the reviewing official who is making the final determination on whether an individual is trustworthy and reliable be trustworthy himself or herself, and has undergone the same background investigation as any individual who would be granted unescorted access, including fingerprinting and the FBI criminal records check.

Any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material is required to establish, implement, and maintain a security program meeting

the requirements of 10 CFR part 37 of subpart C. (The NRC considers material to be "aggregated" if an adversary could gain access to a category 2 or greater quantity by breaching a single physical barrier.) In addition, any applicant for a license or license amendment to possess category 1 or category 2 quantities of radioactive material at a facility is required to establish a security program before obtaining the radioactive material, if it will be aggregating the material at or above the category 2 threshold.

The Federal regulations require affected licensees to establish, implement, and maintain a security program. The objective of the security program is to monitor, and without delay detect, assess, and respond to any actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive materials. A licensee's security program needs to include a written security plan, implementing procedures, training, use of security zones, protection of information, coordination with the local law enforcement agency (LLEA), testing and maintenance of security-related equipment, security measures, and a program review.

The purpose of a security plan is to establish, in writing, the licensee's overall security strategy to ensure that all of the required security measures work effectively and in an integrated way for all facilities and operations where aggregated quantities of category 1 or category 2 quantities of radioactive material will be used or stored. The plan should, among other things, include a description of the measures and strategies to implement the security requirements and identify the security resources being used to meet the requirements. A licensee can revise its security plan to address changing circumstances. Any changes to the security plan, as well as the original plan, must be approved by the individual with overall responsibility for the security program. The security plan must be retained for three years after it is no longer needed. The licensee must retain any superseded portions of the security plan for three years. Security plans

are important for the implementation of a performance-based regulation. An adequate plan requires a licensee to analyze the particular security needs of its individual facilities and to explain how it will implement its chosen security measures to ensure that they work together to meet the applicable performance objectives.

Licensees are required to develop and maintain written implementing procedures that document how the security requirements and the security plan will be met. These procedures must be designed to meet the individualized security needs of each location where an aggregated category 1 or category 2 quantity of radioactive material is used or stored. Procedures need to be approved, in writing, by the individual with overall responsibility for the security program. Licensees are required to keep a copy of the current procedures as a record for three years. Superseded portions of the procedures are retained for three years. Licensees should not submit procedures to the Department as part of the license application.

As part of its physical protection program, each licensee is required to conduct training on the security plan to ensure that those individuals responsible for implementation of the plan possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The extent of the training needs to be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material. Individuals need to be instructed in the licensee's security program and implementing procedures, their responsibilities, and the appropriate response to alarms. Licensees with dedicated security staff are encouraged to train their security personnel in the timely notification of affected local law enforcement agencies (referred to in the Federal regulations as LLEAs) during emergencies.

An individual subject to the training requirements needs to complete the training before being allowed unescorted access to category 1 or category 2 quantities of radioactive material. The licensee needs to provide refresher training annually or when significant changes have been made to the security program. The refresher training addresses any significant changes; reports on relevant security issues, problems, or lessons learned; relevant results from Department inspections; and relevant results from the licensee's program review and the testing and maintenance program. Training records must be maintained for three years and need to include training topics, training dates, and the list of personnel that attended the training. Training is essential if the licensee is to be adequately prepared for an effective and coordinated response to any effort to steal or divert category 1 or category 2 quantities of radioactive material. Adequate training is indispensable for an appropriate licensee response to an unauthorized intrusion.

Licensees are required to protect information concerning their security program. To prevent unauthorized disclosure, licensees are required to limit access to their security plans, implementing procedures, and the list of individuals that have unescorted access to the material. These efforts include measures to allow access to these documents only to those individuals who have a need to know the information to perform their duties and have been determined to be trustworthy and reliable based on the background investigation requirements. Licensees are required to store security information in a manner to prevent unauthorized removal, such as storage in a locked office or desk drawer.

To ensure that only trustworthy and reliable individuals with a need to know are allowed access to security plans and procedures, licensees need to develop, implement, and maintain written policies and procedures to control access to their security plan and security procedures. The licensee's information protection policies and procedures need to ensure the proper handling

and protection of security plans and implementing procedures against unauthorized disclosure. Licensees are required to retain copies of the policies and procedures.

The Federal regulations require the licensee to establish a security zone, which is any area established by a licensee to provide physical protection for category 1 or category 2 quantities of radioactive material. All category 1 and category 2 quantities of radioactive material need to be used and stored within a security zone. The purpose of security zones is to isolate and control access to the material to protect it more effectively and deter theft or diversion by providing, among other things, more time for licensees and LLEAs to respond. Isolation measures protect category 1 or category 2 quantities of radioactive material by allowing access to security zones only through established access control points. Access control measures allow only approved individuals to have unescorted access to the security zone, and ensure that other individuals with a need for access are escorted by approved individuals. A security zone effectively defines where the licensee will apply these isolation and access control measures. To limit unescorted access to only approved individuals, licensees could isolate the radioactive materials using continuous physical barriers that allow access to the security zone only through established access control points; or licensees could exercise direct control of the security zone by approved individuals at all times.

Security zones may be permanent or temporary. Temporary security zones need to be established to meet transitory or intermittent operating requirements such as periods of maintenance, source delivery, and source replacement. A licensee could meet the requirements for a security zone at some temporary job sites (such as those involving onsite operations lasting less than a day) simply by keeping the area under “direct supervision” by authorized personnel. Similarly, when work is being done inside a temporary zone, a licensee could meet the

requirements for controlling unescorted access by having the material, persons, and area within the zone under direct control of approved individuals at all times.

Because the purpose of security zones is different from the radiation safety purposes of the restricted areas and controlled areas defined in 10 CFR Part 20, Standards for protection against radiation, incorporated into the State's rules at N.J.A.C. 7:28-6, the security zone does not have to be the same as either of these areas. Because measures to control access are required for both radiation protection and security, however, a licensee does have the flexibility to use an area required for radiation protection purposes to fulfill the required functions of a security zone. Because materials licensee sites are differently configured and do not lend themselves to generically defined physical areas, the security zone concept permits significant flexibility for licensees to account for a range of site-specific concerns. It also provides regulators with a well-defined and enforceable requirement keyed to performance objectives of isolation and access control.

Category 1 quantities of material require additional security measures under certain circumstances. During periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, licensees are required to provide, at a minimum, an approved individual to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow the specified activities.

Due to the natural decay of their radioactivity, sources lose their effectiveness as they get older and have to be replaced or replenished periodically with new sources to maintain a device's expected performance. Tamper-indicating devices and other intrusion detection equipment typically must be disabled to permit the device to be opened without tripping alarms. The new

sources are typically shipped by an offsite supplier, who also often performs removal and exchange or reinstallation. After replacement, the removed older sources must be prepared onsite for shipment back to the manufacturer or for storage and eventual disposal. These non-routine operations by non-licensee employees at the licensee's site, during a time when devices for detecting theft or diversion are disabled, call for additional measures to compensate for the temporary increase in vulnerability.

A licensee is required to establish and maintain the capability to continuously monitor and detect all unauthorized entries into its security zone(s). Monitoring and detection are performed by either a monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; electronic devices for intrusion detection alarms that would alert nearby facility personnel; monitoring by a video surveillance system; or direct visual surveillance by individuals. A licensee also needs the capability to detect unauthorized removal of the radioactive material. For category 1 quantities of radioactive material, a licensee needs to immediately detect any attempted unauthorized removal through the use of electronic sensors linked to an alarm or continuous visual surveillance. For category 2 quantities of radioactive material, a licensee needs to verify the presence of the radioactive material through weekly physical checks, tamper indicating devices, actual usage of the material, or other means.

Licensees are required to maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems for any personnel and automated or electronic systems used to support the site security systems. Licensees are required to have alternative capability for any system in the event of loss of the primary means of communication or data transmission and processing. The alternative means cannot be subject to the same failure mode as the primary systems.

The licensee must respond to an intrusion into a security zone. The response depends on the licensee's assessment of the purpose of the intrusion, but a response is required without delay. If the unauthorized access appeared to the licensee to be an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee needs to immediately notify and request an armed response from the appropriate LLEA. An immediate response by the licensee permits a more timely response from law enforcement, thereby, reducing the risk that the material could be used for malevolent purposes. Immediate notification also allows for early warning to other possible targets of a simultaneous attempt to divert material from multiple locations.

A licensee's decision to call the LLEA and the Department depends not only on the licensee's assessment of the intent of the unauthorized access but also on whether the area where the breach occurred is an area the licensee had previously determined needed to be monitored in order to meet the physical protection requirements in the regulations. Thus, a licensee's assessment and response to an intrusion alarm in the business office section of its facility could be entirely different from its assessment and response to an intrusion alarm in a radioactive materials storage area.

Licensees are required to coordinate, to the extent practicable, with the LLEA to discuss the LLEA response to threats to the licensee's use of Category 1 or 2 quantities of radioactive material. An LLEA is defined as a public or private organization that has been approved by a Federal, State, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported. In the event of an actual or attempted theft, sabotage, or diversion of radioactive material, an armed response is

likely to be necessary. Adversaries could be well armed, and the small unarmed or lightly-armed private security guard service typically used at byproduct material licensee sites would not be an adequate substitute for an LLEA. However, the LLEA need not be a municipal or county police force. If a hospital or university campus police force is the nearest law enforcement agency to the licensee's operation capable of providing an armed response and making arrests, that police force would meet the definition of an LLEA.

Coordination activities include providing a description of the facility, radioactive materials, and security measures and notification that the licensee will request a timely and armed response to any actual or attempted theft, sabotage, or diversion of the licensee's radioactive materials. The licensee is required to document its coordination efforts. The documentation could include such items as the dates, times, and locations of meetings or phone calls and a list of licensee and LLEA staff present at the meetings. Licensees are required to coordinate with the LLEA at least every 12 months.

Coordination with an LLEA is essential in developing an effective and efficient physical protection program. Because certain situations may necessitate an armed response, a strategy that is consistent in scope and timing with realistic potential vulnerabilities of the subject radioactive material should be coordinated well in advance with the LLEA. Another purpose of coordination is to provide the responsible LLEA with an understanding of the potential consequences associated with unauthorized use of the radioactive material of concern, so that the LLEA can determine the appropriate priority of its response. The LLEA response is needed not only to interdict and disrupt an attempted theft or sabotage onsite, but also possibly for offsite coordination to protect public health and safety and to mitigate the potential consequences of unauthorized use of the radioactive material.

A licensee is required to notify the Department within three business days if the LLEA has not responded to a request for coordination within 60 days of the coordination request, or if the LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities. The notification allows the Department to contact the LLEA directly to ensure that the LLEA understands the importance of adequate coordination. If the LLEA refuses to coordinate beforehand, the licensee could still comply by making and documenting periodic good-faith efforts to elicit the LLEA's participation in planning for a timely and effective response.

Mobile sources require specific safeguards. The Federal regulations require licensees using mobile devices containing a category 1 or category 2 quantity of radioactive material to have two independent physical controls that form tangible barriers to prevent unauthorized removal of the device. For devices in or on a vehicle or trailer, a licensee is required to use a method to disable the vehicle or trailer when it is not under direct control and constant surveillance by the licensee. Licensees are not allowed to rely on the removal of an ignition key to meet this requirement. The rule does allow for the situation where a site's health and safety procedures prohibit the disabling of the ignition. In those instances, the licensee would not be required to disable the ignition. These provisions are in addition to the other physical protection requirements.

