NOTE: THIS IS A COURTESY COPY OF THIS RULE PROPOSAL. THE OFFICIAL VERSION WILL BE PUBLISHED IN THE MAY 19, 2025, NEW JERSEY REGISTER. SHOULD THERE BE ANY DISCREPANCIES BETWEEN THIS TEXT AND THE OFFICIAL VERSION OF THE PROPOSAL, THE OFFICIAL VERSION WILL GOVERN.

**ENVIRONMENTAL PROTECTION**

**AIR, ENERGY, AND MATERIALS SUSTAINABILITY**

**DIVISION OF AIR QUALITY AND RADIATION PROTECTION**

**COMMISSION ON RADIATION PROTECTION**

**Radiation Protection Programs**

**Proposed Amendments: N.J.A.C. 7:28-3.12, 14.1, 14.2, 14.3, 14.4, 15.2, 15.3, 15.4, 15.5, 15.9, 15.10, 16.2, 16.3, 16.9, and 16.10**

**Proposed New Rules: N.J.A.C. 7:28-14.6, 16.7, and 16.8**

**Proposed Recodifications with Amendments: N.J.A.C. 7:28-15.6 and 15.12 as 14.5 and 15.6, Respectively**

Authorized By: Shawn M. LaTourette, Commissioner, Department of Environmental Protection, and the Commission on Radiation Protection, Donald Denny, 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: 03-25-04.

Proposal Number: PRN 2025-055.

A **public hearing** concerning this notice of proposal will be held on June 18, 2025, at 1:00 P.M. The public hearing will be conducted virtually through the Department of Environmental Protection's (Department) video conferencing software (that is, Microsoft Teams). A link to the virtual public hearing and telephone call-in option will be provided on the Department's website at https://www.nj.gov/dep/rules/notices.html.

Submit written comments by close of business on July 18, 2025, 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 encourages electronic submittal of comments. In the alternative, comments may be submitted on paper to:

Attention: Amanda Parker, Esq.

DEP Docket Number: 03-25-04

Office of Legal Affairs

Department of Environmental Protection

401 East State Street, 7th Floor

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PO Box 402

Trenton, New Jersey 08625-0402

If you are interested in providing oral testimony at the virtual public hearing, please email the Department at Jennifer.Daino@dep.nj.gov, no later than 5:00 P.M. on June 16, 2025, with your contact information (name, telephone number, email address, and if speaking on behalf of an organization, name of organization). You must provide a valid email address so the Department can send you an email confirming receipt of your interest to testify orally at the hearing and provide you with a separate option for a telephone call-in line if you do not have access to a computer that can connect to Microsoft Teams. Please note that the hearing will be recorded. It is requested (but not required) that anyone providing oral testimony at the public

hearing provide a copy of any prepared remarks to the Department through email.

This notice of 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.

In 1958, the Radiation Protection Act, N.J.S.A. 26:2D-1 et seq. (the Act), was enacted. The Act governs the possession, handling, and use of sources of radiation within the State of New Jersey. The 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 Act also authorizes the Department to establish and charge fees, through the promulgation of rules, for the services it performs pursuant to the Act. These fees reflect the actual or projected expenses incurred by the Department in performing the activities for which fees are charged.

In 1969, the Radiologic Technologist Act, N.J.S.A. 26:2D-24 et seq., was enacted. The Radiologic Technologist Act created the New Jersey Radiologic Technology Board of Examiners (Board) and vested in that body the authority to establish the standards for education and licensing of operators of ionizing radiation-producing equipment and the standards for schools in categories of radiologic technology.

Through the 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 that, in relevant part, encompasses therapeutic, medical diagnostic, and dental x-ray machines and equipment. Since the Radiation Protection Programs rules were last adopted or amended, newer and more effective radiation protection practices and procedures have evolved as a result of a better understanding of the biological effects of radiation and the availability of more sophisticated technology and newer radiotherapy devices. Therefore, the Commission and the Department propose the following amendments and new rules at N.J.A.C. 7:28.

This rulemaking will incorporate current technologies, allow flexibility to address emerging and future technologies, and incorporate the latest applicable Federal guidance to reflect national standards in radiation protection. The proposed amendments and new rules are based on the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations and the Code of Federal Regulations (CFR). The CRCPD is a "nonprofit, non-governmental, professional organization whose primary membership is comprised of radiation professionals in State and local government that regulate the use of radiation sources." See https://crcpd.org/. The Suggested State Regulations document is used throughout the country as a guide for establishing individual state rules for the control of radiation. The objective of the Suggested State Regulations is to promote the adoption of similar rules in all states. The Code of Federal Regulations establishes machine performance standards that are effective nationwide.

The Department developed a stakeholder group with representatives of the New Jersey Dental Association, the New Jersey Board of Dentistry, the American Association of Physicists in Medicine, the New Jersey Board of Chiropractic Medicine, the Association of New Jersey

Chiropractors, the New Jersey Board of Podiatric Medicine, and the New Jersey Podiatric Medical Society. The Department held stakeholder meetings on October 4, 2023 and October 11, 2023, and received positive feedback.

**Registration of Ionizing Radiation-Producing Machines, N.J.A.C. 7:28-3**

The Act established New Jersey's Radiological Health Program. As explained above, the Act authorizes the Department to assess and collect fees and directs the Department to charge fees that "reflect the actual or projected expense incurred by the Department in the performance of the service for which the fee is charged." N.J.S.A. 26:2D-9(l). The Act stipulates that the fees charged shall be based on criteria contained in a fee schedule adopted as a rule or regulation in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. Accordingly, the Department adopted the fee schedule at N.J.A.C. 7:28-3.12, Application and annual registration renewal fees for ionizing radiation-producing machines.

The Department is proposing to update the annual registration fee tables at N.J.A.C. 7:28-3.12 to include the most current list of machine category types at dental facilities, hospital facilities, non-hospital facilities, and veterinary facilities. In some instances, the names of the machine category types are amended to reflect the proper usage. The Department is maintaining the fee amounts for existing categories. The fees for the proposed new machine categories are consistent with similar machine categories for facility types. For example, for dental facilities, the Department is proposing to add eight machine categories, each with a fee of $92.00 per x-ray tube. For hospital facilities, the Department is proposing to add various dental machine categories, ranging in fees from $92.00 to $140.00 per x-ray tube. The existing fee for the dental

machine category, which is proposed to be renamed as "dental unit in hospital," is $140.00. As another example, the Department is proposing to add a category for "mobile medical fluoroscopic/O-arm machine" with a fee of $163.00 per x-ray tube, the same fee for other medical fluoroscopic machines at hospital facilities.

Pursuant to N.J.A.C. 7:28-3.12(g), each registrant is required to pay the initial registration application fee and annual registration renewal fee within 60 days of the date of the invoice issued by the Department. The Department is proposing to delete the existing $25.00 per month late charge because the Department addresses late registrations through Administrative Orders and Notices of Violation through program enforcement. In practice, the Department sends multiple late notices to facilities prior to taking enforcement action. The Department is also proposing to allow a registrant to pay fees online at www.xray.nj.gov to provide more flexibility to registrants.

The Department proposes to correct the capitalization of "x-ray" at N.J.A.C. 7:28-3.12(c).

**Therapeutic Installations, N.J.A.C. 7:28-14**

Subchapter 14 establishes the requirements for therapeutic installations used in the healing arts, which include machine performance standards for therapeutic x-ray systems and therapeutic accelerator systems, facility radiation safety operating procedures, calibration and spot check requirements, and recordkeeping requirements. N.J.A.C. 7:28-14, Therapeutic Installations, was first promulgated in 1967 and the last significant amendments were in 1987. The Department, therefore, proposes to amend N.J.A.C. 7:28-14 to update the requirements so they are consistent with current technology and standards. Proposed amendments also clarify

existing requirements and expand the subchapter to apply to radiation therapy devices in current use.

The Department proposes to make clear, at proposed new N.J.A.C. 7:28-14.1(c) that only a licensed practitioner and licensed radiation therapist may operate therapeutic equipment used in the healing arts. As set forth at proposed new N.J.A.C. 7:28-14.1(d), if a registrant seeks to use an emerging therapeutic technology that the rules do not specifically address, the registrant may apply for a special exemption pursuant to N.J.A.C. 7:28-2.8, Special exemptions.

At N.J.A.C. 7:28-14.2, Definitions, the Department is proposing to amend existing definitions and add new definitions that are consistent with the latest technology and scientific principles. The term "qualified radiological physicist" is proposed to be amended as "qualified medical physicist" to be consistent with terminology used by the American Association of Physicists in Medicine (AAPM). "Interlock" and "moving beam therapy" are proposed to be amended to be consistent with the Suggested State Regulations, Part X, Therapeutic Radiation Machines, SSRCR Volume I (Jan. 2023), available at https://crcpd.org/wp-content/uploads/2023/11/Part-X_2023.pdf (referred to as Suggested State Regulations, Part X). Specifically, the proposed amended definition of "interlock" refers to a device that prevents equipment from operating or continuing to operate unless one or more conditions prevail. The existing rule refers to one event occurring before a second event (the operation or continued operation of equipment) can occur. The proposed amended definition of "moving beam therapy" means radiation therapy with any planned displacement of radiation field or patient relative to each other or with any planned change of absorbed dose distribution. The proposed definition provides examples of what constitutes "moving beam therapy."

The Department proposes to delete the definitions of "beam scattering filter" and "spot check" because the terms and definitions are outdated and are no longer relevant. Where the existing rules refer to "spot check," the Department proposes to use the term "periodic quality assurance check." The definition of "spot check" in existing rules is focused on the parameters that affect the beam and radiation output. A spot check is a calibration procedure, whereas a periodic quality assurance check is a broader term. In terms of requirements, periodic quality check assurance has safety device checks, in addition to all of the requirements that were previously within the term "spot check."

The new definitions include: "absorbed dose," "absorbed dose rate," "air kerma," "'air kerma rate' or 'AKR,'" "barrier," "beam scattering foil," "dosimetry system," "detector," "external beam radiation therapy," "filter," "'gray' or 'Gy,'" "'kilovolt' or 'kV,'" "'kilo electron volt' or 'keV,'" "lead equivalent," "light field," "'megavolt' or 'MV,'" "'mega electron volt' or 'MeV,'" "'monitor unit' or 'MU,'" "periodic quality assurance check," "primary protective barrier," "protective barrier," "radiation detector," "radiation head," "redundant beam monitoring system," "scattered radiation," "shutter," "simulator," "stray radiation," "survey instruments," "'target-to-skin distance' or 'TSD,'" "tube," "tube housing assembly," "useful beam," and "x-ray tube." These definitions were added to be consistent with the Federal regulations at 21 CFR 1020.30, pertaining to diagnostic x-ray systems and Suggested State Regulations, Part X, for therapeutic x-ray equipment. Throughout the subchapter, the Department proposes to replace "kVp" (kilovoltage peak) with "kV," the defined term. The energy of a therapy unit is appropriately measured in kV, keV, MV, or MeV.

The definitions of "anti-collision device" and "qualified medical physicist for the

supervision of quality assurance programs for therapy simulator systems" are relocated from N.J.A.C. 7:28-15.2. The terms are used at existing N.J.A.C. 7:28-15.6, which the Department proposes to recodify as N.J.A.C. 7:28-14.5 with amendments, as discussed below. The relocated definition of "qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems" is changed from the existing definition in order to make the structure similar to that of the proposed amended definition of "qualified individual for the performance of radiation surveys for diagnostic x-ray equipment" at N.J.A.C. 7:28-15.2. The proposed relocated definition groups certifications at paragraph 1, rather than individually, as in the existing definition of the term.

Existing N.J.A.C. 7:28-14 includes requirements for therapeutic x-ray systems with energies less than one mega electron volt (MeV) and those with energies of one MeV and greater. See N.J.A.C. 7:28-14.3 and 14.4, respectively. The Department is proposing to amend N.J.A.C. 7:28-14.3, **Therapeutic x-ray systems with energies less than one MeV, to apply to therapeutic x-ray systems with energies less than 500 kV, and to amend the section heading accordingly.** The Department is proposing to amend N.J.A.C. 7:28-14.4, **Therapeutic x-ray systems with energies of one MeV and above, to apply to therapeutic x-ray systems with energies of 500 kV and above, and to amend the section heading accordingly. One MeV is the equivalent of 1,000 kV; therefore, the proposed energy threshold for the requirements at N.J.A.C. 7:28-14.3 to apply is halved from the existing rule. Similarly, the proposed energy threshold for the requirements of amended N.J.A.C. 7:28-14.4 is also halved. This change is consistent with the CRCPD's** Suggested State Regulations, Part X, **for this type of equipment. Currently, there are no facilities that have therapeutic x-ray systems that**

**operate between 500 kV and one-MeV, so this change will not impact any currently registered facilities.**

The proposed amendments to the two sections include updated calibration and periodic quality assurance check requirements that reflect technological advances in therapeutic x-ray equipment, as well as operating parameters that apply to the technology in current use. The proposed amendments again will align the rules with CRCPD's Suggested State Regulations, Part X.

The amendments change the requirements for the level of the air leakage, testing frequency, testing and calibration, and record retention. The amendments also change the energy thresholds that separate the requirements at N.J.A.C. 7:28-14.3 from 14.4. The change in this energy threshold is not expected to have any impact to systems that currently operate under one MeV. All the machines currently registered in categories with energies below one MeV also have energies below 500 kV. Therefore, this change will not affect any currently registered equipment.

"Periodic quality assurance check" is replacing "spot check." The existing definition of "spot check" focuses on the parameters that affect the beam and radiation output and is a calibration procedure. "Periodic quality assurance check" is a broader term that includes safety device checks in addition to all the requirements that were previously within the term "spot check." This change is consistent with CRCPD's Suggested State Regulations, Part X.

The Department is proposing to recodify with amendments N.J.A.C. 7:28-15.6, Radiation therapy simulators, as 14.5. As the equipment in the section is used for therapy, the section is more appropriately included within N.J.A.C. 7:28-14, Therapeutic Installations, rather than

N.J.A.C. 7:28-15, Medical Diagnostic X-ray Installations. The recodified section is largely the same as the existing section, with amendments for grammar and clarity. The Department is proposing to amend the testing intervals for the operation of an anti-collision device from 12 months to 14 months, and the recordkeeping requirement to at least five years. The Department is requiring therapeutic facilities to retain calibration records for at least five years to be consistent with the record retention provisions elsewhere at Subchapter 14 and the recommendations of the AAPM. The proposed annual testing interval (not to exceed 14 months) is consistent with the testing interval elsewhere in the chapter. See, for example, N.J.A.C. 7:28-22.3 (radiographic, fluoroscopic, x-ray bone densitometry, or computed tomography (CT) equipment).

At new N.J.A.C. 7:28-14.6, Proton therapy systems, the Department is proposing requirements for equipment used in proton therapy, which is a therapy technology that developed after N.J.A.C. 7:28-14 was last amended. As with the rules for the operation of other therapeutic installations, proposed N.J.A.C. 7:28-14.6 includes acceptance testing, commissioning, and calibration requirements. The requirements also include quality assurance, safety checks, and operating procedures. The standards for proton therapy are based on Commission on Radiation Protection-issued exemption requests and CRCPD's Suggested State Regulations, Part X. CRCPD has protons combined with photons and electrons, leading to similarities between N.J.A.C. 7:28-14.4 and 14.6.

**Medical Diagnostic X-Ray Installations, N.J.A.C. 7:28-15**

Existing Subchapter 15 establishes the requirements for medical radiographic installations, which include equipment performance standards, structural shielding requirements,

and facility operating procedures. As with therapeutic installations, there have been many technological advances in the design and use of medical x-ray equipment since the rules were last updated in 1993. The Department, accordingly, proposes amendments and additions to N.J.A.C. 7:28-15.

At N.J.A.C. 7:28-15.2, the Department is proposing to amend existing definitions and add new definitions consistent with the technology and scientific principles and based on Federal regulations at 21 CFR 1020.30. "Diagnostic x-ray system" is being amended to refer to "diagnosis or visualization" rather than "diagnostic imaging or measurement." "Image receptor" is being amended to include other examples of devices that fit the definition. Amendments to the definition of "qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems" include deleting the reference to "therapy simulator systems" since therapeutic installations are subject to N.J.A.C. 7:28-14, and minor revisions for clarity. "Scan time" is being amended to more generally refer to the time elapsed during the accumulation of x-ray transmission data for a single scan, rather than the time between the beginning and end of photon transmission data. The Department is also amending the following definitions to clarify that each term's abbreviation has the same meaning as the term itself: "computed tomography," "computed tomography dose index," "contrast scale," "positive beam-limiting device," "source-to-image receptor distance," and "source-to-skin distance."

The Department is proposing to add the following new definitions based on current technology and scientific principles as reflected in Federal regulations at 21 CFR 1020.30 and the CRCPD Suggested State Regulations, Part F: "air kerma," "'air kerma rate' or 'AKR,'" "bone densitometer," "C-arm fluoroscope," "'computed radiography' or 'CR,'" "'digital

radiography' or 'DR'," "extremity," "fluoroscopy," "'gray' or 'Gy,'" "handheld radiographic x-ray equipment," "kerma," "lead equivalent," "mode of operation," and "pulsed mode." The Department proposes to delete the following definitions because they are outdated: "C-arm x-ray system," "radiation therapy simulation system," and "xeromammography." The following definitions are proposed to be relocated to Subchapter 14, as discussed above: "anti-collision device" and "qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems." These two definitions are related to therapeutic installations.

Existing N.J.A.C. 7:28-15.3 establishes general requirements for radiographic installations. The Department proposes to replace Table 1, "Table of Half Value Layers," with new standards for equipment manufactured before and after June 10, 2006. The change is consistent with the Federal regulations at 21 CFR 1020.30, Diagnostic x-ray systems and their major components, which establish June 10, 2006, as the effective date for the changes. The U.S. Food and Drug Administration (FDA) has separate requirements for units manufactured before June 10, 2006, and units manufactured on or after June 10, 2006. Additionally, the Department is updating the exposure reproducibility and linearity requirements to include air kerma terminology and corresponding units to be consistent with Federal regulations at 21 CFR 1020.30.

