ARTICLE V. RADIOLOGICAL HEALTH

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Authority

The provisions of this Article V issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed), unless otherwise noted.

Source

The provisions of this Article V adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This article cited in 28 Pa. Code § 211.14 (relating to diagnostic services); and 55 Pa. Code § 1230.41 (relating to participation requirements).

CHAPTER 215. GENERAL PROVISIONS

GENERAL PROVISIONS

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Authority

The provisions of this Chapter 215 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 215 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

The provisions of this chapter cited in 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 220.2 (relating to posting of notices to workers); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 232.1 (relating to purpose and scope).

GENERAL PROVISIONS

§ 215.1. Purpose and scope.

(a) This article establishes requirements for the protection of public health and safety as related to radiation sources and implements the requirements of the act.

(b) This article, except as otherwise specifically provided in the act, applies to persons who use, manufacture, produce, transport, transfer, receive, acquire, possess, own or dispose of a radiation source.

(c) A person who, when required, fails to register or obtain a license for radiation sources in the possession or control of the person, shall comply with the act or with this article.

(d) This article does not apply to the extent the person is subject to regulation by the NRC.

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and §§ 150.1, 150.2, 150.3, 150.11 and 150.20 of the CFR are incorporated by reference with the exceptions set forth in paragraphs (1)—(13). Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

(1) Sections 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated.

(2) Sections 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated.

(3) Sections 30.5, 30.6, 30.8, 30.21(c), 30.34(d) and (e)(1) and (3), 30.41(a)(6), 30.55, 30.63 and 30.64 are not incorporated.

(4) Sections 31.4 and 31.14 are not incorporated.

(5) Sections 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29 and 32.40 are not incorporated.

(6) Sections 33.8, 33.21 and 33.23 are not incorporated.

(7) Sections 34.5, 34.8, 34.121 and 34.123 are not incorporated.

(8) Sections 35.8, 35.4001 and 35.4002 are not incorporated.

(9) Sections 36.5, 36.8, 36.91 and 36.93 are not incorporated.

(10) Sections 39.5, 39.8, 39.101 and 39.103 are not incorporated.

(11) Sections 40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated.

(12) Sections 70.1(c), (d) and (e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1), (c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b), 70.23a, 70.24, 70.25(a), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7), 70.32(b)(1), (3) and (4), (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55(c)(1), (2) and (3), 70.56(c) and (d), 70.57, 70.58, 70.59, 70.62, 70.71 and 70.72 are not incorporated.

(13) Sections 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100 are not incorporated.

(f) If a provision of the CFR incorporated by reference in this article includes a section which is inconsistent with this title, this title controls to the extent Federal law does not preempt Commonwealth law. If a provision of the CFR incorporated by reference in this article is beyond the scope of authority granted the Department under statute, or is in excess of the statutory authority, the provisions shall be and remain effective only to the extent authorized by the Pennsylvania law.

(g) Appropriate parts of 10 CFR (relating to energy) may be obtained from the following:

(1) The United States Government Printing Office, Book Store, Room 118, Federal Building, 1000 Liberty Avenue, Pittsburgh, Pennsylvania 15222, (412) 664-2721.

(2) The United States Government Printing Office, Book Store, 100 North 17th Street, Robert Morris Building, Philadelphia, Pennsylvania 19103, (215) 597-0677.

(3) The United States Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

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(h) To reconcile differences between this chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 215.1 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282327) to (282329).

§ 215.2. Definitions.

The definitions in 10 CFR Chapter 1, Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and 150 are incorporated by reference in this article unless indicated otherwise. In addition, the following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

AEC—United States Atomic Energy Commission.

Accelerator-produced material—Material made radioactive by a particle accelerator.

Act—The Radiation Protection Act (35 P. S. §§ 7110.101—7110.703).

Bioassay—The determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this article, "radiobioassay" is an equivalent term.

Brachytherapy—A method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary or interstitial application.

Entrance or access point—An opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radiation sources. The term includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

FDA—The Federal Food and Drug Administration.

Human use—The internal or external administration of radiation or radioactive material to human beings.

Inspection—An official examination or observation including, but not limited to, tests, surveys and monitoring to determine compliance with this article, rules, orders, requirements and conditions of the Department.

Ionizing radiation—Radiation consisting of directly ionizing charged particles—such as electrons, protons, alpha particles and the like—having sufficient kinetic energy to produce ionization by collision, or consisting of either indirectly ionizing uncharged particles—such as neutrons—or photons which can liberate directly ionizing particles or can initiate a nuclear transformation.