Mobile devices, particularly portable ones, are likely to be more vulnerable to attempted theft or diversion because an adversary could more easily remove these devices before the licensee or LLEA has an opportunity to respond. The objective of this requirement is to delay intruders long enough for a timely licensee and LLEA response. A mobile device is defined in the rule as a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters or otherwise equipped for moving without a need for disassembly or

dismounting, or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location, such as an irradiator, but the definition includes radiography cameras, source changers, well logging equipment, and gauges or controllers. The definition could also include storage containers, lead pigs for holding sources during a source exchange, and onsite or offsite transportation packages, if they contained category 1 or category 2 quantities of radioactive material.

Licensees are required to test intrusion alarms, physical barriers, and other systems used for securing and monitoring access to radioactive material, and these items need to be maintained in operable condition. Each intrusion alarm and associated communication system subject to the rule's requirements for monitoring, detection, and assessment needs to be inspected and tested for performance. The licensee only needs to test the equipment that it relies on to meet the requirements of 10 CFR part 37, incorporated by reference. This would include any backup equipment or systems relied upon in the event of a primary system failure. If the licensee has additional equipment or systems that are not relied on to meet the rule requirements, the extra equipment and systems would not need to be tested and maintained. The frequency of testing is based on the manufacturer's suggested timing. If the manufacturer does not suggest a frequency, the licensee must conduct the maintenance and testing at least annually. Licensees are required to maintain records of the maintenance and testing activities for three years.

A licensee must report any actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material as soon as possible after initiating a response, which includes notification of the LLEA. The licensee is required to submit a written report to the Department within 30 days after the initial notification. A licensee is also required to assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category

2 quantities of radioactive material and notify the LLEA as appropriate. If the licensee notifies the LLEA, it must also notify the Department. The written 30-day report is not required for suspicious activity reports.

Licensees are required to review the security program annually to confirm compliance with the requirements. The review is to evaluate the security program content and implementation. The licensee is required to document any review findings and corrective actions, and the records need to be maintained for three years.

On occasion, category 1 and category 2 quantities of radioactive material may be shipped, such as to medical institutions, companies that support medical and academic institutions, and companies that manufacture and distribute radioactive material for various industrial applications. As radioactive sources get older, radioactive decay decreases the sources' strength and the sources lose their effectiveness and have to be replaced or replenished with new sources. The older sources must be transported for disposal or back to the manufacturer.

The Federal regulations include requirements for pre-transfer checks, preplanning and coordination of shipments, advance notification of shipments, control, monitoring, and communications during shipments, procedures, investigations of missing shipments, and reporting of missing material. These requirements apply to ground transport of category 1 or category 2 quantities of radioactive material shipped in a single package or in multiple packages in a single conveyance. Note that a licensee is not responsible for complying with these requirements when a carrier aggregates radioactive material, during transport or storage incidental to transport, for two or more conveyances from separate licensees that individually do not exceed the limits. The shipping licensee is responsible for meeting the requirements unless

the receiving licensee agrees in writing to arrange for the in-transit physical protection, including preplanning and coordination activities.

Any licensee transferring category 1 or category 2 quantities of radioactive material to a licensee of the NRC or an Agreement State are required to verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. Licensees that transfer material within the same organization do not need to verify the validity of the license (that is, for companies that have licenses in several states). The licensee should know if its licenses are valid. For transfers of category 1 quantities of radioactive material, the transferring licensee is also required to verify that the licensee is authorized to receive radioactive material at the address requested for delivery. These verifications are conducted with the license issuing authority, that is, the NRC or the appropriate Agreement State, or by using the NRC’s web-based system to verify the validity of a license issued by either NRC or an Agreement State. Licensees are required to document any method of verification, except for use of the license verification system.

Preplanning and coordination of shipment information for shipments of category 1 quantities of radioactive material is required. The shipping licensee (licensee sending the licensed material) is required to coordinate the departure and arrival times with the receiving licensee (licensee receiving the licensed material). This coordination reduces the risk that theft or diversion of the material would go unnoticed or unreported. The licensee also needs to preplan and coordinate the shipment information with the NRC and the state or states through which the shipment will pass. As part of the coordination activities, the licensee is required to discuss the state's intention to provide law enforcement escorts for the shipments and identify safe havens. Safe havens are sites at which security is present or from which the transport crew can notify and

wait for the local law enforcement authorities in the event of an emergency. The licensee is responsible for identification of the safe havens. The purpose of the information sharing is to ensure minimal delay of the shipment.

For shipments of category 2 quantities of radioactive material, the shipping licensee must verify the shipment no-later-than arrival time and the expected arrival time with the receiving licensee. The term “no-later-than arrival time” is defined as the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than-arrival time may not be more than six hours after the estimated arrival time for category 2 shipments. Verifying that the shipment arrives on time provides the licensee with the means to identify and immediately report an unusual occurrence that could lead to the theft or diversion of the material.

A safe haven is a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the LLEA. Licensees should use the following criteria in identifying safe havens for shipments: close proximity to the route, that is, readily available to the transport vehicle; security from local, State, or Federal assets is present or is accessible for timely response; the site is well lit, has adequate parking, and can be used for emergency repair or to wait for LLEA response on a 24-hour-a-day basis; and additional telephone facilities are available should the communications system of the transport vehicle not function properly. Possible safe haven sites include Federal sites having significant security assets; secure company terminals; state weigh stations; truck stops with secure areas; and LLEA sites, including state police barracks.

If the no-later-than arrival time will not be met, the shipping licensee must inform the receiving licensee of the new no-later-than arrival time for shipments of category 2 quantities of

radioactive material. This provision allows licensees the ability to modify departure and arrival times due to unforeseen events. The receiving licensee is required to notify the shipping licensee when the shipment of a category 2 quantity of radioactive material arrives at its destination. This requirement ensures positive communication between the shipper and recipient. Additionally, this requirement ensures that the shipper does not unnecessarily start an investigation because they are not sure that the shipment has arrived. The receiving licensee must notify the shipping licensee if the shipment has not arrived by the no-later-than arrival time. This notification is the trigger to initiate an investigation into where the package is located.

The Federal regulation as incorporated into the Department's rules requires advance written notifications to the NRC and the Department for shipments containing category 1 quantities of radioactive material. In addition, notice must be provided to any state through which a shipment is being transported. The state notification is to the governor or the governor's representative. Advance notification provides the NRC, the Department and the affected states with knowledge of shipments so that in the event there is an increase in the risk of theft or diversion of the material, the regulator could delay or reroute the shipment to minimize the risk. This advance notification also allows states with escort requirements to engage in planning to support the shipment. Under most circumstances, advance notifications are not required for shipments of category 2 quantities of radioactive material.

The following information must be included in an advance notification for a category 1 shipment of radioactive material, if available at the time of notification: the name, address, and telephone number of the shipper, carrier, and receiver of the shipment; the license number of the shipper and receiver; a description of the radioactive material contained in the shipment, including the radionuclides and quantity; the point of origin of the shipment and the estimated

time and date that shipment will commence; the estimated time and date that the shipment is expected to enter each state along the route; the estimated time and date of arrival of the shipment at the destination; and the contact and telephone number for the point of contact. Any information that is not available at the time of the initial notification would be provided in a revised notification once the information becomes available.

If the category 1 shipment schedule is revised or cancelled, the proposed rule requires the shipping licensee to notify the appropriate states, the NRC, and the Department. A licensee that has shipped category 2 quantities of radioactive material must initiate an investigation for any shipment that has not arrived at the receiving licensee's facility by the designated no-later-than arrival time. The no-later-than arrival time is defined as the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than-arrival time may not be longer than six hours after the estimated arrival time for a shipment of category 2 quantities of radioactive material. A no-later-than arrival time was not included for category 1 shipments as the licensee is required to maintain continuous position monitoring and detect any unauthorized access to or removal of the material immediately. This would enable the shipping licensee of a category 1 shipment to know right away if the shipment was late or experiencing problems.

When a licensee determines that a shipment of a category 1 quantity of radioactive material is lost or missing, the rule requires the licensee to notify the LLEA in the area of the shipment's last confirmed location within one hour and then to notify the Department. Notification to the Department should be as prompt as possible, but not at the expense of causing delay or interference with the LLEA response to the event. When a licensee determines that a

shipment of category 2 quantities of radioactive material is lost or missing, the rule requires the licensee to notify the Department within four hours of such determination. The licensee is also required to immediately notify the Department if, after 24 hours from its determination that the shipment was lost or missing, the location of the material still cannot be determined. Early notification provides for a more timely response from law enforcement, thereby reducing the risk of the misuse of the material. The Federal regulations, as incorporated by reference, require the licensee to notify the Department when a lost or missing shipment has been located. This notification is considered an update on the initial notification. Without this notification, regulatory authorities and LLEA may waste resources continuing any search for the material.

For shipments of category 1 quantities of radioactive material, a licensee who discovers an actual or attempted theft or diversion of a shipment, or any suspicious activity related to a shipment, is required to notify the designated LLEA along the shipment route as soon as possible. After notifying the LLEA, the licensee is required to notify the Department. For shipments of category 2 quantities of radioactive material, a licensee who discovers an actual or attempted theft or diversion of a shipment, or any suspicious activity related to a shipment, is required to notify the Department as soon as possible. These security measures enhance the likelihood that the material will be successfully protected or recovered and allows for early warning of other possible victims of a simultaneous attempt to divert material from multiple locations.

Licensees shipping category 1 quantities of radioactive material by road are required to ensure that normal and contingency procedures are developed to cover notifications; communication protocols; loss of communication; and response to an actual or attempted theft or diversion of a shipment, or any suspicious activity related to a shipment. The licensees are

required to ensure that drivers, accompanying personnel, railroad personnel, and movement control center personnel have access to the normal and contingency procedures. Procedures provide reasonable assurance that these individuals are prepared for most situations and are able to act without delay to prevent the theft or diversion of shipments. Communication protocols include a strategy for the use of authentication and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost.

Any licensee that ships category 1 quantities of radioactive material by road must either establish or use a carrier that has established, movement control centers that maintain position information from a location remote from the activity of the transport vehicle or trailer. The control centers are required to monitor shipments on a continuous and active monitoring basis (24 hours a day, seven days a week), and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies. The licensee must ensure that redundant communications are in place that would allow the transport to contact an escort vehicle (if used) and the movement control center at all times. The redundant communication must not be subject to the same interference factors as the primary communication method. The same interference factors mean any two systems that rely on the same hardware or software to transmit their signal (for example, cell tower or proprietary network). Redundant communications provide drivers with the means to immediately report an unusual occurrence that could lead to the theft or diversion of the material. Early notification would permit a more timely response from law enforcement, thereby reducing the risk of the misuse of the material.

Category 1 shipments must be continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. The movement control center is required to provide positive confirmation of the location,

status, and control over the shipment and be prepared to implement preplanned procedures in response to deviations from the authorized route or to a notification of actual or attempted theft or diversion or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures include the identification of, and contact information for, the appropriate LLEA along the shipment route. A telemetric position monitoring system is a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations. The gathering of this information permits remote monitoring and reporting of the location of a transport vehicle or package. Global positioning systems (GPS) and radiofrequency identification (RFID) are examples of telemetric position monitoring systems.