At proposed new N.J.A.C. 7:28-15.3(l), the Department is proposing standards and requirements for handheld radiographic units. The existing rules do not specifically allow for the sale and use of handheld radiographic units in New Jersey. For many years, the Department, with approval from the Commission, issued special exemptions pursuant to N.J.A.C. 7:28-2.8 to allow for the sale and use of handheld units that meet safety criteria. Pursuant to the existing

rules, each handheld device needs a separate exemption request submitted to the Department and the Commission prior to sale and use. The proposed rule eliminates the need for the Commission to review and approve a special exemption for each handheld device. The proposed requirements are consistent with recommendations in FDA Guidance Document number 1680, https://www.fda.gov/media/73890/download, and at 21 CFR 1020.31, for the safe use of the handheld devices. The Department developed quality assurance/control measures and personnel monitoring requirements based on those established in other subchapters for similar types of radiographic equipment.

At N.J.A.C. 7:28-15.4, Mammography radiographic installations, the Department is exempting mammography units that are used exclusively for specimen imaging from the requirements of the section. As these units are not used for radiographic exposures on humans, they do not need to meet the same requirements and are instead regulated pursuant to N.J.A.C. 7:28-3 and 7. The Department is deleting xeromammography and screen-film requirements from this section because the technology is obsolete and all mammography units in the State are now digital or computed radiography units. Additionally, the Department is deleting the linearity requirements because the test is no longer required by manufacturers of mammography units.

At N.J.A.C. 7:28-15.5, Medical fluoroscopic x-ray systems, the Department proposes amendments to be consistent with 10 CFR 1020.32 and suggested state regulations from CRCPD, Part F. Specifically, the Department proposes to update field limitations requirements for fluoroscopic equipment, automatic exposure rate control requirements, high-level control requirements, air kerma rate determination, source-to-skin distance for fluoroscopes, fluoroscopic timers, requirements for procedures that prohibit the use of protective barriers, last

image hold display, and air kerma rate and cumulative air kerma display for fluoroscopic equipment. The Department is deleting language for systems that are outdated.

As explained above, the Department is proposing to recodify with amendments existing N.J.A.C. 7:28-15.6 as 14.5. The Department is proposing to recodify existing N.J.A.C. 7:28-15.12 as 15.6 and 15.13 as 15.12, respectively. Proposed amendments to recodified N.J.A.C. 7:28-15.6 are grammatical and provide a more generic cross-reference to N.J.A.C. 7:28-22.

Existing N.J.A.C. 7:28-15.9 establishes requirements for individual radiation safety. The Department is adding the individual radiation safety requirements of shielding when the patient must hold the image receptor to be consistent with the most recent recommendations of the NCRP, Statement No. 13, January 12, 2021, https://ncrponline.org/wp-content/themes/ncrp/PDFs/Statement13.pdf, and the AAPM 2019 position statement, https://www.aapm.org/org/policies/details.asp?id=2552&type=.

Existing N.J.A.C. 7:28-15.10 establishes requirements for structural shielding of an x-ray facility and radiation safety surveys. The Department is proposing to add a requirement to include in the radiation safety survey report, a picture of the serial plate that shows the model number, generator serial number, and control panel serial number. This will aid inspection staff in determining if any changes have been made to the x-ray equipment since the previous inspection.

**Dental Radiographic Installations, N.J.A.C. 7:28-16**

Subchapter 16 establishes the requirements for dental radiographic installations, which include equipment performance standards, structural shielding requirements, and facility operating procedures. The Department proposes amendments and additions at N.J.A.C. 7:28-16

to reflect the technological advances since the rules were adopted in 1990.

At N.J.A.C. 7:28-16.2, Definitions, the Department is proposing new definitions for the following terms as reflected in Federal regulations at 21 CFR 1020.30 and 21 CFR 872.1810, and definitions from 25 PA. Code 221.2 and Michigan Administrative Code R333.5396: "cone beam computed tomography" or "CBCT," "handheld dental x-ray system," "initially," "intraoral source x-ray system," "mobile x-ray equipment," "panoramic radiography," "phantom," "QA," "QC," and "stationary x-ray equipment." The proposed new terms are used in the proposed new sections at N.J.A.C. 7:28-16, discussed below. The new definitions assist facilities in identifying the types of dental x-ray equipment and, therefore, the applicable regulation.

Existing N.J.A.C. 7:26-16.3, Dental radiographic equipment, sets forth the requirements for the operation of ionizing radiation-production equipment used in dentistry practice. The Department is proposing to update Table 1, Table of Half-Value Layers for Dental Units to reflect the current 10 CFR 1020.30 operating standards for kVp. The Department is also proposing to include a maximum deviation not to exceed 10 percent of the indicated value for certified dental x-ray equipment that do not have manufacturer's standards for kVp.

The Department is proposing to establish new standards and requirements for two new dental radiologic technologies, cone-beam computed tomography (CBCT) installation and handheld dental installations. See proposed new N.J.A.C. 7:28-16.7, Cone-beam computed tomography (CBCT) installations, and 16.8, Handheld dental x-ray systems. The existing rules do not include language for these specific types of radiographic units that have developed with technological advances in diagnostic and dental radiography. These two proposed new sections will align the rules with suggested state regulations for CBCT and handheld dental installations

developed by CRCPD, FDA Guidance Document number 1680, and 21 CFR 1020.31 for the safe use of the handheld devices.

At N.J.A.C. 7:28-16.7, the Department is proposing quality assurance regulations for dental CBCT units that the existing rules require compliance with N.J.A.C. 7:28-22.7, Quality assurance program for diagnostic computed tomography equipment. Existing N.J.A.C. 7:28-22.10(a), specifies that only a medical physicist may perform the annual quality control (QC) survey, but not all dental CBCT facilities employ a medical physicist. Accordingly, the dental CBCT facilities must hire a medical physicist to perform the testing. The Department proposes requiring dental facilities that use CBCT units to follow the manufacturer's recommended quality control testing. Currently, manufacturers must submit to the Department quality control tables that include the computed tomography testing as required at N.J.A.C. 7:28-22.7 and 22.10. N.J.A.C. 7:28-22.7 and 22.10 were implemented for dental CBCT units because the FDA classified them as computed tomography units. Existing N.J.A.C. 7:28-16 does not address CBCT units. Due to the differences in the software and hardware between dental CBCT equipment and standard CT equipment, dental CBCT units are not able to meet all the testing requirements at N.J.A.C. 7:28-22.7 and 22.10. This is further complicated by the variations in the software, hardware, and proprietary designs between the different makes and models of dental CBCT equipment. As a result, the task of submitting tables that meet the requirements at N.J.A.C. 7:28-22.7 and 22.10 can take months to complete one quality control table for one CBCT model. Allowing facilities to follow the manufacturer's quality control tests gives the Department the ability to reduce the amount of time for reviewing data in tables and allocate more resources to focus on the inspections to ensure that the public is not exposed to unnecessary

radiation. The Department has developed proposed new Table 2, Medical Physicist's Dental CBCT QC Survey, that specifies the testing that must be included in the annual physics testing.

The Department's proposed rules for handheld dental units are at new N.J.A.C. 7:28-16.8. As discussed above, in the absence of specific rules governing handheld dental units, the Department has issued several special exemptions in order for these units to be sold and used in New Jersey. Existing N.J.A.C. 7:28-16.3(a)11 and 16.10(a)2, which apply to dental units, require an operator to stand 1.83 meters (six feet) from the patient when performing exposures. The use of handheld dental units does not allow the operator to stand six feet from the patient; rather, the nature of a handheld dental unit necessitates that the operator stand beside the patient when using the unit. Additionally, at N.J.A.C. 7:28-16.10(a)4, the cone of an x-ray unit cannot be held in the hand. These handheld units are portable and can be used in various settings. The operator holds the unit and the cone is within inches from their hands. The proposed rules account for the proximity to the patient and the "handheld" nature of the unit.

As the Department is proposing new N.J.A.C. 7:28-16.7 and 16.8, the Department is proposing to recodify N.J.A.C. 7:28-16.7 through 16.10 as 16.9 through 16.12. At recodified N.J.A.C. 7:28-16.10, Radiation safety surveys, the Department proposes to update the requirements for information to be included in the radiation safety survey report. The Department is updating the registration application form number and including the form title in the rule. The Department is also proposing to require a picture of the generator serial plate that shows the model number, generator serial number, and control panel serial number. This will aid inspection staff in determining if any changes have been made to the x-ray equipment.

## Social Impact

Radiation is known to cause cancer and other adverse health effects in humans and there are ongoing 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. The Department anticipates that the proposed rulemaking will have a positive social impact.

The proposed amendments at N.J.A.C. 7:28-3, Registration of Ionizing Radiation-Producing Machines, 14, Therapeutic Installations, 15, Medical Diagnostic X-ray Installations, and 16, Dental Radiographic Installations, will have a positive social impact on the citizens of New Jersey and all persons who have radiological procedures performed in New Jersey by continuing to provide protections against unnecessary radiation exposure.

The proposed amendments at N.J.A.C. 7:28-3 provide facilities with the most up-to-date machine categories and increase efficiency by allowing them to renew their annual registration fees online.

The proposed amendments at N.J.A.C. 7:28-14 relate to new rules for proton therapy, the recodification of the radiation therapy simulator rules, and the updating of the existing rules, as a whole. The proposed amendments will continue the positive impact of the existing rules.

The proposed amendments at N.J.A.C. 7:28-15 and 16 include new rules for handheld x-ray units. Through these proposed amendments, manufacturers will not have to go through the extensive exemption process for their units to be sold in New Jersey, thereby making the units more available in the State. Additionally, the proposed amendments allow medical facilities to

have more purchasing options for different models and manufacturers. By reducing the need for exemptions, the proposed rules will enable Department staff and Commission members to address other radiation concerns.

**Economic Impact**

The Department anticipates that the proposed rules will have an economic impact. The proposed amendments that are likely to have an economic impact are discussed below.

The proposed amendments to the registration fees could result in some economic impact. As explained in the Summary, the Department is proposing to maintain the fee amounts for existing categories, while updating the registration fee table to include the most current list of machine category types at dental, hospital, non-hospital, and veterinary facilities. These facilities have already registered their machines, so the proposed amendments will not subject a facility to additional registration fee expenses.

The proposed amendment to the mammography radiographic installation rules at N.J.A.C. 7:28-15.4(e)2 applies to non-MQSA mammography units (units that are used exclusively for specimen imaging). The amendment exempts certain equipment used specifically for specimen imaging and are not used on humans from quality assurance (QA) requirements. This will save the regulated facility time that would otherwise be required to perform QA testing. Further, the regulated facility will not need to hire a qualified medical physicist to perform initial and annual surveys, resulting in overall cost savings to the regulated community. The cost of the survey can vary depending on the hourly rates charged by the individual medical physicist. A typical survey takes a medical physicist approximately three hours to complete and medical physicists charge between $100.00 and $350.00 per hour.

Therefore, the Department estimates the savings to be $300.00 to more than $1,000 annually.

Proposed amended N.J.A.C. 7:28-15.10, Structural shielding and radiation safety surveys, requires facilities that purchase handheld radiographic equipment to provide personnel monitoring ring devices for all operators. This will result in an additional expense for the facility. The personnel monitoring ring devices cost approximately $3.87 per individual if replaced monthly ($46.44 annual cost per employee), or $7.15 if replaced quarterly ($28.60 annual cost per employee).

The proposed amendments at N.J.A.C. 7:28-16, Dental Radiographic Installations, require an initial and annual (not to exceed 14 months) Medical Physicist's Dental CBCT QC Survey to be performed by a certified medical physicist. There will be no additional costs for dental CBCT facilities because these facilities have already been paying these costs since the Alternative CBCT Program was initiated in 2014. Existing N.J.A.C. 7:28-22, Quality Assurance Programs for Medical Diagnostic X-Ray Installations, requires the facilities to perform an initial and annual survey.

The proposed amendments to N.J.A.C. 7:28-16, Dental Radiographic Installations, reduce the need for manufacturers to obtain a special exemption for handheld dental units, as they must obtain them pursuant to the existing rules. Manufacturers incur substantial costs preparing the necessary documentation required for an exemption request, particularly for foreign manufacturers that may need to employ consultants to address language translations. The cost to prepare the exemption request depends on the complexity of the unit and the specific application; accordingly, the Department is unable to estimate the anticipated savings to manufacturers. The Department will also see savings as a result of the proposed amendments, in

that staff will no longer need to complete a technical evaluation of safety and operational parameters for the unit that is subject to the exemption request. These technical evaluations often require the Department to request additional information from the manufacturer, which adds time for review and evaluation. On average, the Department receives four to six exemption requests per year.

## Environmental Impact

The Department anticipates that the proposed amendments will 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, insofar as the proposed amendments continue to prevent or reduce unnecessary radiation exposure.

## Federal Standards Statement

N.J.S.A. 52:14B-1 et seq., requires State agencies that adopt, readopt, or amend State rules that exceed any Federal standards or requirements to include in the rulemaking document, a Federal standards analysis. The proposed amendments are not promulgated pursuant to the authority of or in order to implement, comply with, or participate in any program established

pursuant to Federal law, or a State statute that incorporates or refers to Federal law, Federal standards, or Federal requirements. Therefore, no further analysis is required.

**Jobs Impact**

The proposed amendments are not anticipated to have an impact on job creation or retention in the State.

**Agriculture Industry Impact**

The proposed amendments govern the use of sources of radiation within the State of New Jersey. The proposed amendments 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 amendments at N.J.A.C. 7:28 to determine their impact on small businesses. "Small business" is defined as any business that is resident in this State, independently owned and operated and not dominant in its field, and that employs fewer than 100 full-time employees.

There are approximately 8,500 licensed facilities in the State. Some veterinary, dental, and medical facilities, individual medical physicists, and medical physicist companies can be considered small businesses. Although the Department maintains records that show the number of its licensees, the records do not include the number of employees; therefore, the Department cannot estimate the number of small businesses that may be affected by the proposed rulemaking. The compliance, recordkeeping, and reporting requirements are discussed in the Summary above. See the Economic Impact for a discussion of anticipated costs.

In proposing these amendments, the Department has evaluated the need to protect the public from unnecessary exposure to radiation against the economic impact of the rules, and has determined that to provide a different standard for small businesses would endanger the environment and public health and safety. See the Social Impact for a discussion of the effects of radiation exposure.

**Housing Affordability Impact Analysis**

Pursuant to N.J.S.A. 52:14B-4.1b, the Commission and the Department have evaluated the proposed amendments to determine their impact, if any, on the affordability of housing. The proposed amendments govern the use of sources of radiation within the State. None of these relate to housing. Accordingly, the Department has determined that the proposed amendments 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 amendments to determine their impact, if any, on housing production within Planning Areas 1 or 2, or within designated centers, pursuant to the State Development and Redevelopment Plan. The proposed amendments govern the possession, handling, and use of sources of radiation within the State. Therefore, the proposed amendments will not evoke a change in housing production in Planning Areas 1 or 2, or within designated centers.

**Racial and Ethnic Community Criminal Justice and Public Safety Impact**

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

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

SUBCHAPTER 3. REGISTRATION OF IONIZING RADIATION-PRODUCING MACHINES

7:28-3.12 Application and annual registration renewal fees for ionizing radiation-producing machines

(a) On initial registration of each x-ray tube, each registrant shall pay an application fee of $40.00**,** plus the prorated portion of the applicable annual registration renewal fee set forth [in] **at** (b), (c), (d)**,** or (e) below for the remainder of the first year of registration.

(b) Each registrant of an [ionizing-radiation-producing] **ionizing radiation-producing** machine used in a dental facility shall pay:

1. (No change.)