License—Permission issued by the Department in accordance with this article to possess and use radiation sources. Types of licenses are as follows:

(i) *General license*—Permission to possess and use radioactive material without the formal review and issuance of documents by the Department.

(ii) *Specific license*—Written permission to possess and use radioactive material issued by the Department after the Department reviews and approves an application for the possession and use of the radiation sources.

Licensed practitioner of the healing arts—An individual licensed by the Commonwealth to practice the healing arts, which for the purposes of this article shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

Licensee—A person who is licensed by the Department under this article and the act.

Licensing state—A state that has regulations equivalent to the Suggested State Regulations for Control of Radiation (United States Department of Health and Human Services) relating to, and has an effective program for, the regulatory control of NARM and which has been granted final designation as a licensing state by the Conference of Radiation Control Program Directors, Inc.

Major X-ray system component—A tube housing assembly, X-ray control, X-ray high voltage generator, X-ray table, cradle, film changer, fixed cassette holder, beam limiting device, fluoroscopic or digital radiographic imaging assembly, spot film device, image intensifier or cephalometric device.

NARM—A naturally occurring or accelerator-produced radioactive material. The term does not include by-product, source or special nuclear material.

NORM—Naturally occurring radioactive material—A nuclide which is radioactive in its natural physical state—that is, not man-made—but does not include source or special nuclear material.

NRC—United States Nuclear Regulatory Commission or its authorized representatives.

Person—An individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency or political subdivision of this Commonwealth; another state or political subdivision or agency thereof; and a legal successor, representative, agent or agency of the entities listed in this paragraph. The term does not include Federal government agencies.

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Pharmacist—An individual licensed by the Commonwealth to compound and dispense drugs, prescriptions and poisons.

Physician—An individual licensed by the Commonwealth to practice medicine or osteopathy in this Commonwealth.

Prescribed dose for therapy using radiation-producing machines—For X-ray, electron or other particle beam therapy, the total dose and dose per fraction as documented in the written directive.

Qualified expert—

(i) For radiation protection, an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs; for example: individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics or those having equivalent qualifications.

(ii) For radiation therapy calibrations, an individual having, in addition to the qualifications in subparagraph (i), training and experience in the clinical applications of radiation physics to radiation therapy.

(iii) For diagnostic X-ray performance evaluations, an individual having, in addition to the qualifications of subparagraph (i), training and experience in the physics of diagnostic radiology.

Radiation—Ionizing radiation.

Radiation producing machine—A device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

Radiation safety officer—An individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

Radiation source—An apparatus or material, other than a nuclear power reactor and nuclear fuel located on a plant site, emitting or capable of emitting ionizing radiation.

Radioactive material—A material—solid, liquid or gas—which emits radiation spontaneously.

Radioactivity—The transformation of unstable atomic nuclei accompanied by the emission of radiation.

Registrant—A person who is legally obligated to register with the Department under this article and the act.

Registration—The act of registering with the Department under this article.

Roentgen (R)—The special unit of exposure to external X-ray and gamma radiation. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air. See § 215.3 (relating to units of exposure).

Traceable to a National standard—A system which has been calibrated by the National Institute of Science and Technology or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine.

Waste handling licensees—Persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

Written directive for therapy using radiation-producing machines—An order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiation therapy treatment:

(i) For X-ray therapy at potentials less than 1 MeV: the total dose, dose per fraction, treatment site, field sizes, tube potential and filtration, and overall treatment period.

(ii) For X-ray, electron or other particle beam therapy at energies of 1 MeV and above: the total dose, dose per fraction, treatment site, field size, beam type and energy, applicator, use of beam blocking or shaping devices, treatment geometry and overall treatment period.

Source

The provisions of this § 215.2 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282329) to (282332).

Cross References

This section cited in 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 236.2 (relating to definitions).

§ 215.3. Units of exposure.

As used in this article, the unit of exposure to external X-ray and gamma radiation expressed in standard international (SI) units is the coulomb per kilogram (C/kg) of air. This represents the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The "roentgen" is a special unit of exposure. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air. One milliroentgen (mR) is equal to 1/1000 roentgen.

Source

The provisions of this § 215.3 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249207) to (249208) and (203799).

Cross References

This section cited in 25 Pa. Code § 215.2 (relating to definitions).

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§ 215.4. [Reserved].

Source

The provisionis of this § 215.4 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203799).