If the driving time period is greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the U.S. Department of Transportation's Federal Motor Carrier Safety Administration, the licensee must ensure that an accompanying individual is provided for the entire shipment. The accompanying individual may be another driver. This security measure provides reasonable assurance that the material will be protected from theft or diversion when it is stationary, as well as in emergency situations where it becomes necessary for the driver to stop or leave the vehicle.

Each licensee that ships category 1 quantities of radioactive material by rail must ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to a licensee, third party, or railroad communications center which meets certain criteria. The communications center needs to provide positive confirmation of the location of the shipment and its status. Rail shipment tracking provides the means for a communications center to immediately report an unusual occurrence that could lead to the theft

or diversion of the material. Early notification provides for a more timely response from LLEAs, thereby reducing the risk of the misuse of the material.

A licensee shipping category 2 quantities of radioactive material by road must maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance. In the case of the licensee using a common carrier, the final rule requires that licensees use a carrier that has an established package tracking system. An established package tracking system means a documented, proven, and reliable system routinely used to transport objects of value. The package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control. The licensee is required to use a carrier that maintains constant control and surveillance during transit and has the capability for immediate communication to summon appropriate response or assistance. The carrier must also require an authorized signature prior to releasing the package for delivery or return. In general, the licensee must be able to contact the shipping carrier and determine the approximate location of the shipment. Package tracking systems, such as common overnight delivery service with standard tracking, are acceptable. These requirements mitigate with reasonable assurance the risk of loss, theft, or diversion of the material.

The proposed general provisions regarding incorporation of the Code of Federal Regulations by reference, N.J.A.C. 7:28-1.6, apply to this new subchapter, unless proposed N.J.A.C. 7:28-65.1(b) and (c) indicate otherwise. For example, at proposed N.J.A.C. 7:28-65.1(c)1, "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," are not replaced with "Department," as would otherwise be the case

under N.J.A.C. 7:28-1.6. In the context of the identified Federal regulations, these terms refer to the NRC.

Miscellaneous Amendments

The Department and Commission propose miscellaneous amendments to the existing rules. A proposed amendment to N.J.A.C. 7:28-6.1, the incorporation by reference of the standards for protection against radiation at 10 CFR Part 20, adds a missing reference. Existing N.J.A.C. 7:28-6.1(a) states that "Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 20, Standards for Protection against Radiation." N.J.A.C. 7:28-6.1(d) also incorporates 10 CFR Part 20 by reference with specified changes. Therefore, the Department and the Commission propose to correct the omission of subsection (d) in N.J.A.C. 7:28-6.1(a).

Throughout N.J.A.C. 7:28-24, Nuclear Medicine and Fusion Imaging Computed Tomography (CT) Technology, discussed above, references to "registration" of radioactive materials are proposed to be replaced with "license." The Department does not register radioactive materials, but licenses them. At proposed amended N.J.A.C. 7:28-24.1(e), the reference to a Nuclear Regulatory Commission license is deleted because the NRC no longer regulates byproduct material in New Jersey. Existing N.J.A.C. 7:28-55 incorporates Federal regulations regarding medical use of byproduct material, 10 CFR Part 35, by reference. At N.J.A.C. 7:28-24.1(b), the Department and Commission propose to make it clear that the proposed rules governing fusion imaging CT technology and nuclear medicine technology do not limit the application of N.J.A.C. 7:28-55. A reference to N.J.A.C. 7:28-55.1 is added to the proposed amended definition of "authorized user" at N.J.A.C. 7:28-24.2 and elsewhere in the

subchapter to identify the New Jersey regulation that allows for authorized user delegation and supervision. The term "authorized medical user" is being changed to "authorized user," to be consistent with the term in the Agreement State rules. Existing N.J.A.C. 7:28-24.3(*l*) sets forth the responsibility of a supervisor to oversee procedures that a nuclear medicine technologist performs. The subsection is no longer necessary and is proposed to be deleted, since the Agreement State regulations at 10 CFR Part 35, incorporated into N.J.A.C. 7:28-55, govern such supervision.

In the subchapter governing domestic licensing of source material, N.J.A.C. 7:28-58, which incorporates 10 CFR Part 40, N.J.A.C. 7:28-58.1(c)11 is proposed to be amended as a result of NRC amendments to 10 CFR 40.22. The NRC identified certain provisions as compatibility category NRC, meaning they are outside of the State's jurisdiction. The proposed amendments conform the incorporation by reference to the Federal rules. Proposed amended N.J.A.C. 7:28-58.1(c)23 and 60.1(c)14 correct the citations of Federal regulations incorporated by reference.

Social Impact

Radiation is known to cause cancer and other adverse health effects in humans, and there are ongoing legitimate concerns about the adverse effects caused by overexposure to radiation, particularly as the use of radioactive materials and the use of ionizing radiation-producing machines for industrial, commercial, and medical applications continues to rise. The increased use of such materials and devices results in increased exposure to radiation and increased associated risks.

Proposed amended N.J.A.C. 7:28-24, which allows a licensed nuclear medicine technologist to be licensed in fusion imaging CT technology, makes it possible for only one person to perform the entire fusion imaging procedures, instead of two different technologists (that is, one licensed in nuclear medicine technologist to perform the PET or SPECT procedure and the other a licensed diagnostic radiologic technologist to perform the CT portion of the fusion imaging procedures). This will result is less patient wait time and greater patient satisfaction.

The goal of the radiation protection regulatory program is to prohibit and prevent the use or presence of unnecessary radiation in such a manner as to be, or tend to be, injurious or dangerous to the health of the people, the ecology, wildlife, agriculture and industry of the State. The proposed incorporation of 10 CFR Part 37 by reference ensures that risk-significant quantities of radioactive materials are protected, and includes measures intended to prevent the theft or diversion of these materials for malicious use. For these reasons, the Commission and the Department anticipate that proposed new N.J.A.C. 7:28-65 will have a positive social impact on the regulated community and the public.

Economic Impact

The proposed new rules, repeals, and amendments at N.J.A.C. 7:28-25 and 65 will have an economic impact on some regulated individuals and facilities. The costs of compliance include fees for licensing, and the costs associated with developing procedures, reporting and recordkeeping, and training.

<u>Nuclear Medicine and Fusion Imaging Computed Tomography (CT) Technology</u>

Facilities that perform fusion imaging procedures will experience a positive economic impact from the proposed amendments in N.J.A.C. 7:28-24. Under the existing rules, a facility that provides fusion imaging procedures must have a licensed nuclear medicine technologist and a licensed diagnostic radiologic technologist to perform one procedure. The proposed rules authorize a licensed nuclear medicine technologist to also be licensed in fusion imaging CT technology, as set forth in the amendments to the Act. As a result, a facility may elect to have only one properly trained licensed person perform the entire fusion imaging procedures, rather than two. Additionally, since most fusion imaging scanners are located in the nuclear medicine department of a facility, and diagnostic CT scanners are usually in the radiology department, under the existing rules a facility must ensure that both the nuclear medicine department and the radiology department are sufficiently staffed with licensed diagnostic radiologic technologists. This often results in radiologic technologists moving between the two departments, perhaps delaying the fusion imaging procedure if the patient must wait for the radiologic technologist to arrive. Under the proposed rules allowing a licensed nuclear medicine technologist to also be a licensed fusion imaging CT technologist, a facility may instead choose to employ its licensed diagnostic radiologic technologists only in the radiology department, and employ licensed nuclear medicine technologists who are also licensed in fusion imaging CT technology in the nuclear medicine department. There would also be a corresponding reduction in administrative scheduling efforts. Fusion imaging procedures could be performed more quickly, resulting in more efficient scheduling of patients, and more efficient use of the equipment.

The Department conducted an analysis of a hospital with two fusion imaging scanners to determine whether the proposed new license category would result in a savings to the hospital. The hospital had a licensed diagnostic radiologic technologist assigned to both the nuclear

medicine department to perform the CT portion of the fusion imaging procedures and to the radiology department to perform diagnostic CT procedures. The analysis revealed that as many as three more diagnostic CT procedures could be performed daily if the diagnostic radiologic technologist were not needed to perform the CT portion of the fusion imaging procedures, but instead one properly trained licensed nuclear medicine technologist who is also licensed in fusion imaging CT technology could complete the entire fusion procedure. The Department estimates that the proposed amendments to N.J.A.C. 7:28-24 could save this single facility up to 200 person hours annually.

Some individuals who are licensed diagnostic radiologic technologists may experience a negative economic impact from the proposed amendments to N.J.A.C. 7:28-24. In a facility that elects to employ a licensed nuclear medicine technologist who is also licensed in fusion imaging CT technology, instead of both a nuclear medicine technologist and a diagnostic radiologic technologist, the services of the licensed diagnostic radiologic technologist may no longer be needed for fusion imaging procedures. The actual number of licensed diagnostic radiologic technologists that could be affected and to what degree they could be affected are not known. It is anticipated that most diagnostic radiologic technologists will be reassigned to other areas of medical imaging within a facility. Please refer to the Jobs Impact below for a further discussion.

Proposed N.J.A.C. 7:28-24.11(b) includes new fees for nuclear medicine technologists who are also licensed in fusion imaging CT technology, which will have an economic impact on the technologists. The proposed examination application fee is $75.00, which is the same as the existing examination fee for nuclear medicine technologists. As stated in the summary of N.J.A.C. 7:28-24.6, at the time of this proposal there is no examination in fusion imaging CT technology available for the Board to approve. The Department and Commission do not believe

many licensed nuclear medicine technologists will apply for examination, since approximately 60 nuclear medicine technologists are already certified by the ARRT in CT, and therefore will be eligible for a license without taking the State examination. Additionally, in November 2014, the NMTCB started to offer a CT examination. It is anticipated that in future most applicants for a license in fusion imaging CT technology will also already be certified by the ARRT or NMTCB in CT, making them exempt from the State examination, and not subject to the proposed examination fee.

The proposed initial license application fee is $40.00, the same as the existing initial license fee for nuclear medicine technologists. The Department estimates that approximately 60 initial license applications will be submitted during the first year after the operative date of the proposed rules. These are licensed nuclear medicine technologists that are already certified by the ARRT or NMTCB in CT, and are now eligible for the new license. Based upon 60 initial license applications, the Department anticipates revenue of $2,400 in the first year. The proposed biennial license renewal application fee, also the same as the existing fee for nuclear medicine technologists, is $40.00; therefore, if each of the first 60 licensees renews his or her license, the revenue from these renewal licenses will be $2,400 after two years. The estimated number of initial license applications submitted after the first year cannot be determined at this time. As these licenses are issued and renewed, the Department will receive additional revenue.

Under the existing fee schedule, which includes fees associated with nuclear medicine technology, the Department's annual revenue is approximately $26,400, which does not cover the Department's $104,000 cost to administer the program. As discussed above, the Department anticipates additional annual revenue of $2,400 the first year, and thereafter $2,400 every two years, an annual average of $1,200, from renewal of the licenses of the 60 individuals who are

already certified by the ARRT or NMTCB in CT, and are now eligible for the proposed new license. The Department estimates its annual cost to administer the nuclear medicine and fusion imaging computed tomography (CT) technology rules at proposed amended N.J.A.C. 7:28-24 to be $109,000, which is based upon $140.00 per hour in salary, fringe, and indirect costs, plus operational expenses. In determining this cost, the Department reviewed the labor rate, and fringe and indirect costs, including the average salary of the staff assigned to the activity plus a component for direct support staff and division overhead, and fringe benefits such as pensions, health benefits, workers' compensation, disability benefits, and the employer's share of the Federal Income Compensation Act contribution. The hourly rate also include indirect costs, which consist of management salaries, operating expenses, divisional indirect salaries and related expenses, building rent, and the Department's allocation of indirect costs listed in the Statewide Allocation Plan prepared annually by the State Department of the Treasury. In addition, the Department considered the operational expenses attributable to the employees and the program, which include postage, telephone, training, travel, supplies, equipment maintenance, maintenance of vehicles used during enforcement and school inspections, data system management and on-line license renewal maintenance, and the cost for each licensee who renews on-line. There is also included a component for Departmental legal services.