2. In each year after the expiration of the first year of registration established pursuant to (f) below, the annual registration renewal fee per x-ray tube as follows:

DENTAL FACILITIES

| Machine Category and Description | | Annual Registration Renewal Fee Per X-Ray Tube |
|---|---|---|
| 01D | Dental [Machine] **Unit In Dental Facility** | [$92] **$92.00** |
| **67D** | **Cone Beam Computed Tomographic Machine (CBCT)** | **$92.00** |
| **81D** | **CT Motor Vehicle Mounted CBCT Machine** | **$92.00** |
| **60D** | **Dental Panoramic Machine** | **$92.00** |
| **61D** | **Dental Cephalometric Machine** | **$92.00** |
| **62D** | **Dental Pan-Ceph Combination Machine** | **$92.00** |
| **68D** | **Dental Unit — Van Mounted** | **$92.00** |
| **71D** | **Mobile Dental Unit** | **$92.00** |
| **73D** | **Handheld Dental Unit** | **$92.00** |

(c) Each registrant of an [ionizing-radiation-producing] **ionizing radiation-producing** machine used in a hospital facility shall pay:

1. The initial application and registration fees for each [X-ray] **x-ray** tube pursuant to (a) above; and

2. In each year after the expiration of the first year of registration [establish] **established** pursuant to (f) below, the annual registration renewal fee per [X-ray] **x-ray** tube follows:

HOSPITAL FACILITIES

| | Machine Category and Description | Annual Registration Renewal Fee Per X-Ray Tube |
|---|---|---|
| 01H | Dental [Machine] **Unit In Hospital** | $140.00 |
| **73H** | **Handheld Dental Unit** | **$140.00** |
| **61H** | **Dental Cephalometric Machine** | **$140.00** |
| **60H** | **Dental Panoramic Machine** | **$140.00** |
| **62H** | **Dental Pan-Ceph Combination Machine** | **$140.00** |
| **67H** | **Cone Beam Computed Tomographic Machine** | **$92.00** |
| **68H** | **Dental Unit - Van Mounted** | **$106.00** |
| **71H** | **Mobile Dental Unit** | **$140.00** |
| 02H | Fixed Medical Radiographic Machine | $208.00 |
| 03H | Mobile Medical Radiographic Machine | $208.00 |
| 31H | Portable Medical Radiographic Machine ([hand carried] **Hand-Carried**) | $208.00 |
| 06H | Motor Vehicle Mounted Medical Radiographic Machine | $208.00 |
| 04H | Fixed Medical Fluoroscopic Machine | $163.00 |
| 05H | Mobile Medical Fluoroscopic Machine | $163.00 |
| **76H** | **Mobile Medical Fluoroscopic\O-Arm Machine** | **$163.00** |
| 32H | Portable Medical Fluoroscopic Machine ([hand carried] **Hand-Carried**) | $163.00 |
| 33H | Motor Vehicle Mounted Medical [Fluroscopic] **Fluoroscopic** Machine | $163.00 |
| 07H | Fixed Medical Radiographic Fluoroscopic Machine | $253.00 |
| 08H | Mobile Medical Radiographic Fluoroscopic Machine | $253.00 |
| 34H | Portable Medical Radiographic Fluoroscopic Machine ([hand carried] **Hand-Carried**) | $253.00 |
| 35H | Motor Vehicle Mounted Medical Radiographic Fluoroscopic Machine | $253.00 |
| 09H | CT Scan Machine | $163.00 |
| 10H | Mammography Machine (**Stereotactic and Non-MQSA Only)** | $298.00 |

| | | |
|---|---|---|
| 36H | Motor Vehicle Mounted Mammography Machine **(Non-MQSA Only)** | **$**298.00 |
| 37H | Mobile Mammography Machine **(Non-MQSA Only)** | **$**298.00 |
| 44H | [MQSA] Mammography Machine **(Federal MQSA Units Only)** | **$**73.00 |
| 45H | [MQSA] Motor Vehicle Mounted Mammography Machine **(Federal MQSA Units Only)** | **$**73.00 |
| 46H | [MQSA] Mobile Mammography Machine **(Federal MQSA Units Only)** | **$**73.00 |
| 11H | Medical Therapeutic Machine ≤ 60 [kVp] **kV** | **$**253.00 |
| 12H | Medical Therapeutic Machine 61 [kVp] **kV** to 999 [kVp] **kV** | **$**253.00 |
| 14H | Medical Therapeutic Machine ≥ 1 MeV [and above] | **$**343.00 |
| 30H | Radiation Therapy Simulator Machine | **$**208.00 |
| 38H | Biomedical ([non-human] **Non-Human**) Research Machine | **$**140.00 |
| 21H | Electron Microscope Machine | **$**140.00 |
| 22H | Cabinet X-ray Machine | **$**140.00 |
| 28H | Bone Densitometer **(Axial)** Machine | **$**118.00 |
| **65H** | **Bone Densitometer (Peripheral) Machine** | **$118.00** |
| **49H** | **Bone Densitometer (CT) Machine** | **$163.00** |
| **84H** | **Bone Densitometer (CT) Mobile Machine** | **$163.00** |
| **29H** | **Bone Densitometer Research Machine** | **$118.00** |
| **81H** | **Motor Vehicle Mounted CBCT Machine** | **$140.00** |
| **78H** | **Mobile CT Unit** | **$163.00** |
| **63H** | **Motor Vehicle Mounted CT** | **$163.00** |
| **72H** | **SPECT (Single Photon Emission CT)** | **$208.00** |
| **48H** | **CT PET Scanner** | **$208.00** |
| **20H** | **Analytical X-Ray Machine >16 kVp** | **$118.00** |
| **24H** | **Particle Accelerator MAC (Non-Medical Use) ≤ 30 kVp** | **$185.00** |
| **25H** | **Particle Accelerator MAC (Non-Medical Use) > 30 kVp** | **$196.00** |
| **74H** | **RT Simulator 4 Modalities** | **$208.00** |
| **75H** | **Electronic Brachytherapy** | **$253.00** |
| **47H** | **CT Simulator (Radiation Therapy)** | **$208.00** |

| | | |
|---|---|---|
| **66H** | **Therapy Auxiliary Imaging Machine** | **$208.00** |

(d) Each registrant of an ionizing-radiation-producing machine used in a non-hospital facility (including, but not limited to, doctors' offices, medical facilities, industrial facilities, schools, and government facilities) shall pay:

1. The initial application and registration fees for each [X-ray] **x-ray** tube pursuant to (a) above; and

2. In each year after the expiration of the first year of registration established pursuant to (f) below, the annual registration renewal fee per [X-ray] **x-ray** tube as follows:

NON-HOSPITAL FACILITIES

| | Machine Category and Description | Annual Registration Renewal Fee Per X-Ray Tube |
|---|---|---|
| 01N | Dental [Machine] **Unit In Non-Hospital** | $106.00 |
| **60N** | **Dental Panoramic Machine** | **$106.00** |
| **61N** | **Dental Cephalometric Machine** | **$106.00** |
| **62N** | **Dental Pan-Ceph Combination Machine** | **$106.00** |
| **67N** | **Cone Beam Computed Tomographic (CBCT) Machine** | **$92.00** |
| **68N** | **Dental Unit - Van Mounted** | **$106.00** |
| **71N** | **Mobile Dental Unit** | **$106.00** |
| **76N** | **Mobile Medical Fluoroscopic/O-Arm Machine** | **$118.00** |
| **73N** | **Handheld Dental Unit** | **$106.00** |
| 02N | Fixed Medical Radiographic Machine | **$**140.00 |

| | | |
|---|---|---|
| 03N | Mobile Medical Radiographic Machine | **$**140.00 |
| 31N | Portable Medical Radiographic Machine ([hand carried] **Hand-Carried**) | **$**140.00 |
| 06N | Motor Vehicle Mounted Medical Radiographic Machine | **$**140.00 |
| 04N | Fixed Medical Fluoroscopic Machine | **$**118.00 |
| 05N | Mobile Medical Fluoroscopic Machine | **$**118.00 |
| 32N | Portable Medical Fluoroscopic Machine ([hand carried] **Hand-Carried**) | **$**118.00 |
| 33N | Motor Vehicle Mounted Medical Fluoroscopic Machine | **$**118.00 |
| 07N | Fixed Medical Radiographic Fluoroscopic Machine | **$**163.00 |
| 08N | Mobile Medical Radiographic Fluoroscopic Machine | **$**163.00 |
| 34N | Portable Medical Radiographic Fluoroscopic Machine ([hand carried] **Hand-Carried**) | **$**163.00 |
| 35N | Motor Vehicle Mounted Medical Radiographic Fluoroscopic Machine | **$**163.00 |
| **48N** | **CT PET Scanner** | **$118.00** |
| 09N | CT Scan Machine | **$**118.00 |
| **63N** | **Motor Vehicle Mounted CT** | **$118.00** |
| 10N | Mammography Machine **(Stereotactic and Non-MQSA Only)** | **$**298.00 |
| 36N | Motor Vehicle Mounted Mammography Machine **(Non-MQSA Only)** | **$**298.00 |
| 37N | Mobile Mammography Machine **(Non-MQSA Only)** | **$**298.00 |
| 44N | [MQSA] Mammography Machine **(Federal MQSA Units Only)** | **$**73.00 |
| 45N | [MQSA] Motor Vehicle Mounted Mammography Machine **(Federal MQSA Units Only)** | **$**73.00 |
| 46N | [MQSA] Mobile Mammography Machine **(MQSA Units Only)** | **$**73.00 |
| 11N | Medical Therapeutic Machine ≤ 60 [kVp] **kV** | **$**118.00 |
| 12N | Medical Therapeutic Machine > 61 [kVp] **kV** to 999 [kVp] **kV** | **$**253.00 |
| 14N | Medical Therapeutic Machine ≥ 1 MeV [and above] | **$**343.00 |
| 30N | Radiation Therapy Simulator Machine | **$**208.00 |
| **66N** | **Therapy Auxiliary Imaging Machine** | **$208.00** |
| **75N** | **Electronic Brachytherapy** | **$253.00** |

| | | |
|---|---|---|
| **74N** | **RT Simulator 4 Modalities** | **$208.00** |
| **47N** | **CT Simulator (Radiation Therapy)** | **$208.00** |
| 38N | Biomedical ([non-Human] **Non-Human**) Research Machine | $140.00 |
| 17N | Industrial/Research Radiography Machine | $151.00 |
| 39N | Portable [Industrial] **Industrial/Research** Radiography Machine | $151.00 |
| 40N | Shielded Room Radiography Machine | $151.00 |
| 18N | Electron Beam Welder/Furnace Machine | $129.00 |
| 19N | Analytical X-ray Machine ≤ 16 kVp | $118.00 |
| 20N | Analytical X-ray Machine > 16 kVp | $118.00 |
| **80N** | **Handheld Analytical X-Ray Machine > 16 kVp** | **$118.00** |
| **79N** | **Handheld Analytical X-Ray Machine ≤ 16 kVp** | **$118.00** |
| **83N** | **Body Scanner > 51 kVp To 999 kVp** | **$118.00** |
| **77N** | **Neutron Generator < 31 kVp** | **$253.00** |
| **70N** | **Product Inspection Machine** | **$151.00** |
| **69N** | **Cargo Security Machine (3.5 MeV Accelerator)** | **$196.00** |
| **64N** | **Bomb Detection Radiographic Machine** | **$151.00** |
| 21N | Electron Microscope Machine | $106.00 |
| 22N | Cabinet X-ray Machine | $106.00 |
| 23N | X-ray Baggage Machine | $106.00 |
| 24N | Particle Accelerator Machine ([non-medical] **Non-Medical** use) ≤ 30 kVp | $185.00 |
| 25N | Particle Accelerator Machine ([non-medical] **Non-Medical** use) > 30 kVp | $196.00 |
| [28N | Bone Densitometer Machine | 95.00] |
| **29N** | **Bone Densitometer Research Machine** | **$95.00** |
| **28N** | **Bone Densitometer (Axial) Machine** | **$95.00** |
| **65N** | **Bone Densitometer (Peripheral) Machine** | **$95.00** |
| **49N** | **Bone Densitometer (CT) Machine** | **$118.00** |
| **84N** | **Bone Densitometer (CT) Mobile Machine** | **$118.00** |
| **72N** | **SPECT (Single Photon Emission CT)** | **$118.00** |
| **78N** | **Mobile CT Unit** | **$118.00** |

| | | |
|---|---|---|
| **81N** | **Motor Vehicle Mounted CBCT Machine** | **$106.00** |
| 41N | Machine not specifically listed above, ≤ 50 kVp | **$**118.00 |
| 42N | Machine not specifically listed above, 51 [kVp] **kV** to 999 [kVp] **kV** | **$**118.00 |
| 43N | Machine not specifically listed above, ≥ 1 MeV [and above] | **$**140.00 |

(e) Each registrant of an ionizing-radiation-producing machine used in a veterinary facility shall pay:

1. The initial application and registration fees for each [X-ray] **x-ray** tube pursuant to (a) above[,]**;** and

2. In each year after the expiration of the first year of registration established pursuant to (f) below, the annual registration renewal fee per [X-ray] **x-ray** tube as follows:

VETERINARY FACILITIES

| | Machine Source Category and Description | Annual Registration Renewal Fee Per X-Ray Tube |
|---|---|---|
| 01V | Dental [Machine] **Unit In Veterinary Office** | [$ 86.00] **$86.00** |
| **71V** | **Mobile Dental Unit** | **$86.00** |
| **73V** | **Handheld Dental Unit** | **$86.00** |
| **68V** | **Veterinary - Van Mounted Dental** | **$86.00** |
| **60V** | **Dental Panoramic Machine** | **$86.00** |
| **67V** | **Cone Beam Computed Tomographic (CBCT) Machine** | **$86.00** |
| 02V | Fixed Medical Radiographic Machine | **$**100.00 |
| 03V | Mobile Medical Radiographic Machine | **$**100.00 |
| 31V | Portable Medical Radiographic Machine ([hand carried] **Hand-** | **$**100.00 |

| | | |
|---|---|---|
| | **Carried**) | |
| 04V | Fixed Medical Fluoroscopic Machine | **$**91.00 |
| 05V | Mobile Medical Fluoroscopic Machine | **$**91.00 |
| 32V | Portable Medical Fluoroscopic Machine ([hand carried] **Hand-Carried**) | **$**91.00 |
| 07V | Fixed [medical] **Medical** Radiographic Fluoroscopic Machine | **$**109.00 |
| 08V | Mobile Medical Radiographic Fluoroscopic Machine | **$**109.00 |
| **82V** | **Van Mounted Radiographic Unit (Veterinary)** | **$100.00** |
| **28V** | **Bone Densitometer (Axial) Machine** | **$95.00** |
| **09V** | **CT Scan Machine** | **$118.00** |
| **14V** | **Veterinary Therapeutic Machine ≥ 1 MeV** | **$196.00** |
| **66V** | **Therapy Auxiliary Imaging Machine** | **$208.00** |
| **23V** | **X-Ray Baggage Machine** | **$106.00** |
| **25V** | **Particle Accelerator Machine (Non-Medical Use) > 30 kVp** | **$196.00** |

(f) (No change.)

(g) Each registrant shall pay the initial registration application fee and annual registration renewal fee within 60 days of the date of the invoice billing issued by the Department. [Any fee payment postmarked or hand-carried to the Department after the invoice due date will be subject to a $25.00 per month late charge. If necessary, the Department will issue a second invoice. Late charges must be paid within 30 days of the second invoice.] If a registrant fails to pay a fee by the original invoice due date, the registration of the [ionizing-radiation-producing] **ionizing radiation-producing** machine shall be deemed expired.

(h) (No change.)

(i) Each registrant shall make payment [only] **either online at www.xray.nj.gov or** by check or money order made payable to "Treasurer, State of New Jersey." Each payment **made by check**

**or money order** shall be accompanied by the invoice issued by the Department and shall be submitted to the address specified on the invoice: Department of **the** Treasury, Division of Revenue, PO Box 417, Trenton, New Jersey 08646-0417.

[(j) An application fee will not be charged for any machine registered pursuant to the Radiation Protection Code prior to November 16, 1987. However, the registrant shall pay the applicable annual registration renewal fee for any such machine.]

[(k)] **(j)** (No change in text.)

## SUBCHAPTER 14. THERAPEUTIC INSTALLATIONS

### 7:28-14.1 Scope

(a) This subchapter covers therapeutic installations used in the healing arts. [These therapeutic] **Therapeutic** installations include x-ray, accelerator**,** and teletherapy installations.

**(b)** No registrant shall operate or permit the operation of therapeutic equipment used in the healing arts unless the equipment and installation meet the applicable requirements of this subchapter.

**(c) Only a licensed practitioner, as defined at N.J.A.C. 7:28-19.2, or a licensed radiation therapist shall operate radiation therapeutic equipment used in the healing arts.**

**(d) A registrant seeking to utilize a therapeutic technology not specified in this subchapter may apply for a special exemption pursuant to N.J.A.C. 7:28-2.8.**

### 7:28-14.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings

unless the context clearly indicates otherwise.

**"Absorbed dose" means the energy imparted by ionizing radiation to matter.**

**"Absorbed dose rate" means absorbed dose per unit time for machines with timers, or dose monitor unit per unit time for electronically generated radiation producing devices.**

**"Air kerma" means the kinetic energy released in the air by ionizing radiation.**

**"Air kerma rate" or "AKR" means the air kerma per unit time.**

**"Anti-collision device" means either an electronic position sensor combined with a microprocessor or a mechanical touch bar microswitch that will stop all equipment movement and radiation exposures to prevent collision of any part of the radiation therapy simulator system with the patient, or damage to other components of the simulator system.**

…

**"Barrier" see "protective barrier."**

…

["Beam scattering filter" means a filter used to scatter a beam of electrons.]

**"Beam scattering foil" means a thin piece of material placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.**

…

"Contact therapy system" means an x-ray system used for therapy not capable of operating above 60 [kVp] **kV** and with a source distance less than or equal to five centimeters.

…

**"Detector" see "radiation detector."**

**"Dosimetry system" means an ion chamber and electrometer used as a dosimeter for measurement of clinical photon and electron beams with calibration coefficients determined either in air or in water and are traceable to a national primary standards dosimetry laboratory. Specialized dosimetry systems are available for detecting different radiation types.**

**"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body, also known as teletherapy.**

…

**"Filter" means material placed in the useful beam to change beam quality.**

…

**"Gray" or "Gy" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to one joule per kilogram. The previous unit of absorbed dose (rad) is replaced by the gray (one Gy = 100 rad).**

"Interlock" means a device [arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur] **preventing the start or continued operation of equipment unless certain predetermined conditions prevail.**

…

**"Kerma" or "kinetic energy released per unit mass" means a measure of the energy released by ionizing radiation in a material per unit mass of that material. Kerma quantifies the energy transferred from photons and charged particles to the material through interactions, such as Compton scattering and photoelectric effect. When the**

**material is air, the quantity is referred to as "air kerma." The formula for kerma (K) is given by:**

$$\mathbf{K = \frac{dE_{tr}}{dm}}$$

**where:**

**K = kerma (expressed in Gray, Gy).**

**$dE_{tr}$ = the change in kinetic energy transferred to charged particles per unit mass of the material (expressed in joules per kilogram, J/kg).**

**dm = the change in mass of the material.**

**"Kilovolt" or "kV" and "kilo electron volt" or "keV" mean the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.**

**"Lead equivalent" means the thickness of the material in question, affording the same attenuation, under specified conditions, as lead.**

…

**"Light field" means the area illuminated by light, simulating the radiation field.**

**"Megavolt" or "MV" and "mega electron volt" or "MeV" mean the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. Note: the current convention is to use MV for**

**photons and MeV for electrons.**

**"Monitor unit" or "MU," see "Dose monitor unit."**

"Moving beam therapy" means radiation therapy with [relative movement of the useful beam and the patient during irradiation.] **any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes, but is not limited to, arc, skip, conformal, intensity modulation, and rotational therapy.**

…

**"Periodic quality assurance check" means a procedure that is performed to ensure that a previous parameter or condition continues to be valid.**

…

**"Primary protective barrier," see "protective barrier."**

**"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:**

1. **"Primary protective barrier" means the material, excluding filters, placed in the useful beam; and**
2. **"Secondary protective barrier" means the material that attenuates stray radiation.**

"Qualified [radiological] **medical** physicist" means a person who holds at least a bachelor's degree in one of the physical sciences and who is certified by the American Board of Radiology either in radiological physics, x- and gamma ray physics**,** or therapeutic radiological physics, is eligible for such certification, or has equivalent training and experience.