§ 215.5. Effect of Incorporation of the CFR.

(a) *Title and name changes.* To reconcile differences between this chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means "Department, NRC or agreement state."

(b) *Forms and documents.* References to forms in the Federal regulations incorporated by reference will be replaced by the appropriate forms prescribed by the Department.

(c) *Notifications, reports and correspondence.* Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 215.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.11. Records.

(a) Registrants shall maintain records showing the receipt, transfer and disposal of radiation producing machines.

(b) Licensees shall maintain records showing the receipt, transfer and disposal of radioactive material as described in 10 CFR 30.51 (relating to records).

Source

The provisions of this § 215.11 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203799).

§ 215.12. Inspections and investigations.

(a) *Maintenance of records.* Licensees and registrants shall maintain records under this article and have these records available for inspection by the Department at permanent sites or facilities of use identified in a license or registration issued under this article.

(b) *Rights of the Department.* The Department and its agents and employees will:

(1) Have access to, and require the production of, books, papers, documents and other records and physical evidence pertinent to a matter under investigation.

(2) Require a registrant or licensee to make reports and furnish information as the Department may prescribe.

(3) Enter the premises of a licensee or registrant for the purpose of making an investigation or inspection of radiation sources and the premises and facilities where radiation sources are used or stored, necessary to ascertain the compliance or noncompliance with the act and this chapter and to protect health, safety and the environment.

(c) *Inspections and investigations by the Department.* The Department, its employees and agents may conduct inspections and investigations of the facilities and regulated activities of registrants of radiation-producing machines and licensees of radioactive material necessary to demonstrate compliance with the act or this article.

(d) *Additional inspections and investigations.* The Department, its employees and agents may conduct additional follow-up inspections and investigations if violations of the act or regulations promulgated thereunder were noted at the time of the original inspection, or if a person presents information, or circumstances arise which give the Department reason to believe that the health and safety of a person is threatened or that the act or this article are being violated.

Source

The provisions of this § 215.12 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282334).

§ 215.13. Tests.

Licensees and registrants, upon instruction from the Department, shall perform, or permit the Department to perform, reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

(1) Radiation sources.

(2) Facilities in which radiation sources are used or stored.

(3) Radiation detection and monitoring instruments.

(4) Other equipment and devices in connection with utilization or storage of licensed or registered radiation sources.

§ 215.14. Availability of records for public inspection.

The following Department records are not available for public inspection, unless the Department determines that disclosure is in the public interest and is necessary for the Department to carry out its duties under the act:

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(1) Trade secrets or secret industrial processes customarily held in confidence.

(2) A report of investigation, not pertaining to safety and health in industrial plants, which would disclose the institution, progress or results of an investigation undertaken by the Department.

(3) Personnel, medical and similar files, the disclosure of which would operate to the prejudice or impairment of a person's reputation or personal safety.

Source

The provisions of this § 215.14 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282335).

§ 215.15. Additional requirements

The Department may impose upon a person requirements additional to those established in this article which it may deem reasonable and necessary to protect the public health and safety. As an example, when necessary or desirable to determine the extent of an individual's exposure to concentrations of radioactive material, the Department may require a licensee to provide to the individual appropriate bioassay services, medical services and the services of a qualified expert and to furnish a copy of the reports of these services to the Department.

Source

The provisions of this § 215.15 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203801).

PROHIBITIONS AND RESTRICTIONS

§ 215.21. Sale or installation of radiation sources.

No person may sell or install within this Commonwealth a radiation source which does not meet the requirements of this article.

§ 215.22. Prohibited uses.

(a) No person may operate or maintain within this Commonwealth fitting devices or machines which use fluoroscopic, X-ray or radiation principles for the purpose of selling footwear through commercial outlets.

(b) Hand-held fluoroscopic screens may not be used.

§ 215.23. Penalties.

A person who violates this article is subject to the civil and criminal penalties in the act.

§ 215.24. Human use.

(a) No human use of radiation sources may be permitted except under this article, and the following:

(1) Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45).

(2) The Osteopathic Medical Practice Act (63 P. S. §§ 271.1—271.18).

(3) The Chiropractic Registration Act of 1951 (63 P. S. §§ 601—624).

(4) The Dental Law (63 P. S. §§ 120—130g).

(5) The Podiatry Practice Act (63 P. S. §§ 42.1—42.21c).

(b) Auxiliary personnel employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices may use radiation sources in the healing arts provided those individuals comply with the applicable requirements of 49 Pa. Code Part I, Subpart A (relating to professional and occupational affairs), located in the following chapters:

(1) Chapter 5 (relating to the State Board of Chiropractic).