Packaging and Transportation of Radioactive Materials

Proposed amendments to N.J.A.C. 7:25-61 will have no economic impact. The existing rule incorporates 10 CFR Part 71 by reference. The proposed amendments relate to provisions in the NRC rules that affect activities that are within the NRC's exclusive jurisdiction.

Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material

Proposed new N.J.A.C. 7:28-65 incorporates 10 CFR Part 37 by reference. The NRC published its final regulations on March 19, 2013 (78 Fed.R. 17007). Although the NRC's regulations have not yet been incorporated into the Department's rules, the NRC nevertheless implements the requirements through license conditions, generally called the Increased Control Orders. In the absence of incorporated rules, the Increased Control Orders govern. The NRC's rules at 10 CFR Part 37 differ from the Increased Control Orders in several aspects, outlined in the table below. The table shows the estimated person-hours that these new requirements would add or save. A detailed comparison of the Federal regulations at 10 CFR Part 37 and the Increased Control Orders is provided in the NRC's "Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material Implementation Plan," Attachment 1, beginning on page 13, "Part 37 Rule/Order Comparison," which is available among the NRC's guidance documents for the Federal regulations at http://www.nrc.gov/security/byproduct/10-cfr-part-37.html.

Table 2: Estimated cost or savings associated with 10 CFR Part 37, compared to the Increased Control Orders

Requirement in 10 CFR Part 37 as Compared to Increased Control Orders	**Person-Hours Saved (-) or Spent (+) per Year**	**Basis for Change in Person-Hours**

Reviewing official(s) who makes "trustworthiness and reliability" determinations must be fingerprinted as part of background check. Fingerprinting by law enforcement agency, authorized Federal or state agency, or state-authorized commercial fingerprinting service	+2	New requirement in Part 37
Background investigation every seven years (every three years under Increased Control Orders)	0	Most facilities are already complying with the Part 37 requirement
Background reinvestigation every 10 years	+10	New requirement in Part 37
Background checks for individuals that do not require unescorted access, but have access to clearance lists, security plans, etc.	+1 per individual background check Average +5 per facility	New requirement in Part 37
Annual security program review	+10	New requirement in Part 37
Security plan and procedures must	+10	New requirement

be approved by an individual with overall responsibility for the program. Training must be conducted on the plan and procedures annually		in Part 37
No requirement that Local Law Enforcement Agency (LLEA) be notified of source exchanges	-5	Notification required under Increased Control Orders, but not required under Part 37
Maintenance, testing and calibration of security detection equipment	+10	New requirement in Part 37
Coordination of response to threats with LLEA, but no pre-arranged plan required	-5	Pre-arranged threat response plan with LLEA required under Increased Control Orders, but not required under Part 37
Written report not required for suspicious activities	-10	Report required under Increased

		Control Orders, but not required under Part 37
Shipping licensee of Category 2 shipments must verify the shipping times with the receiving facility	+1	New requirement in Part 37
Notification to governor's designee if shipment canceled	+2	New requirement in Part 37
Notification to DEP when a lost or missing Category 1 or Category 2 source is found	+2	New requirement in Part 37
Notification to LLEA and the DEP when an actual or attempted theft or diversion of a shipment or other suspicious activity	+2	New requirement in Part 37
Shipment personnel must have access to normal and contingency procedures, but no formal training required	-4	Training of shipment personnel on normal and contingency procedures required under Increased Control

		Orders, but not required under Part 37
Verification of each shipment	+1	New requirement in Part 37
Total	**+31**	

Radioactive Materials licensees with category 1 or category 2 quantities of radioactive materials will see an increase of approximately 30 person-hours per year as a result of the incorporation of 10 CFR Part 37 into the State's rules at proposed N.J.A.C. 7:28-65, as compared with the requirements of the NRC's Increased Control Orders. The average hourly wage of affected employees is approximately $30.00 per hour. This translates to a cost of approximately $1,000 per year per licensee for the additional requirements. Licensees that possess these materials are typically hospitals, industrial radiographers, blood irradiators, broad scope users (such as a larger research or medical facility for training, research and development, medical studies or therapy), and pool irradiators.

There will be no increased cost to the Department as a result of proposed new N.J.A.C. 7:28-65. The licensing and inspection requirements of the incorporated Federal regulations will take approximately the same number of person hours as the Department spends enforcing and administering the Increased Control Orders.

Environmental Impact

The proposed new rules, repeals, and amendments continue to limit the amount of radiation allowed in the environment. Human exposure to radiation causes cancer and other adverse health effects. Limits on the amount of radiation allowed in the environment continue to 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). Plant, animal, and aquatic life benefit from the proposed amendments. repeals, and new rules insofar as the proposed amendments, repeals, and new rules continue to prevent or reduce unnecessary radiation exposure.

Federal Standards Statement

Executive Order No. 27 (1994) and N.J.S.A. 52:14B-1 et seq. require State agencies that adopt, readopt, or amend State regulations that exceed any Federal standards or requirements to include in the rulemaking document a Federal standards analysis. Proposed amended N.J.A.C. 7:28-24 includes the educational and licensing requirements and scope of practice for the new license category in fusion imaging CT technology, which was created pursuant to State law at N.J.S.A. 26:2D-24 et seq. The Federal regulations contain no comparable licensure requirement. Although the United States Department of Health and Human Services regulations at 45 CFR Part 75 require individuals who operate ionizing radiation-producing equipment or perform nuclear medicine procedures at Federally owned or operated facilities to meet certain educational requirements, neither the proposed amendments and new rules nor any of the Department's rules governing ionizing radiation-producing equipment apply to Federal facilities.

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

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

Jobs Impact

The proposed new rules, repeals, and amendments regulate the possession, handling, and use of sources of radiation within the State. With the exception of proposed amended N.J.A.C. 7:28-24, the Commission and the Department do not anticipate that the proposed amendments, repeals, and new rules will have an impact on employment in New Jersey, including the generation or retention of jobs.

Regarding proposed N.J.A.C. 7:28-24, there are 54 New Jersey facilities that have fusion imaging equipment registered with the Department. Forty-nine of these facilities have also registered diagnostic ionizing radiation-producing equipment. The proposed amendments, repeals, and new rules authorize a licensed nuclear medicine technologist to also be licensed in fusion imaging CT technology, as required under the Act. As a result, a facility may elect to have only one person perform the entire fusion imaging procedures. In facilities that currently employ two technologists, the possibility does exist that the licensed diagnostic radiologic technologist's service in performing the CT portion of the fusion imaging procedure will not be

needed. This impact cannot be clearly determined, since whether or how a facility will change its personnel or employment practices when licensed fusion imaging CT technologists are available is up to the facility.

The impact on licensed diagnostic radiologic technologists may be mitigated, however, because in the 49 New Jersey facilities with fusion imaging equipment as well as diagnostic ionizing radiation producing equipment, technologists can be reassigned to operate only the diagnostic radiation producing equipment. In most cases, the licensed diagnostic radiologic technologists do not perform only procedures associated with fusion imaging; rather, they also perform CT procedures unrelated to a fusion imaging procedures. These unrelated procedures are not affected by the proposed new rules, repeals, and amendments to N.J.A.C. 7:28-24.

There are five facilities in the State that have fusion imaging equipment, but do not have diagnostic ionizing radiation producing equipment. The licensed diagnostic radiologic technologists in these facilities are at most risk of being displaced. A facility that does not have diagnostic ionizing radiation producing equipment may choose to employ a single technologist (a licensed nuclear medicine technologist also licensed in fusion imaging CT technology), rather than the two technologists that are required in the absence of these proposed rules.

Agriculture Industry Impact

The proposed new rules, repeals, and amendments regulate the possession, handling, and use of sources of radiation within the State. The proposed amendments, repeals, and new rules are not anticipated to impact the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

As required by the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., the Commission and the Department have evaluated the proposed new rules, repeals, and amendments to N.J.A.C. 7:28 to determine their impact on small business. The proposed amendments, repeals, and new rules affect owners, possessors, and users of radioactive materials and machine sources of ionizing radiation. The Department estimates that at least 80 percent of those affected by the proposed amendments, repeals, and new rules meet the definition of "small businesses" under the New Jersey Regulatory Flexibility Act. The various reporting, recordkeeping, and compliance requirements and their associated costs are discussed in the Summary and Economic Impact above.

The Radiologic Technologist Act, which creates the new license category of fusion imaging CT technologist, does not allow for different degrees of radiation protection standards, since it was enacted based upon the finding that all citizens of New Jersey are entitled to maximum radiation protection. Therefore, the proposed new rules and amendments to N.J.A.C. 7:28-24 do not exempt small businesses, or provide a different standard for small businesses. Similarly, the NRC's rules regarding the security of Category 1 and Category 2 quantities of radioactive material do not distinguish between small businesses and other businesses. The harm resulting from loss, theft, or diversion of the materials does not depend on the size of the licensee.

In proposing these new rules, repeals, and amendments, the Commission and the Department have evaluated the need to protect the public from unnecessary exposure to radiation against the economic impact of the rules and have determined that to provide a different standard for small businesses would endanger the environment and public health and safety. The hazard

posed by radiation is the same whether the owner of the source is a small business or not. Therefore, no reduction in compliance standards is provided based on small business status.

Housing Affordability Impact Analysis

Pursuant to N.J.S.A. 52:14B-4.1b, the Commission and the Department have evaluated the proposed new rules, repeals, and amendments to determine their impact, if any, on the affordability of housing. The proposed amendments, repeals, and new rules govern the possession, handling, and use of sources of radiation within the State of New Jersey, which do not relate to housing. Accordingly, the Commission and the Department have determined that the proposed amendments, repeals, and new rules are extremely unlikely to evoke a change in the average costs associated with housing in the State.

Smart Growth Development Impact Analysis

In accordance with N.J.S.A. 52:14B-4.1b, the Commission and the Department have evaluated the proposed new rules, repeals, and amendments to determine their impact, if any, on housing production within Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan. The proposed amendments, repeals, and new rules are not expected to impact the residential sector; rather, they regulate the possession, handling, and use of sources of radiation within the State. Therefore, the proposed amendments, repeals, and new rules will not evoke a change in housing production in Planning Areas 1 or 2, or within designated centers.

Full text of the rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 7:28-24.10 and 24.11.

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

SUBCHAPTER 1. GENERAL PROVISIONS

7:28-1.5 Communications

(a) (No change.)

(b) All communications regarding radioactive materials including byproduct, source, special nuclear materials less than a critical mass, or diffuse naturally occurring radioactive materials shall be addressed to the New Jersey Department of Environmental Protection, Bureau of Environmental Radiation, Mail Code 25-01, PO Box 420, Trenton, NJ 08625-0420. Telephone: (609) 984-5400, Fax: (609) 984-5595. The physical location of the office is 25 Arctic Parkway, Ewing, NJ 08638.