1. "Equivalent training and experience" means a person has:

i. A bachelor's degree in physical sciences and three years [full time] **full-time** experience working under the direction of a physicist certified by the American Board of Radiology;

ii.-iii. (No change.)

**"Qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems" means an individual who meets at least one of the following criteria:**

**1. Certification by one of the following agencies in the specialty listed:**

**i. The American Board of Radiology in Therapeutic Radiological Physics or by the American Board of Medical Physics with special competency in radiation oncology physics;**

**ii. The American Board of Radiology in Radiological Physics in all three subspecialties of diagnostic radiological physics, therapeutic radiological physics, and medical nuclear physics;**

**iii. The American Board of Radiology or the American Board of Medical Physics in a specialty other than therapeutic radiological physics or radiation oncology physics, with at least three years of professional, clinical, and technical experience obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems;**

**iv. The Fellowship in the Canadian College of Physicists in Medicine, which certification is equivalent to i, ii, or iii above; or**

**v. Any other national certifying boards that may be recognized by the Commission where the person seeking recognition as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems has petitioned the Commission, in writing, and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems pursuant to this definition;**

**2. Possesses a master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering, or a related field and has at least three years of professional, clinical, and technical experience in the field of radiological physics under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems; or**

**3. Does not meet at least one of the foregoing criteria, but has successfully petitioned the Commission to be recognized as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems. To qualify through this criterion, the individual shall submit a written petition to the Commission that contains sufficient information on his or her educational, professional, clinical, technical, employment, and/or any other relevant experience. The Commission may approve a petition if it determines that the individual demonstrates competence to act as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems.**

**"Radiation detector" means a device that, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.**

**"Radiation head" means the structure from which the useful beam emerges.**

**"Redundant beam monitoring system" means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.**

…

**"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.**

…

["Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.]

**"Shutter" means a device attached to the tube housing assembly that can totally intercept the useful beam and that has a lead equivalency not less than that of the tube housing assembly.**

**"Simulator" or "radiation therapy simulation system" means any x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field.**

…

**"Stray radiation" means the sum of leakage and scattered radiation.**

**"Survey instruments" mean detectors used for measuring radiation exposure levels. Specialized survey instruments are available for detecting different radiation types.**

…

**"Target-to-skin distance" or "TSD" means the distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.**

…

**"Tube" means an x-ray tube, unless otherwise specified.**

**"Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such elements are contained within the tube housing.**

**"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.**

…

**"X-ray tube" means any electron tube that is designed to be used primarily for the production of x-rays.**

**7**:28-14.3 Therapeutic x-ray systems with energies less than [one MeV] **500 kV**

(a) Equipment requirements for therapeutic x-ray systems with energies less than [one MeV] **500**

**kV** are as follows:

1. Leakage radiation shall be measured under conditions [which] **that** provide maximum leakage radiation. The leakage [radiation] **air kerma rate** shall not exceed the value specified at the distance specified for the classification of that x-ray system. Compliance shall be determined by measurements averaged over an area of 100 square centimeters. Measurement shall be performed at installation and whenever the tube is changed. [Measurement shall be performed at least once every five years; ]

i. For Contact Therapy Systems, **the** leakage [radiation] **air kerma rate** shall not exceed 100 milliroentgens in one hour at five centimeters from the surface of the tube housing assembly;

[ii. For 0-150 kVp Systems which are installed prior to October 1, 1987, leakage radiation shall not exceed one roentgen in one hour at one meter from the target;

iii. For 0-150 kVp Systems which are installed on or after October 1, 1987, leakage radiation shall not exceed 100 milliroentgens in one hour at one meter from the target;

iv. For 151 to 500 kVp Systems**,** the leakage radiation shall not exceed one roentgen in one hour at one meter from the target;

v. For 501 to 999 kVp Systems the leakage radiation shall not exceed 0.1 percent of the useful beam exposure rate at one meter from the target; and]

**ii. For 0 to 50 kV systems, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one mGy (0.1 rad) in any one hour;**

**iii. For 51 to 500 kV systems, the leakage air kerma rate measured at one meter from the target in any direction shall not exceed 10 mGy (one rad) in any one hour. In addition, the leakage air kerma rate at a distance of five centimeters from the tube housing assembly shall not exceed 300 mGy (30 rad) per hour; and**

[vi.] **iv.** Records of leakage [radiation] **air kerma** shall be maintained at the facility [for at least five years] and shall be made available for inspection by the Department[.]**;**

[2. Beam limiting devices for equipment installed on or after October 1, 1987 shall transmit no more than one percent of the useful beam, for the portion of the beam which is to be attenuated by the beam limiting device, when the equipment is operating at maximum kVp and with maximum filtration. Measurements shall be made at a distance of one meter from the beam limiting device and in a plane perpendicular to the central axis of the beam. For equipment installed before October 1, 1987, transmissions shall not exceed five percent of the useful beam;]

**2. Beam limiting devices shall be designed so that:**

**i. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly;**

**ii. All adjustable or removable beam limiting devices, diaphragms, cones, or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used; and**

**iii. When adjustable beam limiting devices are used, a means shall be provided to visually indicate the position and shape of the radiation field;**

3. The filter system shall be [so] designed **so** that:

[i. It will minimize the possibility of error in filter selection; ]

**i. An interlock system prevents irradiation if the proper filter is not in place;**

ii.- iii. (No change.)

iv. It shall be possible for the operator to determine the presence or absence of any filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation; **and**

[v. For equipment installed prior to October 1, 1987, the radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under any operating conditions; and

vi. For equipment listed on or after October 1, 1987, the radiation from the filter slot shall not exceed the leakage radiation specified in (a)1 above.]

**v. The leakage air kerma rate from the filter slot shall not exceed one cGy (one rad) per hour at one meter under any operating conditions;**

4. [A] **The x-ray tube shall be mounted so that it cannot accidentally turn or slide with respect to the housing aperture and a** means shall be provided to immobilize the tube housing assembly during stationary treatments;

5. (No change.)

6. [Equipment employing Beryllium or other low-filtration windows] **Contact therapy tube housing assemblies** shall have a removable shield of **material, equivalent in attenuation to** at least 0.5 millimeter lead equivalency at 100 kV[p] that can be positioned over the entire useful beam exit port during periods when the beam is not in use;

7. Radiotherapy systems of greater than 150 [kVp installed on or after October 1, 1987] **kV** shall be provided with a beam monitor system [which] **that** shall:

i.- vii. (No change.)

8. The following are the equipment requirements for timer systems:

i. A timer system shall be provided [which] **that** has a display at the treatment control panel. It shall be graduated in minutes and seconds and/or fractions of minutes. It shall have a pre-set time selector[. For equipment installed on or after October 1, 1987, it shall also have] **and** an elapsed time indicator;

ii. [The] **If a dose monitoring system has not previously terminated irradiation, the** timer shall terminate irradiation when a pre-selected time has elapsed;

[iii. The timer shall permit pre-setting and determination of exposure times to an accuracy of one second or less;]

[iv.] **iii.** (No change in text.)

**iv. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for a mechanical lag;**

[v. When patient irradiation is controlled by a shutter mechanism the timer shall not begin to run until the shutter is opened;

vi. Equipment installed on or after October 1, 1987 shall have an elapsed-time indicator which is activated when radiation is emitted and retains its reading after irradiation is interrupted or terminated; and

vii. After irradiation is terminated and before irradiation can be reinitiated, it shall

be necessary to cycle the pre-set time selector through zero time.]

**v. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated;**

**vi. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator; and**

**vii. The timer shall be accurate to within one percent of the selected value or one second, whichever is greater;**

9. In addition to the control panel displays required in other provisions of this subsection, the control panel shall have:

i. - ii. (No change.)

iii. Means for indicating [kVp] **kV** and x-ray tube current; [and]

iv. The means for terminating an exposure at any time[.]**;**

**v. A control device that will prevent the unauthorized use of the therapeutic radiation machine; and**

**vi. A positive display of specific filter(s) in the beam;**

[10. There shall be a means of determining the source-to-patient distance to within 10 percent or one centimeter, whichever is smaller; and]

**10. When a control panel may energize more than one x-ray tube:**

**i. The control panel shall be capable of activating only one x-ray tube at any time;**

**ii. The control panel shall have an indication identifying which x-ray tube is activated; and**

**iii. The tube housing assembly shall have an indication when that tube is energized;**

**11. There shall be a means of determining the central axis target-to-skin distance (TSD) to within one centimeter and of reproducing this measurement to within two millimeters thereafter;**

[11.] **12.** Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds **after the x-ray "ON" switch is energized**, the entire useful beam shall be attenuated automatically by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition:

i. (No change.)

ii. An indication of shutter position shall appear at the control panel[.]**; and**

**13. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.**

(b) In addition to shielding adequate to meet the requirements [of] **at** N.J.A.C. 7:28-5 and 6, the treatment room design and shielding requirements for systems capable of operating [above 50 kVp] **in the range of 50 to 500 kV**, shall be the following:

1. – 3. (No change.)

4. Treatment rooms [which] **that** contain an x-ray system capable of operating above 150 [kVp] **kV** shall meet the following additional requirements:

[i. All required shielding, except for any beam interceptor, shall be provided by fixed barriers; ]

**i. All protective barriers shall be fixed, except for entrance doors or beam interceptors;**

ii. (No change.)

[iii. All entrance doors of the treatment room shall be electrically connected to the control panel in such a way that x-ray production cannot occur unless all doors are closed;]

**iii. Interlocks shall be provided, such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued;**

iv. When any [entrance] door [of] **to** the treatment room is opened while the x-ray tube is activated, x-ray production shall terminate within one second **and the leakage air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mrad) per hour**; and

v. (No change.)

(c) The following are the calibration requirements for therapeutic x-ray systems with energies less than [one MeV] **500 kV**:

**1. Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed. Acceptance testing and**

**commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;**

**2. Full calibration shall be performed in accordance with current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed. Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall meet the following requirements:**

[1.] **i.** System calibrations shall be performed before the system is first used for irradiation of a patient and thereafter at time intervals [which] **that** do not exceed [12] **14** months and after any change [which] **that** might significantly alter the calibration or other characteristic of the therapy beam;

[2.] **ii.** The calibration of the radiation output of the x-ray system shall be performed by a qualified [radiological] **medical** physicist;

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

[4.] **iv.** The calibration shall be such that the dose at a reference point in soft tissue can be calculated to within +/- [5] **five** percent;

**v. The calibration shall be performed before medical use under the following situations:**

**(1) Whenever quality assurance check measurements indicate that the**

**radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled.**

**(A) Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and**

**(2) Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.**

**(A) If the repair, replacement, or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures;**

[5.] **vi.** The calibration of the x-ray system shall include, but not be limited to, the following determinations[;]**:**

Recodify existing i.-iii. as **(1)-(3)** (No change in text.)

[iv.] **(4)** The uniformity of the radiation field symmetry for representative field sizes used[.]**; and**

[6. Records of calibration performed pursuant to 1 above shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the calibration.]

**3. The records of each calibration shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the**

**calibration. The records shall include:**

**i. The date of the calibration;**

**ii. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;**

**iii. Calibration reports of the instruments used to calibrate the therapeutic radiation machine; and**

**iv. The signature of the qualified medical physicist responsible for performing the calibration.**

(d) [Spot] **Periodic quality assurance** checks shall be performed on therapeutic x-ray systems with energies greater than [0.018 MeV and less than one MeV] **50 kV and less than 500 kV** and shall meet the following requirements:

1. The qualified [radiological] **medical** physicist will determine those parameters to be [spot-checked] **checked** and the procedure to be used when performing those [spot] **quality assurance** checks. The [spot] **quality assurance** check procedure shall be in writing and specify the frequency at which tests or measurements are to be performed, not to exceed [one month] **36 days**, and the acceptable tolerance for each parameter measured in the [spot-check] **check**. [A qualified radiological physicist need not actually perform the spot-check measurement. If a qualified radiological physicist does not perform the spot-check measurement, the results of the spot-check measurement shall be reviewed by a qualified radiological physicist within 15 days;] **The procedures shall be performed in accordance with current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of**

**therapeutic radiation techniques. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols shall be followed;**

**2. A qualified medical physicist need not actually perform the quality assurance check measurement. If a qualified medical physicist does not perform the quality assurance check measurement, the results of the measurement shall be reviewed and signed by a qualified medical physicist within 30 days of the date that the check was performed;**

[2.] **3.** The measurements taken during [spot] **quality assurance** checks shall demonstrate the degree of consistency of the operating characteristics [which] **that** can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure;

**4. The registrant shall ensure that monthly safety quality assurance checks of therapeutic radiation machines are performed at intervals not to exceed 36 days. The monthly safety quality assurance check shall ensure proper operation of:**

**i. Electrical interlocks at each external beam radiation therapy room entrance;**

**ii. The "BEAM-ON" and termination switches;**

**iii. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;**

**iv. Viewing and aural systems; and**

**v. If applicable, electrically operated treatment room doors from inside and outside the treatment room;**

[3.] **5.** Whenever a [spot] **quality assurance** check indicates a significant change in the

operating characteristics of a system, as specified in the [spot] **periodic quality assurance** check procedures, the system shall be recalibrated;

[4.] **6.** The cause for a parameter exceeding tolerances set by the qualified [radiological] **medical** physicist shall be promptly investigated and corrected before the system is used for patient irradiation; and

[5.] **7.** Records of [spot-check] **the monthly quality assurance check** measurements shall be maintained by the registrant and made available for inspection by the Department for a period of five years following such measurement. **The record shall include:**

**i. The date of the quality assurance check;**

**ii. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;**

**iii. Calibration reports of the instruments used to measure the radiation output of the therapeutic radiation machine; and**

**iv. The signature of the individual who performed the quality assurance check.**

(e) The following procedures shall be followed when operating therapeutic x-ray systems with energies less than [one MeV] **500 kV**:

1. (No change.)

2. No individual other than the patient shall be in the treatment room [unless such individual is protected by a barrier meeting the requirements of N.J.A.C. 7:28-6. No individual other than the patient shall be in the treatment room during exposure when the kVp exceeds 50;] **during exposures from therapeutic radiation machines operating above 150 kV. At**

**energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements at N.J.A.C. 7:28-6.**

3. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used; [and]

[4. Except for contact therapy devices, the tube housing assembly shall not be held by an individual during exposure.]

**4. The tube housing or any other part of the imaging assembly shall not be held by an individual or patient during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and an apron of not less than 0.5 millimeters lead equivalency at 100 kV; and**

**5. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.**

(f) (No change.)

7:28-14.4 Therapeutic x-ray and therapeutic accelerator installations with energies of [one MeV] **500 kV** and above

(a) The following are the equipment requirements for **therapeutic x-ray and accelerator installations with energies of 500 kV and above** related to leakage radiation [to the patient area]**: in the useful beam**:

[1. Leakage radiation shall be measured under conditions producing maximum leakage

radiation and shall be reported as absorbed dose in rads or grays in water. For equipment installed on or after October 1, 1987, measurements shall include x-rays, electrons and neutrons. For equipment incapable of operating at energies greater than 10 MeV, measurements shall exclude neutrons. For equipment installed before October 1, 1987, measurements shall exclude neutrons. The leakage radiation shall be measured in a plane perpendicular to the central axis of the beam located at the normal treatment distance or passing through the isocenter. The leakage radiation at any point on this plane outside the useful beam but within two meters of the central axis of the beam shall not exceed 0.1 percent of the maximum radiation of the useful beam, measured at the point of intersection of the central axis and the plane;

2. Measurements for leakage radiation shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. For equipment installed on or after October 1, 1987, measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 400 square centimeters. For equipment incapable of operating at energies greater than 10 MeV, measurements shall exclude neutrons. For equipment installed before October 1, 1987, measurements shall exclude neutrons;

3. For each system the registrant shall determine, or obtain from the manufacturer, the amount of leakage radiation at the positions specified in 1 above. Records of leakage radiation shall be maintained at the facility for inspection by the Department.]

**1. The registrant shall obtain from the manufacturer, data sufficient to ensure that stray x-ray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation, and stray neutron radiation in the useful x-ray beam are in compliance with the appropriate manufacturer specifications and perform as intended. Records of leakage radiation shall be maintained at the facility for**

**inspection by the Department.**

(b) The following are the equipment requirements for **therapeutic x-ray and accelerator installations with energies of 500 kV and above for** leakage radiation outside [the patient area] **the maximum useful beam in photon and electron modes**:

[1. Except in the area specified in (a) above as the patient area, the x-ray leakage measured as absorbed dose in rads or grays in water, at any location averaged over 100 square centimeters one meter from the path of the charged particles before they strike the target or the window, shall not exceed 0.1 percent of the maximum absorbed dose in the circular plane specified in (a) above;

2. Except in the area specified in (a) above as the patient area, neutron leakage measured as absorbed dose in rads or grays in water, at any point one meter from the path of the charged particles before they strike the target or the window, shall not exceed 0.05 percent of the maximum absorbed dose in the circular plane specified in (a) above;

3. The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 1 and 2 above for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. For equipment installed on or after October 1, 1987, neutron measurement shall be averaged over an area up to, but not exceeding, 400 square centimeters. For equipment incapable of operating at energies greater than 10 MeV, measurements shall include neutrons. For equipment installed prior to October 1, 1987, measurement of neutrons shall be excluded.]

**1. The absorbed dose due to leakage radiation (excluding neutrons) at any point**

**outside the maximum-sized useful beam, but within a circular plane of radius two meters that is perpendicular to and centered on the central axis of the useful beam at the normal treatment distance (that is, patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the normal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters ($cm^2$) at a minimum of 16 points uniformly distributed in the plane;**

**2. Except for the area defined at (a) above, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters ($cm^2$);**

**3. The neutron absorbed dose outside the useful beam shall be in compliance with the appropriate manufacturer specifications; and**

**4. For each system the registrant shall determine, or obtain from the manufacturer, the amount of leakage radiation at the positions specified at (b)1 above. Records of leakage radiation shall be maintained at the facility for inspection by the Department.**

(c) The following are the equipment **leakage** requirements for beam limiting devices;

[1. For equipment installed on or after October 1, 1987, adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than one percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful

beam shall not be included in this requirement; and

2. For equipment installed prior to October 1, 1987, the beam limiting device shall meet the requirements of (a)1 above except that such device shall transmit no more than two percent of the useful beam.]

**1. For photon radiation, all adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the normal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a 100 $cm^2$ radiation field, or maximum available field size if less than 100 $cm^2$;**

**2. For electron radiation, all adjustable or interchangeable electron applicators shall attenuate the radiation, including, but not limited to, photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the normal treatment distance shall not exceed:**

**i. A maximum of two percent, and an average of 0.5 percent, of the absorbed dose on the central axis of the useful beam at the normal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and**

**ii. A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the normal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.**

(d) The following are the equipment requirements for [filters] **filters/wedges**:

1. If the absorbed dose rate information required [by (p)] **pursuant to (o)** below relates exclusively to operation with a field flattening or beam scattering [filter] **foil** in place, such filter shall be removable only by the use of tools;

2. In systems [installed on or after October 1, 1987, which] **that** utilize a system of wedge filters, interchangeable field flattening filters**,** or interchangeable beam scattering [filters] **foils**:

i. Irradiation shall not be possible until a selection of a filter **or a positive selection to use "no filter"** has been made at the treatment control panel**, either manually or automatically**;

ii. (No change.)

iii. A display shall be provided at the treatment control panel showing the [filter] **wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s)** in use;

iv. Each filter [which] **that** is removable from the system without the use of tools shall be clearly marked with an identification number and accompanying documents **that** shall contain a corresponding drawing or other description of the filter, showing dimensions and materials. The identification number shall appear on the wedge filter**,** as well as on its tray[. The identification number] **and** shall be referable to wedge angle and wedge factor[; and]**. If the wedge or wedge tray is significantly damaged, the wedge shall be removed from clinical service; and**

v. An interlock shall be provided to prevent irradiation if any filter **and/or beam scattering foil** selection operation carried out in the treatment room does not agree with

the filter **and/or beam scattering foil** selection operation carried out at the treatment control panel.

[3. The only filter requirement for equipment installed prior to October 1, 1987 shall be that required by (d)2iv above.

(e) Beam quality data sufficient to assure that the following beam quality requirements are met shall be determined or obtained from the manufacturer by the registrant:

1. For radiotherapy systems capable of electron beam therapy the absorbed dose in water resulting from x-rays in a useful electron beam shall be determined at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons. This shall not exceed the values stated in the following table. Linear interpolation shall be used for values not stated;

TABLE

| Maximum Energy of Electron Beam in MeV | X-Ray absorbed Dose as a Fraction of Maximum Absorbed dose |
|---|---|
| 1 | 0.03 |
| 15 | 0.05 |
| 35 | 0.10 |
| 50 | 0.20 |

2. Compliance with 1 above shall be determined using:

i. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

ii. The largest field size available which does not exceed 15 centimeters by 15 centimeters; and

iii. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters and whose depth is sufficient to perform the required measurement.

3. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall be measured at intervals not to exceed 12 months and the results of such measurements shall be maintained with the records of calibration;

4. The measurements required by (e)3 above shall conform to the following requirements:

i. Measurements shall be made within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

ii. Measurements shall be made using a phantom whose size and placement meet the requirements of 2iii above;

iii. Measurements shall be made after removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

iv. Measurements shall be made over the range of field sizes clinically used.

5. The registrant shall determine, or obtain from the manufacturer, the maximum

percentage absorbed dose due to stray neutrons in the useful beam for specified operating conditions.]

[(f)] **(e)** All [therapy systems] **therapeutic x-ray and accelerator installations with energies of 500 kV and above** shall be provided with [radiation detectors in the radiation head.] **redundant beam monitoring systems. The sensors for such systems shall be fixed and functional in the useful beam during treatment to indicate the dose monitor unit rate.**

1. Equipment [installed on or after October 1, 1987] shall be provided with at least two [radiation detectors. The detectors shall be incorporated into two monitoring systems arranged either as a primary/primary combination or as a primary/secondary combination;] **independently powered integrating dose meters;**

2. Equipment [installed prior to October 1, 1987] shall be provided with at least one radiation detector. This detector shall be incorporated into a [primary] **useful beam monitoring** system. Failure of this detector shall automatically cause the beam to be terminated; and

3. Each detector and system into which the detector is incorporated shall meet the following requirements:

i. Each detector shall be removable only with tools and**, if removable,** shall be interlocked to prevent incorrect positioning;

ii. (No change.)

iii. Each detector shall form part of a [dose] **beam** monitoring system from whose readings in dose monitor units the absorbed dose at a reference point [in the treatment volume] can be calculated;

iv. [For equipment installed on or after October 1, 1987, the] **The** primary dose

monitoring system shall have a full beam transmission detector [which] **that** is placed on the patient side of any fixed added filters other than a wedge filter;

v. [For equipment installed on or after October 1, 1987, the] **The** design of the [dose] **beam** monitoring system [of (f)3iii] **at (e)3iii** above shall [assure] **ensure** that:

(1) The malfunctioning of one system shall not affect the correct functioning of the [second] **other** system**(s)**; and

(2) The failure of [any element which may be common to both systems shall terminate the useful beam.] **either system shall terminate irradiation or prevent the initiation of radiation.**

vi. Each [dose] **beam** monitoring system shall have a legible display at the treatment control panel. Each display shall:

(1) Maintain a reading until intentionally reset [to zero];

(2) (No change.)

(3) [In equipment installed on or after October 1, 1987 have] **Have** only one scale and no scale multiplying factors when employed for routine therapy. A scale multiplying factor may be applied to the regularly used accumulated dose indicator when used in conjunction with special treatment modes [which] **that** use higher than normal dose rates and require specially safeguarded operating procedures to initiate.

vii. In the event of power failure, the [dose] **beam** monitoring information required [in 3vi] **at (e)3vi** above displayed at the control panel at the time of failure shall be retrievable in at least one system.

**(f) Beam flatness and symmetry shall be in accordance with current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of protocol established by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.**

[(g) Beam symmetry requirements are the following:

1. For equipment installed on or after October 1, 1987 and which is inherently capable of producing useful beams with asymmetry exceeding five percent, at least four different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device. If the difference in dose rates between any two of these different parts exceeds five percent an indication of this condition is to be made at the control panel and the irradiation shall automatically terminate; and

2. The beam symmetry requirements of 1 above shall be met if the user can demonstrate to the satisfaction of the Department that adequate fail-safe protection against the beam asymmetry is incorporated into the inherent design of the accelerator.]

[(h)] **(g)** Equipment requirements for the selection and display of dose monitor units are the following:

1. (No change.)

2. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset [manually] for the next irradiation; and

3. After termination of irradiation, it shall be necessary to [manually cycle the pre-

selected dose monitor units through zero or manually change at least one digit on the dose monitor units selector before treatment can be initiated.] **reset the treatment delivery parameters before subsequent treatment can be initiated; and**

**4. After interruption of irradiation, it shall be necessary for the operator to follow the manufacturer and facility procedures before irradiation can be reinitiated.**

[(i)] **(h)** Equipment requirements for termination of irradiation by the [dose] **beam** monitoring system **or systems during stationary beam radiation therapy** are the following:

1. – 2. (No change.)

3. [Each] **The** secondary dose monitoring system shall [terminate] **be capable of terminating** irradiation when [10 percent or 30] **not more than 15 percent or 40 dose** monitor units above the pre-selected number of dose monitor units **set at the control panel** has been detected by the **secondary dose monitoring** system; **and**

4. [For equipment installed on or after October 1, 1987, the] **An** indicator on the control panel shall show which monitoring system has terminated [the beam] **irradiation**.

[(j)] **(i)** Interruption switches shall be provided [which] **that** make it possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption [the]**, irradiation and** equipment **movements** shall [go to termination condition] **be automatically terminated**.

[(k)] **(j)** Termination switches shall be provided at the operator's position at the treatment control panel[, which] **and in the treatment room to** make it possible to terminate irradiation and

equipment movements, or to go from an interruption condition to termination condition.

[(l)] **(k)** [The following are the equipment requirements for] **A suitable** timer [systems] **system or irradiation control device shall be provided to terminate the irradiation after a pre-set time interval or pre-set number of monitor units. The timer system or irradiation control device shall have the following equipment requirements**:

1. [A] **If applicable, a** timer system shall be provided which has a display at the treatment control panel. [It shall be graduated in minutes and seconds and/or fractions of minutes.] It shall have a pre-set time selector and an elapsed time indicator;

2. The timer **system or irradiation control device** shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems [fail to do so] **have not previously terminated irradiation**;

3. The timer **system or irradiation control device** shall not permit an exposure if set at zero;

4. [There shall be an elapsed-time indicator which is activated when radiation is emitted and which] **The timer system or monitor unit indicator shall be a cumulative device that activates with an indication of "BEAM-ON" and** retains its reading after irradiation is interrupted or terminated; and

[5. After termination of irradiation on delivery of the present dose, it shall be necessary to manually change at least one digit on the pre-set time control before treatment can be re-initiated.]

**5. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator.**

[(m)] **(l)** Equipment capable of both x-ray therapy and electron therapy shall have the following equipment requirements for selection of radiation type:

1. Irradiation shall not be possible until a selection of radiation type **(x-rays or electrons)** has been made at the treatment control panel;

2. An interlock system shall be provided to [insure] **ensure** that the equipment can emit only the radiation type which has been selected, except as noted [in 4] **at (l)4** below;

3. (No change.)

4. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted except to obtain [a port film] **an image** and to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

5. (No change.)

[(n)] **(m)** [The following are the equipment requirements for the selection of energy for equipment] **Equipment** capable of generating radiation beams of different energies **shall meet the following requirements**:

1. – 2. (No change.)

3. The nominal energy **value** selected shall be displayed at the treatment control panel [before and during irradiation] **until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated**; [and]

[4. For equipment installed on or after October 1, 1987, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than plus or minus five percent or plus or minus 2 MeV, whichever is

smaller, from the selected nominal energy.]

**4. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and**

**5. The selection of energy shall be in compliance with the appropriate manufacturer specifications and perform as intended.**

[(o)] **(n)** The following are the equipment requirements for selection of mode of therapy for equipment capable of both stationary beam therapy and moving beam therapy:

1. (No change.)

2. An interlock system shall be provided to [insure] **ensure** that the equipment can operate only in the mode [which] **that** has been selected;

3. An interlock system shall be provided to prevent irradiation if any selected [operations] **parameters** carried out in the treatment room do not agree with the selected [operations] **parameters** carried out at the treatment control panel;

[4. An interlock system shall be provided to interrupt irradiation if the movement stops during moving beam therapy;]

**4. An interlock system shall be provided to terminate irradiation if movement:**

**i. Occurs during stationary beam radiation therapy; or**

**ii. Does not start or stop during moving beam radiation therapy; unless such stoppage is a pre-planned function;**

5. Moving beam **radiation** therapy shall be [so] controlled [that the required] **to obtain the selected** relationship**s** between [the number of] **incremental** dose monitor units and **incremental** movement [is obtained;] and **shall meet the following requirements:**

**i. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or one cm of linear motion differs by more than 20 percent from the selected value;**

**ii. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent from the dose monitor unit value selected;**

**iii. An interlock shall be provided to prevent motion of more than five degrees or one cm beyond the selected limits during moving beam radiation therapy;**

**iv. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counter-clockwise moving beam radiation therapy; and**

**v. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;**

6. The mode of operation shall be displayed at the treatment control panel[.]**;**

**7. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required at (i) above; and**

**8. In addition to the requirements at (n)1 through 7 above, a facility using equipment where the radiation therapy source is mounted on a ring gantry shall develop a quality assurance program in accordance with the current published recommendations from a recognized national professional association, such as the American Association of**

**Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.**

[(p)] **(o)** [Equipment installed on or after October 1, 1987,] **The equipment** shall be provided with a system from whose readings the **air kerma rate or** absorbed dose rate at a reference point [in the treatment volume] can be calculated. The radiation detectors specified [in (f)] **at (e)** above may form part of this system. In addition[, the quotient of the number of dose monitor units by time shall be displayed at the treatment control panel.]**:**

**1. The dose monitor unit rate shall be displayed at the treatment control panel;**

**2. If the equipment can deliver through any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained in an auditable form by the registrant;**

**3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four Gy (400 rad); and**

**4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified at (p)2 and 3 below for the specified operating conditions. Records of these maximum value(s) shall be maintained in an auditable form at the installation for inspection by the Department.**

Recodify existing (q)-(r) as **(p)-(q)** (No change in text.)

[(s) Shadow trays shall be designed to minimize patient entrance skin dose consistent with achieving their primary purpose of safely supporting beam-modifying accessories while transmitting the light field.]

[(t)] **(r)** The following are the facility **design** and shielding requirements for therapeutic x-ray and therapeutic accelerator installations with energies of [one MeV] **500 kV** and above:

1. (No change.)

2. Except for [entrance] **access** doors or beam interceptors, all [the required] **protective** barriers shall be fixed barriers;

[3. The treatment control panel shall be located outside the treatment room;]

**3. The control panel shall also:**

**i. Be located outside the treatment room;**

**ii. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;**

**iii. Provide an indication of whether radiation is being produced; and**

**iv. Include an access control system that will prevent unauthorized use of the therapeutic radiation machine;**

4.-5. (No change.)

6. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all access doors [which] **that** will indicate when the useful beam is "on" **and when it is "off"**;

7. Interlocks shall be provided such that all [entrance] **access** doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall only be possible to restore the machine to operation by closing the door and reinitiating exposure by manual action at the control panel; [and]

8. At least one "Panic" emergency shut-off button shall be located in the treatment room and one by the control panel. The "Panic" button shall be clearly visible, easily accessible**,** and be capable of immediately terminating machine operation[.]**;**

**9. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with N.J.A.C. 7:28-6, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s); and**

**10. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.**

[(u)] **(s)** The following are the calibration requirements for therapeutic x-ray and therapeutic accelerator installations with energies of [one MeV] **500 kV** and above:

[1. The calibration of systems shall be performed before the system is first used for irradiation of a patient, and thereafter at time intervals which do not exceed 12 months and after any change which might, in the opinion of the qualified radiological physicist, significantly alter

the calibration, spatial distribution, or other characteristics of the therapy beam;

2. The calibration shall be performed with an established calibration protocol which meets or exceeds the requirements set by the American Association of Physicists in Medicine;

3. The calibration shall be performed by a qualified radiological physicist;

4. The calibration shall be performed with a dosimetry system whose calibration shall be directly traceable to a national standard and which shall have been calibrated within the preceding three years;

5. The calibration shall be such that the dose at a reference point in soft tissue may be calculated within plus or minus 5 percent;

6. The full calibration of the therapy beam shall include, but not be limited to, the following determinations:

i. Verification that the equipment is operating in compliance with the design specifications for accuracy of the light localizer, the side light and back pointer alignment with the isocenter;

ii. Verification that the equipment is operating in compliance with the design specifications for acceptable variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths;

iii. The absorbed dose rate at representative depths in a phantom for the range of field sizes used for each effective energy, and for representative distances used for radiation therapy;

iv. The congruence between the radiation field and the field indicated by the localizing device;

v. The uniformity of the radiation field and its dependency upon the direction of the useful beam;

vi. Verification of depth-dose data and isodose curves applicable to the specific machine; and

vii. Verification of the applicability and transmission factors of all accessories such as wedges, shadow trays, compensators, etc. ]

**1. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine shall be performed under the supervision of a qualified medical physicist and reviewed and approved by a qualified medical physicist;**

**2. Acceptance testing and commissioning shall be performed in accordance with current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;**

**3. Full calibration shall be performed in accordance with current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety,**

**and security protocols, shall be followed. Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding 14 months;**

**4. Full calibration shall be performed with a dosimetry system to include external validation of machine output accuracy for all energies prior to clinical use and at least annually thereafter for photons and every two years for electrons. The requirements for dosimetry systems are as follows:**

**i. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration. A system may be cross-calibrated with another system that has been calibrated in accordance with this section. This cross-calibration shall have been performed within the previous 12 months and after each servicing that may have affected system calibration.**

**(1) The dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured; and**

**(2) A field size of less than three x three $cm^2$ is considered to be small and requires a small-volume, micro-detector dosimetry system; and**

**ii. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the**

**manufacturer's name, model name, serial number, date of calibration, and name of the lab where the calibration was performed;**

**5. The qualified medical physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:**

**i. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and**

**ii. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement, or modification does not affect all modes and/or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria at (s)5i above; and**

[7.] **6.** [Records of the] **The records of each** calibration [performed pursuant to 1 above] shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the calibration**.** [; and.] **The record shall include:**

**i. The date of the calibration;**

**ii. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;**

**iii. Calibration reports of the instruments used to calibrate the therapeutic radiation machine; and**

**iv. The signature of the qualified medical physicist responsible for performing the calibration.**

[8. A copy of the latest full calibration shall be available for calculating patient treatment parameters.]