[(b)] **(c)** 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

   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 toll free: 1(877) 927-6337 (1-877 [WARN-DEP] **WARN DEP**)

2. (No change.)

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

(a) Portions of this chapter that are incorporated by reference from any portion of the Code of Federal Regulations (CFR) shall be understood in the manner set forth in this section.

(b) Unless specifically excluded by these rules, when a provision of the CFR is incorporated by reference, all notes, appendices, diagrams, tables, and figures are also incorporated by reference.

(c) Supplements, amendments, or other changes including, without limitation, repeals or stays that affect the meaning or operational status of a Federal regulation incorporated by reference, brought about by either judicial or administrative action and adopted or otherwise noticed by the Nuclear Regulatory Commission (NRC) in the Federal Register, shall be paralleled by a similar automatic update to the New Jersey rule so that the New Jersey rule will have the same meaning and status as its Federal counterpart.

(d) Provisions of the CFR that are excluded from incorporation by reference in these rules are excluded in their entirety, unless otherwise specified. If there is a cross-reference to a Federal citation that is specifically entirely excluded from incorporation, the cross-referenced citation is not incorporated by virtue of the cross-reference.

(e) Federal statutes and regulations that are cited in the CFR that are not specifically adopted by reference shall be used to assist in interpreting the Federal regulations.

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

(g) Nothing in these provisions incorporated by reference from the CFR shall affect the Department's authority to enforce statutes, rules, permits, licenses, or orders administered or issued by the Commissioner.

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

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

2. Each section entitled "violations";

3. Each section entitled "communications"; and

4. Each section that includes "information collection requirements" in the heading.

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

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

Terms in CFR	**Replacement Terms**
Of this part	**Of this subchapter**
To this part	**To this subchapter**
By this subpart	**By this subchapter**
Subject to this subpart	**Subject to this subchapter**
Under this subpart	**Under this subchapter**
In this subpart	**In this subchapter**
Agreement State or Agreement State agency	**Agreement State or the NRC**
Any non-Agreement State	**The State of New Jersey, where the Department maintains jurisdiction**
Commission	**Department**
NRC	
Nuclear Regulatory Commission	
U.S. NRC	
Act	**Radiation Protection Act**
Atomic Energy Act	
Atomic Energy Act of 1954	
Section __ of the Act	**the Act**

Part 19	**N.J.A.C. 7:28-50**
Part 20	**N.J.A.C. 7:28-6**
Part 30	**N.J.A.C. 7:28-51**
Part 37	**N.J.A.C. 7:28-65**
Part 40	**N.J.A.C. 7:28-58**
Part 70	**N.J.A.C. 7:28-60**
Part 71	**N.J.A.C. 7:28-61**
Part 150	**N.J.A.C. 7:28-62**
NRC Operations Center (301-816-5100)	**Department of Environmental Protection's hotline 1-877 WARNDEP (1-877-927-6337)**
Written interpretation by the General Counsel	**Written interpretation signed and approved by the Commissioner of the Department**
NRC regional office or Director of the office of Federal and State Materials and Environmental Management Programs or Director, Division of Security Policy, Office of Nuclear Security and Incident Response	**Bureau of Environmental Radiation at the address specified in N.J.A.C. 7:28-1.5(b)**
10 CFR 20.1401	**N.J.A.C. 7:28-12**
10 CFR 20.1402	
10 CFR 20.1403	
10 CFR 20.1404	

10 CFR 20.1405	

(j) Replace each section entitled "criminal penalties" with the sentence, "The Radiation Protection Act of 1958, N.J.S.A. 26:2D-1 et seq., provides for criminal sanctions for violation of any provision of the Act."

(k) In each section entitled "specific exemptions," replace the sentence "The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest" with "The Department, with approval of the Commission on Radiation Protection, may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this subchapter as it determines are authorized in accordance with the provisions of N.J.A.C. 7:28-2.8."

(*l*) In each section entitled "interpretations," replace "Except as specifically authorized by the Commission in writing, no" with "No."

(m) Replace any NRC contact information with the contact information in N.J.A.C. 7:28-1.5(b).

(n) Unless otherwise specified, all written reports required by a provision of the CFR incorporated by reference shall be sent to the Manager, Bureau of Environmental Radiation at the address specified in N.J.A.C. 7:28-1.5(b).

SUBCHAPTER 6. STANDARDS FOR PROTECTION AGAINST RADIATION

NOTE: THIS IS A COURTESY COPY OF THIS RULE PROPOSAL. THE OFFICIAL VERSION WILL BE PUBLISHED IN THE OCTOBER 19, 2015 NEW JERSEY REGISTER. SHOULD THERE BE ANY DISCREPANCIES BETWEEN THIS TEXT AND THE OFFICIAL VERSION OF THE PROPOSAL, THE OFFICIAL VERSION WILL GOVERN.

7:28-6.1 Incorporation by reference

(a) Except as set forth in (b) [and]**,** (c)**, and (d)** below, this subchapter incorporates by reference 10 CFR Part 20, Standards for Protection Against Radiation.

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

SUBCHAPTER 24. NUCLEAR MEDICINE **AND FUSION IMAGING COMPUTED TOMOGRAPHY (CT)** TECHNOLOGY

7:28-24.1 Purpose, scope**,** and applicability

(a) This subchapter establishes educational and licensure requirements, as well as delineating the scope**s** of practice, for persons engaged in the practice of nuclear medicine technology**, and for persons engaged in the practice of fusion imaging CT technology**. This subchapter further establishes certain responsibilities of authorized [medical] users, owners, and registrants of radiation sources used in the practice of nuclear medicine technology **or the practice of fusion imaging CT technology**. This subchapter also establishes standards for the operation of, and the Department's approval of, educational programs in nuclear medicine technology.

(b) This subchapter shall not be interpreted as precluding persons specializing in nuclear medicine physics, computer science, or engineering from manipulating **nuclear medicine** data under the supervision of an authorized [medical] user **pursuant to N.J.A.C. 7:28-55.1**.

(c) The following are exempt from the requirement to possess a nuclear medicine technology license:

1. Authorized [medical] users;

[2. Hospital residents, hospital interns or hospital fellows specializing in nuclear medicine, who are under the direction of an authorized medical user;

3. Hospital residents, hospital interns or hospital fellows involved in nuclear medicine procedures but not specializing therein**,** provided that they are acting under the direct supervision of either an authorized medical user or a licensed nuclear medicine technologist who is under the direction of an authorized medical user;

4. Students enrolled in and attending a school or college of medicine or osteopathy, who are acting within the school's curriculum, provided that students are under the direct supervision of either an authorized medical user or a licensed nuclear medicine technologist who is under the direction of an authorized medical user; and

5. Students enrolled in and attending a school of nuclear medicine technology , who are acting within the school's approved curriculum, provided that such students are identified on the student list filed by the school with the Department, and are acting in a clinical affiliation approved by the Department, upon the recommendation of the Commission, and are under the direct or immediate supervision of either an authorized medical user or a licensed nuclear medicine technologist who is under the direction of an authorized medical user.]

2. Licensed physicians who are acting under the supervision of an authorized user pursuant to N.J.A.C. 7:28-55.1;

3. Students enrolled in and attending a school of medicine or osteopathy, who are acting within the school's curriculum and under the supervision of an authorized user pursuant to N.J.A.C. 7:28-55.1; and

4. Students enrolled in and attending a Department approved school of nuclear medicine technology, who are acting within the school's curriculum, provided that students are supervised in accordance with N.J.A.C. 7:28-24.13(b)1.

(d) The following are exempt from the requirement to possess a fusion imaging CT technology license:

1. Licensed physicians;

2. Licensed diagnostic radiologic technologists;

3. Students enrolled in and attending a school of medicine or osteopathy, who are acting within the school's curriculum, and are under the direct supervision of a licensed physician or licensed diagnostic radiologic technologist or licensed fusion imaging CT technologist;

4. Students enrolled in and attending a Department approved school of nuclear medicine technology and are acting within the school's curriculum, provided that students are supervised in accordance with N.J.A.C. 7:28-24.13(b)2;

5. Licensed nuclear medicine technologists in accordance with N.J.A.C. 7:28-24.4(e); and

6. Students enrolled in and attending a Board approved school of diagnostic radiologic technology in accordance with N.J.A.C. 7:28-19.1(c)4.

[(d)] **(e)** The requirements of this subchapter shall not apply to a licensed radiopharmacy operating within the scope of its Department radioactive materials license[,] **and** New Jersey Board of Pharmacy license[, and Nuclear Regulatory Commission license].

[(e) The provisions of this subchapter do not apply to the therapeutic use of sealed sources of ionizing radiation.]

(f) Authorized users and owners of nuclear medicine technology equipment must also comply with all other applicable Federal and State radioactive material regulations.

7:28-24.2 Definitions

(a) The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Authorized [medical] user" means a licensed physician who is identified as an authorized user on a Department radioactive materials license [that authorizes the medical use of naturally occurring or accelerator produced radioactive materials or on a Nuclear Regulatory Commission license that authorizes the medical use of by-product materials] **pursuant to N.J.A.C. 7:28-55.1.**

“Board” means the Radiologic Technology Board of Examiners created pursuant to N.J.S.A. 26:2D-24 et seq.

"Clinical education center" means a facility (such as a medical office, hospital, or imaging center) where a person is permitted to engage in the practice of nuclear medicine technology or fusion imaging CT technology for the purposes of clinical education in these disciplines.

. . .

"Direct supervision" means [guidance, direction and instruction by an authorized medical user or license nuclear medicine technologist who is personally aware of, and maintains independent professional responsibility for, the procedure intended for a given patient, and is present in the facility and is

available for immediate assistance] **being present in the room with the person to observe and supervise the nuclear medicine or CT procedure**.

"Engage" means to perform or assist in the performance of an activity.

“Fusion imaging CT technology” means the use of CT equipment as part of a fusion imaging procedure.

“Fusion imaging procedure” means a medical imaging procedure that utilizes equipment capable of performing two or more types of medical imaging procedures simultaneously or in close sequence and merging the data to form a single composite image. For the purpose of this subchapter, fusion imaging procedures are limited to Positron Emission Tomography/Computed Tomography (PET/CT) and Single-Photon Emission Computed Tomography/Computed Tomography (SPECT/CT).

[“Immediate supervision” means in-room presence for instruction, direction and guidance by an authorized medical user or a licensed nuclear medicine technologist, who is available to assume control of the given procedure.]

"Indirect supervision" means being immediately available in the room or adjacent to the room where the person is performing the nuclear medicine procedure.

"Initial application" means the first application submitted by an individual to the Department for a license to practice nuclear medicine technology **or fusion imaging CT technology**.

"JRCNMT" means the Joint Review Committee on Educational Programs in Nuclear Medicine Technology.

"Licensed diagnostic radiologic technologist" means a person who possesses a valid license in diagnostic radiologic technology issued pursuant to N.J.A.C. 7:28-19.

"Licensed fusion imaging CT technologist" means a licensed nuclear medicine technologist that holds an additional license issued by the Board that permits him or her to engage in the practice of fusion imaging CT technology.

. . .

"Operating CT equipment" means using or manipulating CT equipment in any way that leads to or causes the application of radiation to humans or affects the amount or quality of radiation that is received by a human. The term "operating" includes activating or terminating the radiation exposure, setting or adjusting technical factors, and setting or adjusting the size of the exposure field.