[(v)] **(t)** [Spot] **Monthly periodic quality assurance** checks meeting the following requirements shall be performed on all therapeutic x-ray and therapeutic accelerator installations with energies [of one MeV and above] **greater than or equal to 500 kV**:

1. The qualified [radiological] **medical** physicist will determine those parameters to be [spot-checked] **checked** and the procedure to be used when performing those [spot] checks. The [spot-check] **quality assurance check** procedure shall be in writing and specify the frequency at which tests or measurements are to be performed, not to exceed [one month] **36 days**, and the acceptable tolerance for each parameter measured in the [spot-check] **quality assurance checks**. [A qualified radiological physicist need not actually perform the spot-check measurement. If a qualified radiological physicist does not perform the spot-check measurement, the results of the spot-check measurement shall be reviewed by a qualified radiological physicist within 15 days;] **The procedures shall be performed in accordance with current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation techniques. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety,**

**and security protocols, shall be followed;**

[2. The measurements taken during spot-checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure;]

**2. The registrant shall use a dosimetry system that has been calibrated in accordance with (s)4i above to make the periodic quality assurance checks;**

**3. The registrant shall review the results of each periodic radiation output check according to the following procedures:**

**i. The authorized physician and qualified medical physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within their acceptable tolerances;**

**ii. The qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 36 days; and**

**iii. A qualified medical physicist need not actually perform the quality assurance check measurement. If a qualified medical physicist does not perform the check measurement, the results of the check measurement shall be reviewed and signed by a qualified medical physicist within 30 days;**

**4. Therapeutic radiation equipment shall have applicable safety quality assurance checks that meet the following requirements:**

**i. The registrant shall perform safety quality assurance checks in accordance**

**with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed;**

**ii. Safety quality assurance checks shall ensure proper operation of:**

**(1) Electrical interlocks at each external beam radiation therapy room entrance;**

**(2) Proper operation of the "BEAM-ON," interrupt, and termination switches;**

**(3) Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;**

**(4) Viewing and aural systems;**

**(5) Electrically operated treatment room door(s) from inside and outside the treatment room; and**

**(6) At least one termination switch. If more than one termination switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted as recommended by the manufacturer in order to minimize possible stability problems with the therapeutic radiation machine;**

[3.] **5.** The cause for a parameter exceeding tolerances set by the qualified [radiological]

**medical** physicist shall be promptly investigated and corrected before the system is used for patient irradiation;

[4.] **6.** Whenever a [spot-check] **quality assurance check** indicates a significant change in the operating characteristics of a system, as specified in the [spot-check] **quality assurance check** procedures, the system shall be recalibrated as required [in (u)] **at (s)** above; and

[5.] **7.** Records of [spot-check] **quality assurance check** measurements performed shall be maintained by the registrant for a period of five years and made available for inspection by the Department **following such measurement**. **The record shall include:**

**i. The date of the quality assurance check;**

**ii. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;**

**iii. Calibration reports of the instruments used to measure the radiation output of the therapeutic radiation machine; and**

**iv. The signature of the individual who performed the quality assurance check.**

[(w)] **(u)** Operating procedures for therapeutic x-ray and therapeutic accelerator installations with energies [of one MeV and above] **greater than or equal to 500 kV** are as follows:

1. (No change.)

2. No individual other than the patient shall be in the treatment room during treatment of a patient **or during any irradiation for testing and calibration purposes**;

3. If a patient must be held in position during treatment, mechanical supporting**,** or restraining devices shall be used; [and]

4. The system shall not be used in the administration of radiation therapy unless the requirements [of (u) and (v)] **at (s) and (t)** above have been met[.]**;**

**5. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field when applicable; and**

**6. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.**

**(v) The qualified medical physicist shall be responsible for:**

**1. Full calibration(s) and protection surveys required;**

**2. Supervision and review of dosimetry;**

**3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;**

**4. Quality assurance check review;**

**5. Consultation with the authorized physician in treatment planning, as needed;**

**6. Performing calculations/assessments regarding medical events and unintended treatment deviations; and**

**7. If the qualified medical physicist is not a full-time employee of the registrant, the operating procedures shall also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted.**

7:28-[15.6]**14.5** Radiation therapy simulators

(a) (No change.)

[(b) Operation of a radiation therapy simulator system on a patient shall be performed only by a licensed practitioner, a licensed radiation therapy technologist, or a licensed diagnostic x-ray technologist, as prescribed in N.J.A.C. 7:28-19.]

[(c)] **(b)** No person shall operate or permit the operation of a radiation therapy simulator system unless [it meets] the following requirements **are met**:

1. [A] **The registrant has established a** quality assurance program [has been established] in collaboration with a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems, [and implemented by the registrant] **implements the quality assurance program** to ensure congruence of the position and size of the simulated field with the position and size of the irradiation field[.]**, and performs the quality assurance program in accordance with current published recommendations from a recognized national professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols, shall be followed.**

[i. The quality assurance program is consistent with, but not limited to, the guidelines established by the American Association of Physicists in Medicine, (AAPM) Report Number 13;

ii. The quality assurance program is documented by the registrant; and

iii. The quality assurance program records are maintained by the registrant for at least 36 months, and are available for review at the facility by the department during any inspection;]

2. [Any] **A** radiation therapy simulator system[, which] **that** uses a gantry rotation system when performing radiographic examinations[,] shall **meet the following requirements:**

**i. The system shall** be equipped with a sensor mechanism that [shall] stop**s** the gantry motion**,** if necessary**,** to prevent collision. [This requirement shall take effect October 18, 1994.

i.] Restarting the unit shall only be possible when the cause of the termination has been determined and corrected and the sensor mechanism is satisfied that a collision reoccurrence is not possible.

ii. [Tests of the operation] **Operation** of the anti-collision sensor mechanism [are] **shall be tested at intervals not to exceed 14 months. The test shall be** performed and results [are] **shall be** documented by [those individuals listed in (b) above] **the registrant** or [by] a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems [at intervals not to exceed 12 months]. The **registrant shall maintain** records [shall be maintained] for at least [36 months] **five years**[,] and [shall be] **make such records** available at the facility for review by the [department] **Department** during any inspection. A true copy of these records shall be [sent] **provided** to the [department] **Department** upon request[;]**.**

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

Recodify existing 4.-5. as **3.-4.** (No change in text.)

[6.] **5.** [Protective] **A protective** apron[s] of at least 0.25 millimeters lead equivalent shall be worn by the operator or therapy physician during every instance in which entry into the simulator room is necessary while the patient exposure is in progress. Protective gloves of at

least 0.25 millimeters lead equivalent shall be worn by the operator or therapy physician during every instance when the hands must be in the primary beam while the patient exposure is in progress. The exposure of such individuals shall be controlled by the use of shielding and protective clothing**,** as necessary**,** to ensure that they are not exposed to radiation doses in excess of those permitted [by] **at** N.J.A.C. 7:28-6.

**7:28-14.6 Proton therapy systems**

**(a) No person shall operate or permit the operation of equipment used in proton therapy, unless the equipment meets the requirements of this section and complies with all applicable requirements of this subchapter and N.J.A.C. 7:28-20, unless otherwise exempted.**

**(b) The following are the calibration requirements for a proton therapy system:**

**1. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine shall be performed under the supervision of a qualified medical physicist, and reviewed and approved by a qualified medical physicist;**

**2. Acceptance testing and commissioning shall be performed in accordance with the most current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols shall be followed. Acceptance testing and commissioning shall be conducted before the first medical use following installation or**

**reinstallation of the therapeutic radiation machine;**

**3. Full calibration shall be performed in accordance with the most current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a recognized national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocols shall be followed. Although it shall not be necessary to complete all elements of a full calibration at the same time, all applicable parameters shall be completed at intervals not exceeding 14 months;**

**4. Full calibration shall be performed with a dosimetry system that meets the same requirements as for photon beams at N.J.A.C. 7:28-14.4(s)4;**

**5. Quality assurance (QA) testing of the treatment planning system shall be included in the full calibration report and performed in the case of a significant system upgrade of hardware or software. Verifying spatial accuracy must be included in the QA testing;**

**6. Annual quality assurance testing procedures shall be performed in accordance with the most current American Association of Physicists in Medicine (AAPM) or equivalent standards for single and double scattering systems, and pencil beam scanning systems. The procedures adopted should be based on each facility's system used for patient treatment; and**

**7. The records of each calibration shall be maintained by the registrant and made available for inspection by the Department for five years after completion of the calibration. The record shall include:**

**i. The date of the calibration;**

**ii. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;**

**iii. Calibration reports of the instruments used to calibrate the therapeutic radiation machine; and**

**iv. The signature of the qualified medical physicist responsible for performing the calibration.**

**(c) Monthly periodic quality assurance checks shall meet the following requirements for all proton therapy systems:**

**1. The qualified medical physicist shall determine the parameters to be checked and the procedures to be used when performing those quality assurance checks. The quality assurance check procedure shall be in writing and specify the frequency at which tests or measurements are to be performed, not to exceed 36 days, and the acceptable tolerance for each parameter measured in the quality assurance check;**

**2. The procedures shall be performed in accordance with the most current published recommendations from a recognized national professional association, such as the American Association of Physicists in Medicine (AAPM), with expertise in the use of therapeutic radiation techniques. In the absence of a protocol published by a recognized national professional association, the manufacturer’s protocol or equivalent quality, safety, and security protocols shall be followed;**

**3. The registrant shall use a dosimetry system that has been calibrated in accordance with N.J.A.C. 7:28-14.4(s)4 to make the periodic quality assurance checks;**

**4. Safety quality assurance checks shall ensure proper operation of:**

**i. Electrical interlocks at each external beam radiation therapy room entrance;**

**ii. Proper operation of the "BEAM-ON," interrupt, and termination switches;**

**iii. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;**

**iv. Viewing and aural systems;**

**v. Electrically operated treatment room door(s) from inside and outside the treatment room; and**

**vi. At least one termination switch. If more than one termination switch is installed and not all switches are tested at once, each switch shall be tested at least annually (not to exceed 14 months). Safety quality assurance checks of the emergency power cutoff switches may be conducted as recommended by the manufacturer in order to minimize possible stability problems with the therapeutic radiation machine;**

**5. The cause for a parameter exceeding tolerances set by the qualified medical physicist shall be promptly investigated and corrected before the system is used for patient irradiation; and**

**6. Records of quality assurance check measurements shall be maintained by the registrant and made available for inspection by the Department for a period of five years following such measurement. The record shall include:**

**i. The date of the quality assurance check;**

**ii. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube;**

**iii. Calibration reports of the instruments used to measure the radiation output of the therapeutic radiation machine; and**

**iv. The signature of the individual who performed the quality assurance check.**

**(d) Operating procedures for a proton therapy system are as follows:**

**1. The proton therapy system shall not be left unattended unless the system is secured against unauthorized use;**

**2. No individual other than the patient shall be in the treatment room during treatment of a patient;**

**3. No individual shall be in the treatment room during any irradiation for testing and calibration purposes;**

**4. If a patient must be held in position during treatment, then mechanical supporting or restraining devices shall be used; and**

**5. A copy of the most current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.**

## SUBCHAPTER 15. MEDICAL DIAGNOSTIC X-RAY INSTALLATIONS

7:28-15.2 Definitions

The words and terms listed below, when used in this subchapter, shall have the following

meanings, unless the context clearly indicates otherwise.

…

**"Air kerma" means the kinetic energy released in air by ionizing radiation.**

**"Air kerma rate" or "AKR" means air kerma per unit time.**

…

["Anti-collision device" means either an electronic position sensor combined with a microprocessor or a mechanical touch bar microswitch which will stop all equipment movement and radiation exposures to prevent collision of any part of the radiation therapy simulator system with the patient, or damage to other components of the simulator system.]

…

["C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.]

**"Bone densitometer" means a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.**

**"C-arm fluoroscope" means a fluoroscopic x-ray system in which the image receptor and x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with**

**respect to the patient without moving the patient.**

…

"Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. [It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{\sum_{i=1}^{n} (Xi - \bar{X})^2}{n - 1}$$

where:

s = estimated standard deviation of population
$\bar{X}$ = mean value of observations in sample
Xi = ith observation in sample
n = number of observations in sample

]

**"Computed radiography" or "CR" means a digital x-ray imaging method in which a photostimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.**

"Computed tomography" [(CT)] **or "CT"** means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

"Computed tomography dose index" [(CTDI)] **or "CTDI"** means the integral of the dose measured along a line perpendicular to and centered at the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in

a single scan, that is:

$$CTDI = 1/nT \int_{-7T}^{+7T} D(z)dz$$

where:

z = position along a line perpendicular to the tomographic plane.

D(z) = Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan**.**

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"Contrast scale" [(CS)] **or "CS"** for computed tomography means the change in the linear attenuation coefficient per CT number relative to water, that is:

$$\text{Contrast scale} = \frac{\mu_x - \mu_w}{(CT)_x - (CT)_w}$$

where:

$\mu_w$ = Linear attenuation coefficient of water.

$\mu_x$ = Linear attenuation coefficient of material of interest.

$(CT)_w$ = CT number of water.

$(CT)_x$ = CT number of material of interest**.**

…

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of

the human body for the purpose of [diagnostic imaging or measurement] **diagnosis or visualization**.

**"Digital radiography" or "DR" means an x-ray imaging method (or radiography) that produces a digital, rather than analog image. DR includes both computed radiography and direct digital radiography.**

…

**"Extremity" means any body part projecting from the torso other than the head.**

…

**"Fluoroscopy" means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.**

…

**"Gray" or "Gy" means the SI unit of the absorbed dose of ionizing radiation, corresponding to one joule per kilogram.**

…

**"Handheld radiographic x-ray equipment" means an x-ray system that is used to take radiographs, is designed to be handheld during its operation, and is portable.**

…

"Image receptor" means any device, such as a fluorescent screen [or]**,** radiographic film, [which] **x-ray image intensifier tube, solid-state detector, or gaseous detector, that** transforms incident x-ray photons either into a visible image or into another form which can be

made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

…

***"Kerma"*** **or "kinetic energy released per unit mass" means a measure of the energy released by ionizing radiation in a material per unit mass of that material. Kerma quantifies the energy transferred from photons and charged particles to the material through interactions, such as Compton scattering and photoelectric effect. When the material is air, the quantity is referred to as "air kerma." The formula for kerma (K) is given by:**

$$K = \frac{dE_{tr}}{dm}$$

**where:**

**K = kerma (expressed in Gray, Gy).**

**$dE_{tr}$ = the change in kinetic energy transferred to charged particles per unit mass of the material (expressed in joules per kilogram, J/kg); and**

**dm = the change in mass of the material.**

…

**"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.**

…

**"Mode of operation" means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation, per se, does not comprise a mode of operation different from the one that has been selected.**

…

"Positive beam-limiting device" [(PBL)] **or "PBL"** means a device which automatically restricts the x-ray field to the size of the image receptor.

…

**"Pulsed mode" means operation of the x-ray system, such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.**

"Qualified individual for the performance of radiation surveys for diagnostic x-ray equipment [and therapy simulator systems]" as required in this subchapter means an individual

who meets at least one of the following criteria:

1. Certification by one of the following agencies in the specialty listed:

i. -iii. (No change.)

iv. [Certification issued by the] **The** Fellowship in the Canadian College of Physicists in Medicine which is equivalent to **subparagraph** 1i or iii above; or

v. [Certification by other] **Another** national certifying board[s which] **that** may be recognized by the Commission**,** [on Radiation Protection (Commission)] where the person seeking recognition as a qualified individual for the performance of radiation surveys for diagnostic x-ray equipment and therapy simulator systems has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified individual pursuant to this definition;

2.-5. (No change.)

…

["Qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems" means an individual who meets at least one of the criteria listed below:

1. Is certified by the American Board of Radiology in therapeutic radiological physics or by the American Board of Medical Physics with special competency in radiation oncology physics;

2. Is certified by the American Board of Radiology in Radiological Physics which includes all three subspecialties of diagnostic radiological physics, therapeutic

radiological physics, and medical nuclear physics.

3. Is certified by the American Board of Radiology or the American Board of Medical Physics in a specialty other than therapeutic radiological physics or radiation oncology physics and has at least three years of professional, clinical and technical experience obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems;

4. Certification issued by the Fellowship in the Canadian College of Physicists in Medicine which is equivalent to 1, 2, or 3 above;

5. Certification by other national certifying boards which may be recognized by the Commission where the person seeking recognition as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems has petitioned the Commission in writing and where the Commission has issued a written determination that the certification in question meets the criteria of a qualified medical physicist pursuant to this definition;

6. A master's or doctorate degree from an accredited college in radiological health, radiation sciences, physics, chemistry, environmental sciences, engineering or a related field and at least three years of professional, clinical and technical experience in the field of radiological physics obtained under the supervision of a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems; or

7. Any individual who does not meet at least one of the foregoing criteria may petition the Commission for recognition as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems. The individual shall submit a

written petition to the Commission which contains sufficient information on his or her educational, professional, clinical, technical, employment and/or any other relevant experience. The Commission may approve any such petition based on its determination that the individual demonstrates competence to act as a qualified medical physicist for the supervision of quality assurance programs for therapy simulator systems.]

…

["Radiation therapy simulation system" means a radiographic, fluoroscopic or computed tomographic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field. ]

…

"Scan time" means the [period of] time [between the beginning and end of photon transmission data] **elapsed during the** accumulation **of x-ray transmission data** for a single scan.

…

"Source-to-image receptor distance" [(SID)] **or "SID"** means the distance from the source to the center of the input surface of the image receptor.

"Source-to-skin distance" [(SSD)] **or "SSD"** means the distance from the source of radiation to the patient's skin.

…

["Xeromammography" means the recording of an x-ray image of the breast using a uniformly charged photoconductive (selenium alloy) plate held in a light-proof cassette instead

of using conventional x-ray film.]