["Practice of nuclear medicine technology" means preparing radiopharmaceuticals for administration to humans, administering radiopharmaceuticals to humans, positioning of patients for examinations which require the administration of radiopharmaceuticals to humans, setting technical factors for examinations which require the administration of radiopharmaceuticals to humans, operating imaging and/or

measuring equipment for examinations which require the administration of radiopharmaceuticals to humans, or acquiring and manipulating patient data, other than demographic and clinical data, with or without the use of computers for procedures requiring the administration of radiopharmaceuticals.

"Probationary approval" means approval which may be awarded by the Department to a school of nuclear medicine technology which is not in full compliance with N.J.A.C. 7:28-24.10 and 24.11 but which has entered into a written agreement, approved by the Commission, to correct the item(s) of non-compliance.

"Provisional approval" means approval which may be awarded by the Department to a new school of nuclear medicine technology which, upon review by the Commission of an application and self-study document, is found to be in compliance with N.J.A.C. 7:28-24.10 and 24.11. Provisional approval may be awarded to a new school of nuclear medicine technology prior to an on-site evaluation of its program.]

. . .

["Supervision" means guidance and instruction.

"Temporary license" means a license which has been issued by the Department to an individual to act as a nuclear medicine technologist for a limited period of time.]

. . .

(b) (No change.)

7:28-24.3 General provisions

(a) No owner, authorized [medical] user, person**,** or business shall cause, allow**,** or permit any other person to prepare or administer radiopharmaceuticals or to otherwise engage in the practice of nuclear medicine technology or to act as a licensed nuclear medicine technologist unless that other person is an authorized [medical] user or possesses a current, validly obtained license as a nuclear medicine technologist, pursuant to this subchapter.

(b) No owner, authorized user, person, or business shall cause, allow, or permit any other person to engage in the practice of fusion imaging CT technology or to act as a licensed fusion imaging CT technologist unless that other person is a licensed physician, licensed diagnostic radiologic technologist, or possesses both a current nuclear medicine technology and a fusion imaging CT technology license pursuant to this subchapter.

(c) No person other than a licensed fusion imaging CT technologist may use the title "licensed fusion imaging CT technologist" or LRT(FCT) after his or her name.

[(b)] **(d)** No person shall prepare or administer radiopharmaceuticals or otherwise engage in the practice of nuclear medicine technology or act as a licensed nuclear medicine technologist unless such person is an authorized [medical] user or possesses a current, validly obtained license as a nuclear medicine technologist, pursuant to this subchapter.

(e) No person shall engage in the practice of fusion imaging CT technology unless such person is a licensed fusion imaging CT technologist, or is exempt from the licensing requirements in accordance with N.J.A.C. 7:28-24.1(d).

(f) No owner, authorized user, person, or business shall cause, allow, or permit a licensed fusion imaging CT technologist to perform a CT procedure unless it is part of a fusion imaging procedure, or the technologist is authorized to perform the CT procedure in accordance with an appropriate license.

(g) No licensed fusion imaging CT technologist shall perform a CT procedure unless it is part of a fusion imaging procedure, or the technologist is authorized to perform the CT procedure in accordance with an appropriate license.

[(c)] **(h)** No person shall use sealed sources composed of radionuclides for purposes of **[**radiotherapy] **external beam therapy**, except for an authorized [medical] user or a [radiation therapy technologist] **radiologic technologist** as licensed pursuant to N.J.S.A. 26:2D-24 et seq. and N.J.A.C. 7:28-19.

[(d) No licensed nuclear medicine technologist or other person, except for an authorized medical user, shall:

1. Prescribe, determine the dosage for, or order the administration of any form of radionuclides to a human being; or

2. Apply, administer, determine the dosage for, or order the administration of therapeutic doses of any form of radionuclides to a human being.

(e) Subsection (d) above shall not be interpreted as precluding a licensed physician or any other medical professional authorized by their licensing agency from requesting a diagnostic or therapeutic procedure for a human being.

(f) Under the direction of a licensed physician, a licensed nuclear medicine technologist may administer pharmaceuticals provided that the New Jersey State Board of Medical Examiners has authorized the administration of the pharmaceutical through the promulgation of rules at N.J.A.C. 13:35 or the adoption of policy. Any inquiry about the authority to administer a specific pharmaceutical should be directed to the Board of Medical Examiners.]

[(g)] **(i)** The owner[, the registrant,] and the holder of a Federal or State [license for] radioactive materials **license** shall be jointly and severally responsible for identifying and

documenting the identity of an authorized [medical] user for each administration of that radiopharmaceutical. Such authorized [medical] user shall be responsible for any administration of such radiopharmaceutical by a licensed nuclear medicine technologist.

[(h)] **(j)** The authorized [medical] user, the owner,[the registrant,] the holder of a Federal or State [license for] radioactive materials **license**, and the licensed nuclear medicine technologist[,] shall be jointly and severally responsible for complying with all license conditions including, but not limited to, recording such information as may be required as a condition of [registration or] license issued pursuant to this chapter.

[(i) For each administration of a radiopharmaceutical, the authorized medical user, owner, registrant, and licensed nuclear medicine technologist shall be jointly and severally responsible for recording the following information:

1. The generic name, trade name, or standard abbreviation of the radiopharmaceutical, its lot number and its expiration date, and the radionuclide;

2. The patient's or human research subject's name, and identification number if one has been assigned;

3. The prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 30 microcuries;

4. The date and time of the measurement;

5. The date and time of administration;

6. The initials of the individual who made the record; and

7. The name of the identified authorized medical user.]

[(j)] **(k)** A licensed nuclear medicine technologist shall carry out the practice of nuclear medicine technology in a manner consistent with [any applicable State or Federal license conditions] **this chapter**.

(*l*) A licensed fusion imaging CT technologist shall carry out the practice of fusion imaging CT technology in a manner consistent with this chapter.

(m) No school of nuclear medicine technology subject to this subchapter shall enroll students unless the school is approved by the Department.

(n) No school subject to this subchapter shall hold itself out to be an approved school of nuclear medicine technology or claim in any way that completion of the school's curriculum will enable students to be eligible for New Jersey examination and/or New Jersey licensure, unless the school is approved by the Department.

(*o*) No person shall use or permit the use of ionizing radiation-producing equipment or radioactive materials in such a manner as to expose humans to unnecessary ionizing radiation.

[(k)] **(p)** No person shall:

1. Engage in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise**,** or false pretense while engaged in activities relating to nuclear medicine technology **or fusion imaging CT technology** or **in** obtaining a [nuclear medicine technology] license **in those categories**;

2.-5. (No change.)

6. Engage in the practice of nuclear medicine technology **or fusion imaging CT technology** while in an intoxicated state or under the influence of narcotics or any drugs which impair or tend to impair consciousness, judgment**,** or behavior;

7. Engage in negligence, malpractice**,** or incompetence while practicing nuclear medicine technology **or fusion imaging CT technology**;

8. Falsify any records, or destroy or steal property or records, relating to the practice of nuclear medicine technology **or fusion imaging CT technology;**

9. Fail to exercise due regard for safety, life**,** or health while engaged in the practice of nuclear medicine technology **or fusion imaging CT technology**;

10. Violate any condition of a [New Jersey] radioactive materials license issued **by the Department** pursuant to this chapter;

11. Violate any condition and restriction that the Department has placed on his or her nuclear medicine technology license **or fusion imaging CT technology license**; or

12. Fail to display immediately his or her nuclear medicine technology license **or fusion imaging CT technology license**, or a true copy thereof, upon request of the Department, employer**,** or any patient.

[(*l*) Any authorized medical user or licensed nuclear medicine technologist who directly supervises another individual engaging in the practice of nuclear medicine technology shall be personally aware of, and maintain any other legal responsibility for, the procedure intended for a given patient, and shall be present in the facility and available for immediate assistance.]

7:28-24.4 Scopes of practice

(a) Any person who possesses a valid license pursuant to this subchapter shall exercise proper principles of radiation protection with regard to nuclear medicine and CT procedures.

(b) Any person who possesses a valid license to practice nuclear medicine technology issued in accordance with this subchapter may engage in the following activities, which constitute the scope of practice of nuclear medicine technology:

1. Prepare radiopharmaceuticals for administration to humans, administering radiopharmaceuticals to humans;

2. Position patients for examinations that require the administration of radiopharmaceuticals to humans;

3. Set technical factors for examinations that require the administration of radiopharmaceuticals to humans;

4. Operate imaging and/or measuring equipment for examinations that require the administration of radiopharmaceuticals to humans;

5. Acquire and manipulate patient data with or without the use of computers for procedures requiring the administration of radiopharmaceuticals; and

6. Administer pharmaceuticals, provided that the material and its administration comply with the New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35-6.20.

(c) It is not within the scope of practice of a licensed nuclear medicine technologist to:

1. Prescribe or determine the dosage of any form of radionuclide to a human being; or

2. Apply, administer, determine the dosage of, or order the administration of therapeutic doses of any form of radionuclide to a human being.

(d) Any person who possesses a valid license to practice fusion imaging CT technology issued in accordance with this subchapter may engage in the following activities, which constitute the scope of practice of fusing imaging CT technology:

1. Operate CT equipment as part of fusion imaging procedures;

2. Position patients as part of fusion imaging procedures;

3. Set technique factors and make x-ray exposures as part of fusion imaging procedures;

4. Acquire and manipulate the resultant patient imaging data obtained from a fusion imaging procedure; and

5. Perform attenuation correction.

(e) The Board may authorize a licensed nuclear medicine technologist to perform CT procedures for the purpose of gaining competency in CT for New Jersey licensure in Fusion Imaging CT Technology or national certification, provided:

1. The licensed nuclear medicine technologist submits and the Board approves an educational plan, which shall include a list of clinical prerequisites to be completed, the name and address of the clinical education center, a list of the CT equipment to be used, the names and professional credentials of the individuals who will supervise the licensed nuclear medicine technologist while he or she performs CT procedures in accordance with (e)3 below, and a schedule indicating the beginning and ending dates of the period during which the licensed nuclear medicine technologist will perform CT procedures under the educational plan. The plan shall be signed by both the licensed nuclear medicine technologist and the manager or administrator of the clinical education center;

2. The licensed nuclear medicine technologist has fulfilled the requirements at N.J.A.C. 7:28-24.6(a)1;

3. The licensed nuclear medicine technologist performs CT procedures only while under the direct supervision of a licensed physician, licensed diagnostic radiologic technologist, or a licensed fusion imaging CT technologist named in the approved educational plan identified in (e)1 above; and

4. The licensed nuclear medical technologist and clinical education center comply with the terms of the approved educational plan identified in (e)1 above.

7:28-[24.4]**24.5** Examination for licensure of nuclear medicine technologists

(a) Subject to (b) below, the Department shall admit to examination for licensure any applicant who has paid a fee to the Department as specified in N.J.A.C. 7:28-[24.8]**24.11(a)** and submitted satisfactory evidence, verified by oath or affirmation, that the applicant:

1.-3. (No change.)