…

7:28-15.3 General requirements for radiographic installations

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

(e) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the x-ray filtration and beam quality meet the following requirements:

1. The amount of total filtration permanently in the useful beam shall provide the minimum half-value layer specified in the following table:

TABLE 1

[

*TABLE OF HALF VALUE LAYERSOF HALF VALUE LAYERS*

| Designed Operating Range (kVp) | Measured operating potential (kVp) | Minimum half-value layer(HVL) (mm of Al) |
|---|---|---|
| Below 51 | 30 | 0.3 |
| | 40 | 0.4 |
| | 50 | 0.5 |
| 51 to 70 | 51 | 1.2 |
| | 60 | 1.3 |
| | 70 | 1.5 |
| Above 70 | 71 | 2.1 |
| | 80 | 2.3 |
| | 90 | 2.5 |
| | 100 | 2.7 |
| | 110 | 3.0 |
| | 120 | 3.2 |
| | 130 | 3.5 |
| | 140 | 3.8 |
| | 150 | 4.1 |

]

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| **TABLE 1** | | | |
|---|---|---|---|
| **Table of Half-Value Layers** | | | |
| **Design Operating Range** | **Measures Operating Potential** | **Minimum HVL (mm in Aluminum)** | |
| | | **X-ray systems manufactured before June 10, 2006** | **X-ray systems manufactured after June 10, 2006** |
| **Below 51** | **30** | **0.3** | **0.3** |
| | **40** | **0.4** | **0.4** |
| | **50** | **0.5** | **0.5** |
| **51 to 70** | **51** | **1.2** | **1.3** |
| | **60** | **1.3** | **1.5** |
| | **70** | **1.5** | **1.8** |
| **Above 70** | **71** | **2.1** | **2.5** |
| | **80** | **2.3** | **2.9** |
| | **90** | **2.5** | **3.2** |
| | **100** | **2.7** | **3.6** |
| | **110** | **3.0** | **3.9** |
| | **120** | **3.2** | **4.3** |
| | **130** | **3.5** | **4.7** |
| | **140** | **3.8** | **5.0** |
| | **150** | **4.1** | **5.4** |

(f) (No change.)

(g) No person shall operate or permit the operation of any certified or uncertified radiographic x-ray equipment used in the healing arts unless the accuracy, reproducibility**,** and linearity meet the following requirements:

1.-2. (No change.)

3. The following exposure reproducibility requirements shall apply:

i. For certified equipment only, the coefficient of variation of **the air kerma or** radiation exposure reproducibility shall not exceed 0.05 for any specific combination of selected technique factors; **and**

ii. For uncertified equipment only, the coefficient of variation of **the air kerma or of** radiation exposure reproducibility shall not exceed 0.07 for any specific combination of selected technique factors;

4.-5. (No change.)

6. The following linearity requirements apply to x-ray equipment which**,** allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating.

i. For x-ray equipment having independent selection of x-ray tube current (mA), the average ratios of exposure **or air kerma** to the indicated milliampere-seconds product (mR/mAs) or (C/kg/mAs) **for radiation exposure values or (mGy/mAs) for air kerma values** obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.

ii. For [equipment manufactured after May 3, 1994, x-ray] equipment having a

combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure **or air kerma** to the indicated milliampere-seconds product (mR/mAs) or (C/kg/mAs) **for radiation exposure values or (mGy/mAs) for air kerma** values obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum.

iii. The average exposure ratio for (g)6i and ii above shall be expressed as follows:

$$|\bar{x}_2 -- \bar{x}_2| \leq 0.10\ (\bar{x}_1 + \bar{x}_2)$$

where $x_1$ and $x_2$ are the average mR/mAs or C/kg/mAs **radiation exposure values or mGy/mAs air kerma** values obtained at each of two consecutive [tube mA or] mAs **selector** settings **or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.**

(h)-(k) (No change.)

**(l) No person shall operate or permit the operation of any handheld radiographic equipment used in the healing arts, unless the registrant has developed and continuously implemented a quality assurance program that meets the requirements at N.J.A.C. 7:28-22, Quality Assurance Programs for Medical Diagnostic X-Ray Installations, and ensures that the equipment is operated in such a manner as to meet the following requirements:**

**1. The handheld radiographic equipment shall only be used in conjunction with 400 speed film or higher equivalent imaging systems to further minimize patient and operator radiation exposure;**

**2. Each operator shall be provided radiation monitoring badges to be worn on the**

**operator's collar, outside of any protective garments. In addition, each operator shall be provided with a finger ring badge;**

**3. The handheld radiographic equipment shall be secured in a safe location that prevents unauthorized use as required at N.J.A.C. 7:28-2.4;**

**4. A 510(k) (premarket notification) letter from the United States Food and Drug Administration is required at least 90 days before marketing unless the device is exempt from 510(k) requirements. Documentation shall be made available upon the request of the Department;**

**5. The handheld radiographic equipment shall be labeled for "Extremity Use Only";**

**6. An operator shall wear a protective apron and thyroid collar of at least 0.25 mm lead equivalent during every exposure; and**

**7. Handheld radiographic units mounted on a portable stand and used with a six-foot remote control switch are exempt from (l)2 and 6 above.**

[(l)] **(m)** (No change in text.)

7:28-15.4 Mammography radiographic installations

(a) This section establishes the requirements for medical diagnostic and screening radiographic mammography procedures. Hereafter, all references to mammography shall mean mammography performed with [ionizing-radiation-producing] **ionizing radiation-producing** equipment. **A mammography unit that is used exclusively for specimen imaging is exempt from the requirements of this section.**

(b)-(d) (No change.)

(e) [By October 18, 1995 or within two years of the installation of a mammography unit, whichever shall be later, the] **A** registrant shall not operate or permit the operation of each mammography unit under the registrant's jurisdiction unless the mammography unit is accredited by the American College of Radiology (ACR) or meets an equivalent standard acceptable to the Commission. Current accreditation by the ACR**,** or its equivalent**,** acceptable to the Commission shall be maintained for each mammography unit [under] **within** the registrant's jurisdiction.

[1. If a mammography unit is accredited or certified by an agency or organization other than ACR, a registrant may petition the Commission in writing for recognition of this agency's or organization's accreditation or certification as equivalent to ACR accreditation. The registrant shall submit sufficient documentation to the Commission related to machine performance standards, quality assurance, operating safety standards, and any additional information that the Commission may request in order to demonstrate equivalence to ACR accreditation.

2. The Commission may approve the registrant's petition based on the information contained in the petition and the Commission's determination that the alternative agency's or organization's accreditation or certification is equivalent to ACR accreditation.]

[3.] **1.** A mammography unit that is used exclusively for stereotactic biopsies **or needle localizations** is exempt from the requirements [of (e)1 and 2 above] **in this subsection,** but shall meet the other requirements of this subchapter.

(f) No person shall operate or permit the operation of any radiographic equipment for mammography unless the equipment meets the following requirements:

1.-10. (No change.)

[11. The following linearity requirements apply to mammography x-ray equipment which allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating:

i. For x-ray equipment having independent selection of x-ray tube current (mA), the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) or (C/kg/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum.

ii. For equipment manufactured after May 3, 1994, x-ray equipment having a combined x-ray tube current-exposure time product (mAs) selector, the average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) or (C/kg/mAs) values obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum.

iii. The average exposure ratio for (f)11i and 11ii above shall be expressed as follows:

$$|\bar{x}_2 -- \bar{x}_2| \leq 0.10\ (\bar{x}_1 + \bar{x}_2)$$

where $x_1$ and $x_2$ are the average mR/mAs or C/kg/mAs values obtained at each of two consecutive tube mA or mAs settings.]

[12.] **11.** The measured HVL shall be equal to or greater than the value:

$$\text{HVL} \geq \frac{kVp}{100} \text{ (in units of mm of aluminum)}$$

[For film-screen mammography units only, the maximum measured HVL shall be equal to or less than the value:

$$\text{HVL} \leq \frac{kVp}{100} \text{ (in units of mm of aluminum)]}$$

Recodify existing 13.-16. as **12.-15.** (No change in text.)

(g)-(i) (No change.)

(j) The requirements for the quality assurance program shall be as follows:

1. The registrant shall develop and maintain a quality assurance manual that identifies and assigns [over-all] **overall** quality control responsibilities. The following items shall be in the quality assurance manual:

i.-ii. (No change.)

iii. A list of the tests to be performed. For each test, the following items shall be included:

(1) The frequency of performance of each test in accordance with (j)4, **5, and** 6[, 7, 8, 9, 10, and 11] below;

(2) – (3) (No change.)

iv.-vi. (No change.)

2.-3. (No change.)

4. For each mammography unit, the registrant shall perform or have performed**,** at least annually**,** the test procedures listed below and shall maintain the records for as long as the

mammography unit remains registered plus one year.

i.-iii. (No change.)

[iv. Measurement of linearity of exposure at various mA stations or mAs settings;]

Recodify existing v.-x. as **iv.-ix.** (No change in text.)

[5. For each processor used for mammography, the registrant shall ensure that the records of maintenance and quality control tests are maintained in a processor maintenance log. Processor maintenance logs shall include preventive maintenance, cleaning performed and corrective actions taken. A record of each such measure taken shall be maintained in the log for at least 36 months;

6. For each processor used for film-screen mammography, the registrant shall perform or have performed quality control tests for each processor on each day the processor is used for mammography. For motor vehicle and mobile mammographic units with processing capability, quality control tests for each processor shall be performed at each new location.

i. Quality control tests shall include measurement of developer temperature, film sensitometry to indicate film speed, film contrast and base-plus-fog density;

ii. Logs, charts, or graphs of these measurements shall be maintained for 36 months from the dates of such measurements. The registrant may discard such records after 36 months, except that at least one representative set of quality control records from each year shall be maintained for an additional five years;

7. For each darkroom used for loading, storing or processing film used for

mammography, the registrant shall ensure that:

i. Measurement of film fog is performed at least semiannually and test results are maintained for the current year and the preceding year; and

ii. Darkroom cleanliness is maintained and checked daily;

8. For each radiographic cassette used for film-screen mammography, the registrant shall ensure that:

i. The intensifying screen is cleaned and inspected at least weekly;

ii. The film-screen contact is tested at least semiannually and the record of each test is maintained for at least 36 months from the date of the test; and

iii. Uniformity of screen speed is assessed annually and the record of each test is maintained for at least 36 months from the date of the test;

9. For each component used for xeromammography, the registrant shall perform or have performed the quality control tests listed below:

i. For the conditioner, tests for light leaks, temperature of relaxation oven, charging of the plate, and optimization for the kVp used shall be performed on each day the conditioner is used for mammography;

ii. For the processor, tests for light leaks, toner supply, back bias setting, and optimization for the kVp used shall be performed on each day the processor is used for mammography;

iii. Each cassette shall be cleaned and checked for dust particles and pressure artifacts every week; and iv. Each selenium plate shall be examined for powder deficiency spots, powder efficiency spots, dark dusting, scratches, and artifacts on

a monthly basis; ]

[10.] **5.** (No change in text.)

[11.] **6.** Repeat analysis shall be performed at least [quarterly] **semi-annually** for [film-screen] mammography [and xeromammography; and]**; however, mammography units that are used only to perform needle localizations are exempt from this requirement; and**

[12.] **7.** (No change in text.)

7:28-15.5 Medical fluoroscopic x-ray systems

(a) (No change.)

(b) No person shall operate or permit the operation of certified or uncertified fluoroscopic x-ray equipment used in the healing arts**,** unless the equipment meets the following requirements:

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier [which] **that** intercepts the entire cross section of the useful beam at any source-to-image receptor distance.

i. The x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam. [Radiation therapy simulator systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required to be in the manufacturer's specifications manual and provides the registrant with precautions concerning the importance of remote

control operation.]

ii. The exposure rate **or AKR** due to transmission through the primary protective barrier with an attenuation block in the useful beam combined with the radiation from the image [intensifier] **receptor**, if provided, shall not exceed 5.2 E-6 Coulombs per kilogram (two milliroentgens per hour) **or $34x10^{-3}$ percent of the entrance AKR,** at 10 centimeters (four inches) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor [for each Roentgen per minute of entrance exposure rate]. The attenuation block shall be a block or stack, having dimensions**,** 20 centimeters by 20 centimeters by 3.8 centimeters (eight inches by eight inches by 1.5 inches), of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation. [Radiation therapy simulator systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required to be in the manufacturer's specifications manual and provides the registrant with precautions concerning the importance of remote control operation.]

iii. The exposure rate **or AKR** due to transmission through the primary barrier combined with radiation from the image intensifier, if provided, shall be determined by measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (eight inches). If the source is below the tabletop, the measurement shall be made with

the input surface of the fluoroscopic imaging assembly positioned 30 centimeters (12 inches) above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters (12 inches). Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters (four inches) from the point of measurement of entrance exposure rate **or AKR** and between this point and the input surface of the fluoroscopic imaging assembly. For C-arm fluoroscopy equipment, the measurement shall be made with the end of the beam-limiting device at the minimum SID and the attenuation block not closer than 30 centimeters (12 inches) from the imaging assembly[.]**;**

[iv. For uncertified fluoroscopic equipment only, the fluoroscopic screen shall be covered with a transparent protective material such that under normal operating conditions the dose rate measured five centimeters from the viewer's side of the screen shall not be more than 20 milliroentgens per hour (5.2 E-6 Coulombs per kilogram) without a patient and with the screen 20 centimeters (eight inches) from the tabletop or panel);]

2. For fluoroscopic equipment that does not have image intensification, the following field limitation requirements shall be met:

i. – iii. (No change.)

iv. Equipment [manufactured after February 25, 1978, which] **that** permits a

variable angle between the image receptor and the axis of the x-ray beam shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

3. Except for fluoroscopic systems used for radiation therapy simulation, image-intensified fluoroscopic equipment shall meet the following field limitation requirements:

**i. For fluoroscopic equipment using the imaging assembly with inherently circular image receptors:**

**(1) For fluoroscopic equipment manufactured before June 10, 2006, the following shall apply:**

Recodify existing i.-iii. as **(A)-(C)** (No change in text.)

**(2) For fluoroscopic equipment manufactured on or after June 10, 2006, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:**

**(A) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor; or**

**(B) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible**

**area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two cm;**

**ii. For fluoroscopic equipment using imaging assembly with inherently rectangular image receptors:**

**(1) For an x-ray system manufactured on or after June 10, 2006, the following shall apply:**

**(A) Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID; and**

**(B) The error in alignment shall be determined along the length and width dimensions of the x-ray field, which pass through the center of the visible area of the image receptor;**

[iv.] **iii.** Equipment [manufactured after February 25, 1978,] in which the angle between the image receptor and beam axis is variable, shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

[v.] **iv.** Beam-limiting devices [manufactured after May 22, 1979, and] incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters (46.5 square inches) shall be provided with a means for stepless adjustment of the x-ray field;

Recodify existing vi.-viii. as **v.-vii.** (No change in text.)

4. X-ray production in the fluoroscopic mode shall be controlled by a device [which] **that** requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in [progress] **process**;

[5. Fluoroscopic equipment which is provided with automatic exposure rate control or with both automatic exposure rate control and manual mode (dual mode units) shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of 10 Roentgens per minute (2.6 E-3 Coulombs per kilogram per minute) at the point where the center of the useful beam enters the patient except:

i. During the recording of fluoroscopic images; or

ii. When an optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of 5 Roentgens (1.3 E-4 Coulombs/kilogram/minute) at the point where the center of the useful beam enters the patient unless the high-level control is activated;

6. Fluoroscopic equipment which is not provided with automatic exposure rate control (manual mode) shall not be operable at any combination of tube potential and current which will result in an entrance exposure rate in excess of five Roentgens per minute (1.3 E-4 Coulombs/kilogram/minute) at the point where the center of the useful beam enters

the patient, except:

i. During recording of fluoroscopic images; or

ii. When an optional high-level control is activated;]

**5. For fluoroscopic equipment, the following AKR and automatic exposure rate control requirements shall apply:**

**i. The equipment shall be equipped with automatic exposure rate control (AERC) if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (five R/min exposure rate) at the measurement point specified at (b)7 below.**

**ii. The equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified at (b)7 below.**

[7.] **6.** For equipment provided with high-level control, the following requirements shall be met:

i. (No change.)

ii. Continuous manual activation of the high-level control shall be provided by the operator; [and]

iii. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed; **and**

**iv. When high-level control is selected and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per**

**minute (vice 20 R/min exposure rate) at the measurement point specified at (b)7 below;**

[8.] **7.** Measuring compliance of entrance exposure rates **or air kerma rates** shall be determined as follows:

i. When the source is below the table, the entrance exposure rate **or AKR** shall be measured one centimeter (0.4 inch) above the tabletop or cradle;

ii. When the source is above the table, the entrance exposure rate **or AKR** shall be measured at 30 centimeters (12 inches) above the tabletop with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement;

iii. For stationary and mobile c-arm types of fluoroscopes, the entrance exposure rate **or AKR** shall be measured 30 centimeters (12 inches) from the input surface of the fluoroscopic imaging assembly[.]**, with the source positioned at any available SID; provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly;**

**iv. In a C-arm fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD; and**

[iv.] **v.** In a lateral type of fluoroscope, the entrance exposure rate **or AKR** shall be measured 15 centimeters (5.9 inches) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the

tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters (5.9 inches) to the centerline of the x-ray table;

[9. Fluoroscopic radiation therapy simulation systems are exempt from the entrance exposure rate requirements of (b)5 and (b)6 above;]

[10.] **8.** (No change in text.)

[11.] **9.** A means shall be provided to limit the source-to-skin distance to not less than 38 centimeters (15 inches) on stationary fluoroscopes and to not less than 30 centimeters (12 inches) on mobile and portable fluoroscopes.

i. (No change.)

**ii. For any stationary, mobile, or portable C-arm fluoroscopic system manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm:**

**(1) Means shall be provided to limit the source-skin distance to not less than 19 cm;**

**(2) The system shall be labeled for extremity use only; and**

**(3) For a system intended for specific surgical procedures that would be prohibited at the source-skin distance specified at (b)9ii(1) above, provisions may be made for operation at shorter source-skin distances, but in no case less than 10 cm;**

[12.] **10.** The following requirements shall apply to a fluoroscopic timer:

**i. For fluoroscopic equipment manufactured before June 10, 2006:**

[i.] **(1)** A means shall be provided to preset the cumulative [on-time] **irradiation time** of the fluoroscopic tube. The maximum cumulative time of the timer shall not exceed five minutes without resetting; **and**

[ii.] **(2)** The timer shall either terminate the exposure or emit a signal audible to the fluoroscopist when the exposure time reaches five minutes. Such signal shall continue to sound while x-rays are produced until the timer is reset; [and]

[iii. As an alternative to the requirements of (b)12ii above, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations;]

**ii. For an x-ray control manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:**

**(1) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in this subsection. The following requirements shall apply:**

**(A) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds;**

**(B) The fluoroscopic irradiation time shall be displayed within**

**six seconds of termination of an exposure and remain displayed until reset; and**

**(C) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure; and**

**(2) A signal audible to the fluoroscopist shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds;**

[13.] **11.** (No change in text.)

[14.] **12.** The fluoroscopy table that is provided with an undertable tube and a bucky shall have a bucky slot cover that provides protection equivalent to at least 0.5 millimeters of lead. [Radiation therapy simulation systems are exempt from the requirements of this paragraph;]

[15.] **13.** (No change in text.)

[16. When a sterile field will not permit the use of the normal protective barriers, the requirements of (b)15 above may be omitted;]

**14. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met:**

**i. Shielding required pursuant to (b)12 and 13 above shall be maintained to the closest degree possible under the clinical conditions;**

**ii. All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent**

**shielding of at least 0.25 mm;**

**iii. The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest); and**

**iv. Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use and/or non-use of the protective drapes;**

[17.] **15.** A mobile fluoroscopic unit used routinely in one location shall be considered a permanent installation and shall comply with the shielding and survey requirements [in] **at** N.J.A.C. 7:28-15.10; [and]

[18.] **16.** The following requirements shall apply to spot-film devices**,** except when the spot-film device is provided for use with a radiation therapy simulator system:

i. (No change.)

ii. Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum of the differences in length and width, without regard to the sign, shall not exceed four percent of the SID. Spot-film devices [manufactured after February 25, 1978, which] **that** permit a variable angle between the plane of the image receptor and beam axis, shall be provided with a means to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

iii. - iv. (No change.)

v. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows: FOR X-RAY FIELD LIMITATION SYSTEM FAILURE[.]**;**

**17. Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display a last-image-hold (LIH) image following termination of the fluoroscopic exposure.**

**i. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.**

**ii. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.**

**iii. Means shall be provided to clearly indicate, to the user, whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images; and**

**18. Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:**

**i. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second;**

**ii. The cumulative air kerma in units of mGy shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds;**

**iii. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma;**

**iv. The AKR and cumulative air kerma shall represent the value for conditions of free in-air irradiation at one of the following reference locations specified according to the type of fluoroscope:**

**(1) For a fluoroscope with an x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified at (b)7i, ii, and v above.**

**(2) For a C-arm fluoroscope, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray**

**beam with the patient's skin;**

**v. The display of cumulative air kerma will be reset to zero prior to the commencement of a new examination or procedure; and**

**vi. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ±35 percent over the range of six mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three seconds.**

(c) (No change.)

(**Agency Note**: N.J.A.C. 7:28-15.6 is proposed for recodification with amendments as N.J.A.C. 7:28-14.5.)

7:28-[15.12]**15.6** X-ray bone densitometer equipment

(a) The provisions of this section are in addition to and not in substitution for the applicable provisions of [N.J.A.C. 7:28] **this chapter**.

(b)-(d) (No change.)

(e) No person shall operate or permit the operation of [any] x-ray bone densitometer equipment **used in the healing arts,** unless the registrant has developed and [has] **continuously** implemented a quality assurance program that meets the applicable requirements [in] **at** N.J.A.C. 7:28-[22.11]**22**, Quality [assurance program for x-ray bone densitometer equipment] **Assurance Programs for Medical Diagnostic X-Ray Installations**.

7:28-15.9 Individual radiation safety

(a) No person shall operate or permit the operation of certified or uncertified medical radiographic and fluoroscopic equipment or therapy simulation systems**,** unless the following conditions are met:

1. Only individuals required for the medical procedure, for training, or for equipment maintenance shall be in the radiographic or fluoroscopic [or therapy simulator] room during an exposure.

i. Individuals who are present in a radiographic or fluoroscopic [or therapy simulator] room during any exposure shall wear protective aprons of at least 0.25 mm lead equivalent during every exposure.

ii. (No change.)

2. When a patient must be provided with auxiliary support during a radiation exposure and mechanical holding devices are insufficient, the following procedures shall be followed:

i. -v. (No change.)

[vi. No person other than the patient shall hold the film during the exposure;]

**vi. No individual shall be used to routinely hold the image receptor or patient during a radiation exposure;**

3. (No change.)

**4. In those cases where the patient must hold the image receptor, except during intraoral examinations any portion of the body other than the area of clinical**

**interest struck by the useful beam, shall be protected by not less than 0.5 millimeter lead equivalent material.**

Recodify existing 4.-11. as **5.-12.** (No change in text.)

7:28-15.10 Structural shielding and radiation safety surveys

(a) (No change.)

(b) No person shall operate or permit the operation of x-ray equipment used in the healing arts unless the survey requirements listed below are met. To the extent that this section imposes more stringent requirements than the survey requirements [in] **at** N.J.A.C. 7:28-7 and recordkeeping requirements [in] **at** N.J.A.C. 7:28-8, the requirements of this section shall be followed.

1. – 2. (No change.)

3. The minimum requirements for the information to be included in the radiation safety survey report are as follows:

i. The name of the registrant of the installation as [listed on form VRH-001] **it appears on the registration form**, address, telephone number, and room location of the unit;

ii. – vii. (No change.)

viii. Records of the measurement of radiation exposure with a suitable phantom in the average patient position. Measurements shall be taken at the operator's position and at all nearby locations [which] **that** are normally occupied. For each measurement, the kVp, and mA, exposure time, instrument reading, and correction made to the instrument reading (such as

energy response, calibration, etc.) shall be recorded; [and]

ix. Exposure rates at each measured location shall be converted into Coulombs/kilogram/week or mR/week. Records shall include all assumptions of workload, use and occupancy factors used in the calculations[.]**; and**

**x. A picture of the generator serial plate shall be included in the radiation safety survey report showing the model number, generator serial number, and control panel serial number.**

**(Agency Note:** N.J.A.C. 7:28-15.12 is proposed for recodification with amendments as N.J.A.C. 7:28-15.6.)

7:28-[15.13]**15.12** (No change in text.)

SUBCHAPTER 16. DENTAL RADIOGRAPHIC INSTALLATIONS

7:28-16.2 Definitions

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

…

**"Cone Beam Computed Tomography" or "CBCT" means a digital volume tomography method used in some imaging applications. CBCT employs a two-dimensional digital detector array and a cone-shaped x-ray beam (instead of fan-shaped) that rotates around the patient to generate a high resolution, three-dimensional (3D) image with high geometric accuracy. Reconstruction algorithms can be used to generate images of any**

**desired plane.**

…

**"Handheld dental x-ray system" means an x-ray system that is used to take radiographs, is designed to be handheld during its operation, and is portable.**

…

**"Initially" means no later than the date of the required implementation of the quality assurance program specified at N.J.A.C. 7:28-22.2 or within 60 days of the date the x-ray machine is acquired.**

**"Intraoral source x-ray system" means an electrically powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. Intraoral (meaning "inside the mouth") is where the image receptor is placed inside the mouth in order to take the radiograph.**

…

**"Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.**

…

**"Panoramic radiography" or "panoramic x-ray" is a two-dimensional (2D) dental x-ray examination that captures the entire mouth in a single image, including the teeth, upper and lower jaws, surrounding structures, and tissues.**

…

**"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.**

…

**"QA" means quality assurance.**

**"QC" means quality control.**

…

**"Stationary x-ray equipment" means x-ray equipment that is installed in a fixed location.**

…

7:28-16.3 Dental radiographic equipment

(a) A person shall not operate or permit the operation of ionizing radiation-producing equipment used in the practice of dentistry unless the equipment meets the requirements listed below:

1.-5. (No change.)

6. The amount of total filtration permanently in the useful beam shall meet the minimum half-value layer (HVL) specified in the following table:

TABLE 1

[TABLE OF HALF-VALUE LAYERS FOR DENTAL UNITS

X-ray tube voltage (kilovoltage peak)

| Designed operating range (kVp) | Measured operating potential (kVp) | Minimum HVL (mm of A1) |
|---|---|---|
| Below 50 | 30 | 1.5 |
| | 40 | 1.5 |

| | | |
|---|---|---|
| 50 to 70 | 50 | 1.5 |
| | 60 | 1.5 |
| | 70 | 1.5 |
| Above 70 | 71 | 2.1 |
| | 80 | 2.3 |
| | 90 | 2.5 |
| | 100 | 2.7 |
| | 110 | 3.0 |
| | 120 | 3.2 |
| | 130 | 3.5 |
| | 140 | 3.8 |
| | 150 | 4.1] |

**TABLE OF HALF-VALUE LAYERS FOR DENTAL UNITS**

**X-ray tube voltage (kilovoltage peak)**

| **Designed operating range (kVp)** | **Measured operating potential (kVp)** | **Minimum HVL (mm of A1)** |
|---|---|---|
| **Below 51** | **30** | **1.5** |
| | **40** | **1.5** |
| | **50** | **1.5** |
| **51 to 70** | **60** | **1.5** |
| | **70** | **1.5** |
| **Above 70** | **71** | **2.1** |
| | **80** | **2.3** |
| | **90** | **2.5** |
| | **100** | **2.7** |
| | **110** | **3.0** |
| | **120** | **3.2** |

7. For certified units, the x-ray tube voltage (kilovoltage peak) measured operating

potential shall meet the manufacturer's specifications. **In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value.**

8.-21. (No change.)

**7:28-16.7 Cone-beam computed tomography (CBCT) installations**

**(a) No person shall use any dental CBCT equipment or cause it to be used unless the following requirements are met:**

**1. The registrant shall ensure that the equipment is operated in such a manner as to meet the manufacturer's specifications;**

**2. The registrant shall ensure that the operator is trained in the operating procedures for the dental CBCT equipment;**

**3. The registrant shall develop and continuously implement a quality assurance program that meets the requirements of the manufacturer's specifications;**

**4. The registrant shall ensure that the items listed below describing the operation and calibration of the equipment are maintained at the facility:**

**i. A copy of the manufacturer's specific quality assurance program recommendations and the operating manual;**

**ii. Documentation of the quality assurance program and quality control tests for the dental CBCT x-ray unit;**

**iii. Instructions on the use of the phantom(s) or testing appropriate for the system and allowable variations for the indicated parameters; and**

**iv. A radiation safety manual as required at N.J.A.C. 7:28-15.9(a)8;**

**5. The registrant shall ensure that the manufacturer's recommended test procedures and frequencies for the dental CBCT x-ray unit are followed, and the test results are recorded. If any test result indicates that the dental CBCT equipment does not meet the manufacturer standards, the registrant shall immediately initiate steps to repair the dental CBCT equipment to meet the standards. All corrective actions shall be completed within 30 days; and**

**6. The registrant shall ensure that the records of tests required at (a)5 above are maintained for at least one year.**

**(b) In addition to the requirements at (a) above, the registrant shall have a Medical Physicist's Dental CBCT QC Survey performed by a qualified medical physicist for the supervision of quality assurance programs for CT equipment pursuant to N.J.A.C. 7:28-22.12. The initial survey shall be completed within 60 days of acquisition. Each annual survey shall be completed within 14 months of the preceding survey. The Medical Physicist's CBCT Dental QC Survey shall include the requirements identified at Table 2 below. If there is no standard established and the manufacturer does not have a standard for that test, the physicist can put N/A for that specific test.**

| TABLE 2 | | |
|---|---|---|
| **Medical Physicist's Dental CBCT QC Survey** | | |
| **Item** | **Requirement** | **Standard** |
| **1.** | **Scan Localization Light Accuracy** | **CBCT equipment or phantom** |

| | | |
|---|---|---|
| | | **manufacturer's specification** |
| **2.** | **Patient Dose** | **CBCT equipment or phantom manufacturer's specification; or as determined by certified medical physicist** |
| **3.** | **Pre-Patient Collimation Accuracy** | **CBCT equipment or phantom manufacturer's specification** |
| **4.** | **Contrast Scale** | **CBCT equipment or phantom manufacturer's specification** |
| **5.** | **CT Number for Water** | **CBCT equipment or phantom manufacturer's specification** |
| **6.** | **Field Uniformity** | **CBCT equipment or phantom manufacturer's specification** |
| **7.** | **Low Contrast** | **CBCT equipment or phantom manufacturer's specification** |
| **8.** | **High Contrast** | **CBCT equipment or phantom manufacturer's specification** |
| **9.** | **Noise** | **CBCT equipment or phantom manufacturer's specification** |
| **10.** | **Scan Protocol Review** | **Ensure that the adult and pediatric scan protocols are separate and unique** |
| **11.** | **Review of Facility and Technologist QC** | **Review QC tests for proper procedure and corrective action** |
| **12.** | **Physicist Report and Recommendations** | **Communicate results and** |

| | | |
|---|---|---|
| | | **recommendations to registrant** |

**1. If any of the Dental CBCT QC Survey test results at Table 2, Medical Physicist's Dental CBCT QC Survey, above indicate that the CBCT equipment does not meet the standards established at Table 2, the registrant shall immediately initiate corrective actions to meet the standards. All corrective actions shall be completed within 30 days.**

**2. For item 11 at Table 2, Medical Physicist's Dental CBCT QC Survey, above, the medical physicist shall review the completed QC test records that have been performed by the registrant for the previous year to ensure the tests were performed properly and corrective actions were taken.**

**3. For item 12 at Table 2, Medical Physicist's Dental CBCT QC Survey, above, the medical physicist shall prepare a report that reviews the overall quality assurance program being carried out by the registrant and contains:**

**i. Raw data, results, and recommendations of the medical physicist's equipment tests performed in accordance with items 1 through 10 at Table 2, Medical Physicist's Dental CBCT QC Survey, above; and**

**ii. Results and recommendations of the medical physicist's review performed in accordance with item 12 at Table 2, Medical Physicist's Dental CBCT QC Survey, above.**

**7:28-16.8 Handheld dental x-ray systems**

**(a) A handheld dental x-ray system must comply with the requirements of this subchapter, except for N.J.A.C. 7:28-16.3(a)5, 11, and 21 and 16.11(a)2 and 4.**

**(b) No person shall use a handheld dental x-ray system or cause it to be used unless the following requirements are met:**

**1. The handheld dental x-ray system shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (six inches) in diameter that is positioned as close as practicable to the distal end of the position indication device to minimize scatter radiation exposure to the operator.**

**2. The handheld dental x-ray system shall only be used in conjunction with "F-speed" film, Phosphor Storage Plates (PSP), or digital image receptors to further minimize patient and operator radiation exposure.**

**3. The handheld dental x-ray system shall be secured in a safe location that prevents unauthorized use, as required pursuant to N.J.A.C. 7:28-2.4.**

**4. The registrant shall ensure that all authorized operators have been properly trained by reading the manufacturer's user manual and shall document all training. The registrant shall maintain all training records in the facility file and make such records immediately available upon the request of the Department.**

**5. The handheld dental x-ray systems shall be certified by the U.S. Food and Drug Administration (FDA) and bear a certification label/tag, a warning label, and an identification (ID) label/tag on the unit's housing. All labels/tags shall be in the English language and permanently affixed or inscribed on each product so that they are legible and**

**readily accessible when the x-ray unit is fully assembled for use. The CERTIFICATION LABEL shall include one of the following or similar statement: "This product complies with 21 CFR 1020.30 - 1020.31" or "This product complies with 21 CFR Subchapter J."**

**6. A 510(k) (premarket notification) letter from the FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements. Documentation shall be made immediately available upon the request of the Department.**

**7. A warning label shall be on the x-ray panel of the unit and state these exact words: "This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."**

**8. Aside from use in emergency situations, a handheld dental x-ray system shall not be used in areas where there may be unintended exposure of other individuals (for example, occupied waiting rooms and corridors.) Exposures shall be made only when the area adjacent to the clinical area is free of all individuals not directly involved in the imaging procedure.**

7:28-[16.7]**16.9** (No change in text.)

7:28-[16.8]**16.10** Radiation safety surveys

(a) No person shall operate or permit the operation of x-ray equipment used for dental radiography unless the installation meets the following requirements:

1.- 2. (No change.)

3. The minimum requirements for the information to be included in the radiation safety survey report are as follows:

i. The name of the registrant of the installation as it appears on [form VRH- 001] **the registration form**, address, telephone number, and room location of the unit;

ii.-vii. (No change.)

viii. Records of the measurement of radiation exposure with a suitable phantom in the average patient position. Measurements shall be taken at the operator's position and at all nearby locations [which] **that** are normally occupied. For each measurement, the kVp, mA, exposure time, instrument reading, and correction made to the instrument reading (such as energy response, calibration, etc.) shall be recorded; [and]

ix. Exposure rates at each measured location shall be converted into Coulombs/kilogram/week or mR/week. Records shall include all assumptions of workload, use and occupancy factors used in the calculations[.]**; and**

**x. A picture of the generator serial plate showing the model number, generator serial number, and control panel serial number.**

Recodify existing N.J.A.C. 7:28-16.9 and 16.10 as **16.11 and 16.12** (No change in text.)