(b) The Department may deny an examination application if the applicant has committed any act or omission specified at N.J.A.C. 7:28-[24.9(a)]**24.12(a).**

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

7:28-24.6 Examination for licensure of fusion imaging CT technologists

(a) Subject to the conditions in this section, the Board shall admit to examination for licensure any applicant who is of good moral character, has paid a fee to the Department as specified in N.J.A.C. 7:28-24.11(b), is licensed in nuclear medicine

technology pursuant to this subchapter, and has submitted satisfactory evidence, verified by oath or affirmation, that the applicant:

1. Has successfully completed didactic content through educational activities, either in person or on line, that are recognized by the Board, in the following areas:

i. Cross sectional anatomy;

ii. X-ray physics, which shall include the production of x-rays, and operator radiation protection and shielding;

iii. Administration of oral and parenteral contrast media and treatment of adverse reactions;

iv. CT scanner design and operation, which shall include the selection of technical factors for both the scout image and patient scan protocols, verification of correct patient positioning on the scout image, setting the start and end scan location, image processing, equipment maintenance, and identification of equipment malfunctions; and

v. Patient safety, which shall include the expected delivered dose for specified procedures, and the technical factors affecting patient dose; and

2. Has competently performed a minimum of 20 fusion imaging CT procedures, including at least two different types of fusion imaging procedures, such as total body, cardiac, or brain.

(b) The Board may deny an examination application if the applicant has committed any act or omission specified at N.J.A.C. 7:28-24.12(b).

(c) An applicant who fails the examination may reapply in accordance with this section.

(d) Any person who has failed the examination three times shall not be permitted to take the examination a fourth time until the person has submitted proof of completion of a remedial course that includes a full review of course material in areas of low performance as identified by the examination.

(e) After the fourth failure, the person may not retake the examination until that person has submitted proof that he or she has recompleted the requirements of (a)1 and 2 above.

(f) Examinations shall be offered at the discretion of the Board.

7:28-[24.5]**24.7** Nuclear medicine technologist licenses

(a) The Department may issue a license to any applicant who is at least 18 years of age and has paid a fee to the Department as specified in N.J.A.C. 7:28-[24.8]**24.11(a)** and who has submitted satisfactory evidence, verified by oath or affirmation, that the applicant:

[1. Has within three years of the date of application for a license passed a nuclear medicine technology licensing examination approved by the Commission;]

[2.] **1.** Has within three years of the date of application passed a nuclear medicine technology examination administered by the American Registry of Radiologic Technologists, Nuclear Medicine Technology Certification Board [of] **or** American Society of Clinical Pathologists, or another examination approved by the Commission;

[3.] **2.** Holds a current certificate, registration, or license as a nuclear medicine technologist issued by another state or country or by any of the organizations named in [N.J.A.C. 7:28-24.5(a)2] **(a)1 above** and has engaged in the practice of nuclear medicine technology for at least 1,000 hours during the preceding three years in a manner consistent with this chapter;

however, such acceptance shall be conditioned upon the certification, registration**,** or licensure standards in the other state or country being equivalent and satisfactory to the Commission; or

[4.] **3.** (No change in text.)

(b) The Department may deny a license application if the applicant has committed any act or omission specified at N.J.A.C. 7:28-[24.9(a)]**24.12(a)**.

7:28-24.8 Fusion imaging CT technologist licenses

(a) The Board may issue a license to any applicant who is of good moral character, licensed in nuclear medicine technology pursuant to this subchapter, has paid a fee to the Department as specified in N.J.A.C. 7:28-24.11(b), and has submitted satisfactory evidence, verified by oath or affirmation, that the applicant:

1. Is currently certified in CT by either the American Registry of Radiologic Technologists or Nuclear Medicine Technology Certification Board;

2. Has passed the CT examination of the American Registry of Radiologic Technologists, the Nuclear Medicine Technology Certification Board, or the Board, or an equivalent examination as determined by the Board, within five years prior to the date of the initial license application. If the applicant passed an approved examination more than five years prior to the application, the applicant must provide documentation that he or she has competently engaged in the practice of fusion imaging CT technology for at least 500 hours during the three years preceding the application; or

3. Holds a current certificate, registration, or license as a fusion imaging CT technologist issued by another state, provided the Board determines that the other state's standards are equivalent to those of the Board.

(b) The Board may deny a license application if the applicant has committed any act or omission as specified in N.J.A.C. 7:28-24.12(b).

7:28-[24.6]**24.9** [Temporary, conditional] **Conditional** and restricted licenses

[(a) The Department may issue a temporary license to any person who has graduated from a nuclear medicine technology educational program approved by the Department pursuant to N.J.A.C. 7:28-24.11. A temporary license shall be issued only if the Department finds that its issuance will not violate the purposes of the Act or tend to endanger public health and safety.

(b) A temporary license shall expire 60 calendar days after the date of graduation. A single 30 calendar day extension may be granted provided that the applicant has taken an approved licensing examination and is awaiting the results of the examination.]

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

(b) The Board, at its discretion, may issue a conditional or restricted license including, but not limited to, a condition or restriction limiting the scope of practice of a licensed fusion imaging CT technologist.

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

7:28-[24.7]**24.10** License expiration and license renewal

(a) No nuclear medicine technologist shall practice without a valid New Jersey nuclear medicine technology license**, and no fusion imaging CT technologist shall practice without a valid New Jersey fusion imaging technology license**.

(b) A nuclear medicine technologist **or fusion imaging CT technologist** shall inform the Department of any change in the address of record within 30 calendar days of the change.

(c) In order to maintain a valid license, a nuclear medicine technologist **or fusion imaging CT technologist** shall renew his or her license biennially by submitting a renewal application for [a nuclear medicine technology] **the applicable** license and the required renewal fee specified in N.J.A.C. 7:28-[24.8]**24.11.**

(d) (No change.)

(e) A renewal application may be denied if the applicant has committed any act or omission specified in N.J.A.C. 7:28-24.12.

[(e)] **(f)** A nuclear medicine technologist **or fusion imaging CT technologist** who possesses an expired license may renew the license, provided that the license has not been expired for more than [three] **five** years. An individual who wishes to renew an expired license shall submit a renewal application and the current renewal fee to the Department. Such licenses shall be renewed for a period extending from date of renewal to midnight, December 31 of the next even numbered year.

[(f)] **(g)** A nuclear medicine technologist who possesses a license [which] **that** has been expired for more than [three] **five** years may not have that license renewed, but may apply for a new license through re-examination and other applicable requirements for initial license applications at N.J.A.C. 7:28-[24.4]**24.5** or, if applicable, at N.J.A.C. 7:28-[24.5]**24.7**.

(h) A fusion imaging CT technologist who possesses a license that has been expired for more than five years may not have that license renewed, but may apply for a new license through re-examination and other applicable requirements for initial license applications at N.J.A.C. 7:28-24.6 or, if applicable, at N.J.A.C. 7:28-24.8.

7:28-[24.8]**24.11** Fees

(a) Any person who submits [an] **a nuclear medicine technology** application for an examination, license, or license renewal to the Department shall include as an integral part of the application a service fee as follows:

1. – 3. (No change.)

(b) Any person who submits a fusion imaging CT technology application for an examination, license, or license renewal to the Department shall include as an integral part of the application a service fee as follows:

1. Examination application fee: $75.00;

2. Initial license application fee: $40.00;

3. Biennial license renewal fee: $40.00.

[(b)] **(c)** All fees shall be in the form of a check or money order made payable to the Treasurer, State of New Jersey**, or any other manner acceptable to the Department, as identified on the relevant application or renewal form**.

1. The fees submitted to the Department are not refundable **and not transferable**.

2.-3. (No change.)

7:28-[24.9]**24.12** Examination application or license application denial, license revocation and suspension**, and sanctions**

(a) The Department, in addition to any penalties authorized by the Act, may deny any examination or license application, and may revoke or suspend a nuclear medicine technology license, when the applicant or licensed nuclear medicine technologist has:

1. Violated any of the provisions [contained in N.J.A.C. 7:28-24.3(b), (c), (d), (f), (h), (i), (j), (k) or (*1*)] **of this subchapter, or the Act**;

2. -5. (No change.)

[(b) Any revocation or suspension issued pursuant to this section shall be in accordance with the following:

1. Revocation or suspension of a nuclear medicine technologist's license shall be initiated by the Department through issuance of a Notice of Revocation or Notice of Suspension. The Notice shall include the findings of the Department upon which the revocation or suspension is based. The Notice shall also include the date upon which the revocation or suspension shall become effective. The Notice may be accompanied by an Order requiring compliance with the Radiation Protection Act, N.J.S.A. 26:2D-1 et seq. or any rule promulgated pursuant thereto. Within 20 days of delivery of the Notice, an individual whose license is to be revoked or suspended may deliver to the Commissioner a written request for an administrative hearing, pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, to contest such revocation or suspension. The individual's request for an administrative hearing shall include a written statement of all issues of fact or law contained within the Notice which are disputed by the individual.

2. If the Commissioner determines the matter to be a contested case, he shall refer the matter to the Office of Administrative Law for hearing before an administrative law judge, pursuant to the Administrative Procedure Act and the Uniform Administrative Procedure Rules. Upon review of the record of the administrative hearing in contested cases the Commissioner may affirm, modify or reject the Initial Decision of the administrative law judge and/or the findings of the Department. If the Commissioner finds that the charges in a contested case have not been proven, he shall order them dismissed. If the Department's findings are found to be true, the Commissioner may, in his discretion, issue an order suspending or revoking the license

of the individual. In uncontested cases, the revocation or suspension of the individual's license shall be effective as of the date specified in the Notice of Revocation or Notice of Suspension.]

(b) The Board, in addition to any penalty authorized by the Act, may, upon learning of any of the acts or omissions listed in (b)1 through 13 below, deny admission to any examination; deny an application for a license in fusion imaging CT technology; revoke or suspend the license of a fusion imaging CT technologist for a fixed period; and censure, reprimand, or otherwise discipline the technologist in accordance with the provisions and procedures set forth in the Radiologic Technologist Act, N.J.S.A. 26:2D-24 et seq.:

1. Violation of any of the provisions of this subchapter or the Act;

2. Conviction of any crime that reasonably relates to fusion imaging CT technology. For the purpose of this section, a plea of guilty, non vult, no contest, or other such disposition of alleged criminal activity shall be deemed a conviction;

3. Revocation or suspension of a certification, registration, or license to fusion imaging CT technology or censure or reprimand by any other state or certifying agency for reasons consistent with this subchapter;

4. Dishonesty, fraud, deception, misrepresentation, or falsification in:

i. Fusion imaging CT technology or in documenting compliance with the Radiation Protection Act, the Radiologic Technologist Act, or this chapter;

ii. Obtaining a fusion imaging CT technology license, including taking the examination and completing the required education and training;

iii. Statements on any fusion imaging CT technology application for examination or license;

iv. Statements or documentation regarding the status of any national certification relating to the field of computed technology;

v. Statements made to a representative of the Department or Board; or

vi. Any records relating to the practice of fusion imaging CT technology;

5. Altering any fusion imaging CT technology license or examination results;

6. Practicing fusion imaging CT technology or reporting to work as a fusion imaging CT technologist while under the influence of alcohol or a Controlled Dangerous Substance as defined in the New Jersey Code of Criminal Justice, N.J.S.A. 2C:1-1 et seq.;

7. **Acting in a negligent or incompetent manner relating to fusion imaging CT technology;**

8. Maliciously destroying or stealing property or records relating to the practice of fusion imaging CT technology;

9. Failing to exercise due regard for safety, life, or health while engaged in the practice of fusion imaging CT technology;

10. Violating any term limitation, condition, or restriction that the Board has placed on his or her fusion imaging CT technology license;

11. Failing to comply with any State or Federal law or regulation regarding the confidentiality of a patient's medical or dental information;

12. Impersonating a licensed fusion imaging CT technologist;

13. Discriminating in the practice of fusion imaging CT technology as defined in Section 3 of New Jersey Law Against Discrimination, N.J.S.A. 10:5-3, as supplemented or amended.

(c) There is a rebuttable presumption that a person who has been determined by the Board to have committed an act or omission listed in (b) above or has been convicted of a crime involving moral turpitude does not meet the standard of good moral character. A person may rebut the presumption by demonstrating to the Board's satisfaction that he or she is of good moral character.

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

7:28-24.13 School of nuclear medicine technology; standards

(a) In order to be approved by the Department in accordance with N.J.A.C. 7:28-24.14, a school of nuclear medicine technology shall be accredited by JRCNMT, or by an accreditation agency that the Department determines is equivalent, and shall maintain that accreditation.

(b) The school's curriculum shall comply with JRCNMT's standards, or standards that the Department determines are equivalent, and include a valid plan for competency-based clinical education as follows:

1. Nuclear medicine students shall:

i. Perform nuclear medicine procedures under the direct supervision of a licensed nuclear medicine technologist until a school instructor determines that the student has achieved competency in that procedure; and

ii. Perform nuclear medicine procedures for which the student has demonstrated competency in accordance with (b)1i above under either the direct or indirect supervision of a licensed nuclear medicine technologist, as provided in the school's curriculum.

2. Students who perform CT procedures as part of the school's curriculum shall perform these procedures under the direct supervision of a licensed physician or a licensed diagnostic radiologic technologist, or a licensed fusion imaging CT technologist if the CT procedure is part of a fusion imaging procedure.

(c) Neither the school nor its clinical education centers shall assign students to clinical education rotations in such a manner as to substitute for licensed technologists.

(d) The school shall assign students only to clinical education centers that are approved by the Department.

(e) The school shall not have more than two consecutive calendar years in which the pass rate for students taking the American Registry of Radiologic Technologists or Nuclear Medicine Technology Certification Board examination for the first time is below 75 percent.

(f) The school shall forward to the Department a copy of its annual examination report from the American Registry of Radiologic Technologists or Nuclear Medicine Technology Certification Board within 15 calendar days of receipt of the report.

(g) The school shall inform the Department within 15 calendar days after any change that could adversely affect the school's ability to fulfill its responsibility to provide students with appropriate didactic and laboratory instruction and clinical assignments. Such changes include, but are not limited to, a change in status or loss of any official or faculty member, the loss of a clinical education center, a change in the school's curriculum, the sequencing of courses or length of the program, or a change in the sponsorship of the program.

(h) The school shall notify the Department of any change in its accreditation status and the reason for such change no later than seven calendar days after the school is notified of the change in its accreditation status.

(i) The school shall provide the Department in writing the name and address of each new student enrolled in the school's course of study in nuclear medicine technology no later than 30 calendar days after the student's enrollment. The school shall provide the Department in writing the name and address of each student who has successfully completed the school's course of study in nuclear medicine technology no later than 30 calendar days after the student completes the course of study.

(j) The school shall provide all students with whole body and finger radiation monitoring devices and ensure that the devices are worn during all times when students are in a controlled area. Student exposure to radiation shall not exceed the occupational limits and, if applicable, the embryo-fetus exposure limit prescribed in the standards for protection against radiation at N.J.A.C. 7:28-6.1. In the event that a student or embryo-fetus receives an exposure that exceeds the exposure limit, the school shall, within seven calendar days, notify the Department.

(k) The school, including its clinical education centers, shall:

1. Permit the Department to conduct site inspections;

2. Make available to the Department such information, records, or persons that may be needed to determine compliance with the requirements of this subchapter; and

3. Demonstrate to the satisfaction of the Department that it complies with the requirements of this subchapter.

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

(a) In order to be approved by the Department, a school of nuclear medicine technology shall submit to the Department a complete application, which shall include:

1. The name, address, and contact information of the school;

2. The name and credentials of the program director;

3. The name and address of all clinical education centers;

4. A copy of the school's accreditation letter from JRCNMT or an equivalent accreditation agency;

5. Copies of policies governing the supervision of students that comply with N.J.A.C. 7:28-24.13(b);

6. The last three annual examination reports of the school's nuclear medicine technology graduates' first-time examination performance on the American Registry of Radiologic Technologists or Nuclear Medicine Technology Certification Board. A school that has graduated students for less than three years shall submit the most recent annual examination reports, if any; and

7. A written statement permitting Department inspection pursuant to N.J.A.C. 7:28-24.13(k).

(b) The Department shall approve the application if it determines that the school has complied with this subchapter.

(c) Any change to the information contained in school's approved application shall be reported to the Department within 15 calendar days after the change.

(d) A school whose application has been denied shall be notified by letter, via certified mail, which shall contain the findings that resulted in the denial.

(e) Schools that are approved by the Department on or before (one day prior to the operative date of the rules) are deemed approved.

(f) In order to maintain approval, the school shall comply with the requirements of this subchapter.

(g) A school may have its approval terminated by the Department for failure to comply with this subchapter. The Department shall notify the school via certified mail. The notice shall include the findings that led to the termination and specify the effective date of the termination.

7:28-[24.12]**24.15** List of approved schools

A list of approved schools of nuclear medicine technology and their approval status shall be available from the Department, and may be obtained by contacting the Department. (See N.J.A.C. 7:28-[24.8(b) 2]**24.11(d)2** for the Department's address.)

7:28-24.16 Adjudicatory hearings

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

1. The name, address, and telephone number of the person or school and any authorized representative;

2. The date the person or school received the Department's or Board's finding;

3. A copy of the finding or administrative order giving rise to the request for a hearing, and a list of all issues being appealed;

4. The defenses to each of the Department's or Board's findings of fact, stated in short and plain terms;

5. An admission or denial of each of the Department's or Board's findings. If the person or school is without knowledge or information sufficient to form a belief as to the truth of a finding, the person or school shall so state and this shall have the effect of a denial. A denial shall fairly meet the substance of the findings denied. When the person or school intends in good faith to deny only a part or a qualification of a finding, the person or school shall specify so much of it as is true and material and deny only the remainder. The person or school may not generally deny all of the findings, but shall make all denials as specific denials of designated findings. For each finding the person or school denies, the person or school shall state the fact or facts as the person or school believes it or them to be;

6. Information supporting the request and specific reference to or copies of other written documents relied upon to support the request;

7. An estimate of the time required for the hearing (in days and/or hours); and

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

(b) The Department shall deny the hearing request if:

1. The person or school requesting the hearing fails to include all of the information required in (a) above; or

2. The Department does not receive the request in the time specified in (a) above.

(c) The Department shall conduct all adjudicatory hearings in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(d) Requests for adjudicatory hearings shall be sent to:

New Jersey Department of Environmental Protection

Office of Legal Affairs

Attention: Hearing Request

401 East State Street, 7th Floor

Mail Code 401-04L

PO Box 402

Trenton, New Jersey 08625-0402; and

New Jersey Department of Environmental Protection

Bureau of X-ray Compliance

Attention: Hearing Request

Mail Code 25-01

PO Box 420

Trenton, New Jersey 08625-0420

(e) Nothing in this section shall be construed to provide a right to an adjudicatory hearing in contravention of N.J.S.A. 52:14B-3.1 through 3.3.

7:28-24.17 Severability

Each section of this subchapter is severable. In the event that any section, subsection or division, or application thereof, is held invalid in a court of law, the remainder of this subchapter shall continue in full force and effect.

SUBCHAPTER 58. DOMESTIC LICENSING OF SOURCE MATERIAL

7:28-58.1 Incorporation by reference

(a) – (b) (No change.)

(c) **In addition to the changes outlined in N.J.A.C. 7:28-1.6,** [The] **the** following provisions of 10 CFR Part 40 are incorporated by reference with the specified changes:

1.-10. (No change.)

11. [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"] **10 CFR 40.22(b)(3), replace "§§ 40.1 through 40.10" with "§§ 40.1, 40.2, 40.3, 40.4, 40.6 and 40.7, 40.9 and 40.10," and replace "40.41 (a) through (e)" with "40.41(a) through (c) and (e)(2)"**;

12.-22. (No change.)

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

24.-38. (No change.)

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

SUBCHAPTER 60. DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

7:28-60.1 Incorporation by reference

(a) – (b) (No change.)

(c) **In addition to the changes outlined in N.J.A.C. 7:28-1.6,** [The] **the** following provisions of 10 CFR Part 70 are incorporated by reference with the specified changes:

1.-13. (No change.)

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

15.-26. (No change.)

(d) – (f) (No change.)

SUBCHAPTER 61. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL**S**

7:28-61.1 Incorporation by reference

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

(c) **In addition to the changes outlined in N.J.A.C. 7:28-1.6,** [The] **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.-vi. (No change.)

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

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

ix. 10 CFR 71.106;

2.-15. (No change.)

(d) – (e) (No change.)

SUBCHAPTER 65. PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

7:28-65.1 Incorporation by reference

(a) Except as set forth in (b) and (c) below, this subchapter incorporates by reference 10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.

(b) The following provisions of 10 CFR Part 37 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 37.11(b).

(c) In addition to the changes in N.J.A.C. 7:28-1.6, the following provisions of 10 CFR Part 37 are incorporated by reference with the specified changes:

1. "Commission," "Nuclear Regulatory Commission," "NRC," and "U.S. Nuclear Regulatory Commission," as used in the following provisions of Part 37 of the Code

of Federal Regulations that are incorporated by reference, mean the "U.S. Nuclear Regulatory Commission":

i. 10 CFR 37.5 in definition of "fingerprint orders";

ii. 10 CFR 37.25(b)(2);

iii. 10 CFR 37.27(a);

iv. 10 CFR 37.27(c)(1) through (3);

v. 10 CFR 37.29(a)(1);

vi. 10 CFR 37.29(a)(7);

vii. 10 CFR 37.29(a)(8);

viii. 10 CFR 37.71; and

ix. 10 CFR 37.77.

2. "Security Orders," as used in 10 CFR Part 37, means the license conditions imposed in NJ Radioactive Materials licenses that implement NRC's Orders Imposing Fingerprinting (EA-07-305).

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

i. 10 CFR 37.29(a);

ii. 10 CFR 37.29(a)(7); and

iii. 10 CFR 37.29(b);

4. 10 CFR 37.5, Definitions, in the definition of "fingerprint orders," delete "or the legally binding requirements issued by Agreement States";

5. 10 CFR 37.5, Definitions, in the definition of "license issuing authority," replace "or the appropriate agency of an Agreement State" with "the U.S. Nuclear Regulatory Commission or the appropriate agency of an Agreement State";

6. 10 CFR 37.5, Definitions, in the definition of "person," replace "Government agency" with "state or local government agency" and delete "other than the Commission or the DOE except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act or 1982 (96 Stat. 2201), and section 2(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842), and any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity";

7. 10 CFR 37.43(d)(1), delete "Except as provided in paragraph (d)(9)";

8. 10 CFR 37.77 (a)(1), replace "The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to 301-816-5151" with "The notification to the Bureau of Environmental Radiation may be made by email to RAMQC@dep.nj.gov or by fax at the number provided at N.J.A.C. 7:28-1.5(b)"; and

9. 10 CFR 37.81(g), delete "In addition, the licensee shall provide one copy of the written report addressed to the Director, Division of Security Policy, Office of

Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission,

Washington DC 20555-0001."