(2) Chapter 16 (relating to the State Board of Medicine—general provisions).

(3) Chapter 17 (relating to the State Board of Medicine—medical doctors).

(4) Chapter 18 (relating to the State Board of Medicine—practitioners other than medical doctors).

(5) Chapter 25 (relating to the State Board of Osteopathic Medicine).

(6) Chapter 29 (relating to the State Board of Podiatry).

(7) Chapter 33 (relating to the State Board of Dentistry).

(c) Auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government may only use radiation sources in the healing arts in accordance with written job descriptions and employee qualifications.

(d) Subsections (b) and (c) notwithstanding, human use of radiation sources is permitted by individuals enrolled in clinical training programs that satisfy the related accreditation requirements of the boards in subsection (b) and who are under the supervision of a licensed practitioner of the healing arts or of auxiliary personnel authorized under subsections (b) and (c) to use radiation sources in the healing arts.

Source

The provisions of this § 215.24 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282336).

§ 215.25. Deliberate misconduct.

The requirements under 10 CFR 30.10 (relating to deliberate misconduct) are incorporated by reference. This requirement also applies to registrants.

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Source

The provisions of this § 215.25 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 215.26. Employee protection.

The requirements under 10 CFR 30.7 (relating to employee protection) are incorporated by reference. This requirement also applies to registrants.

Source

The provisions of this § 215.26 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 215.27. Vacating premises.

In addition to the decommissioning requirements of 10 CFR 30.36 (relating to expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas) that are incorporated by reference under Chapter 217 (relating to licensing of radioactive material), a licensee shall notify the Department in writing of intent to vacate at least 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's activities. When deemed necessary by the Department, the licensee shall decontaminate the premises as the Department may specify.

Source

The provisions of this § 215.27 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 215.28. Improper use of a monitoring device.

The deliberate exposure of, failure to use, or improper use of, an individual monitoring device or area monitoring device by an individual is prohibited.

Source

The provisions of this § 215.28 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282337).

EXEMPTIONS

§ 215.31. Granting exemptions.

The Department may, upon application therefor or upon its own initiative, grant exemptions from this article when the Department determines that they do not result in significant risk to the health and safety of the public and safeguards that provide equivalent levels of protection in this article are implemented.

§ 215.32. Exemption qualifications.

The following sources, uses and types of users are exempt from Chapters 216—221, 223—228, 230, 232 and 240:

(1) A United States Department of Energy contractor or subcontractor and an NRC contractor or subcontractor of the following categories operating within this Commonwealth to the extent that the contractor or subcontractor under contract receives, possesses, uses, transfers, owns or acquires radiation sources:

(i) Prime contractors performing work for the United States Department of Energy at United States Government-owned or controlled sites, including the transportation of radiation sources to or from the sites and the performance of contract services during temporary interruptions of the transportation.

(ii) Prime contractors of the United States Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, nuclear weapons or components thereof.

(iii) Prime contractors of the United States Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government owned vehicle or vessel.

(iv) Other prime contractors or subcontractors of the United States Department of Energy or of the NRC if the Commonwealth and the NRC jointly determine that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and that the exemption of the contractor or subcontractor is otherwise appropriate.

(2) Federal government agencies.

(3) Electrical equipment that produces radiation incidental to its operation for other purposes if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed .5 mrem (.005 mSv) per hour at 5 centimeters from an accessible surface. The equipment is not exempt when operated without adequate shielding during testing and servicing if radiation levels exceed those specified. Electron beam welders and electron microscopes are not exempt.

(4) Radiation-producing machines in transit or in storage incident thereto.

(5) A material, product or use specifically exempted from licensing requirements by the NRC, the Department or an agreement state or authorized for distribution to persons exempt from license requirements.

Source

The provisions of this § 215.32 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282337) to (282338).

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COMMUNICATIONS

§ 215.41. Address.

Communications and reports concerning this article and applications filed under it shall be addressed to the Bureau of Radiation Protection, Department of Environmental Protection, Post Office Box 8469, Harrisburg, Pennsylvania 17105-8469.

Source

The provisionis of this § 215.41 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial page (123511).

Cross References

This section cited in 25 Pa. Code § 230.5 (relating to communications).

[Next page is 216-1.]

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CHAPTER 216. REGISTRATION OF RADIATION-PRODUCING MACHINES AND RADIATION-PRODUCING MACHINE SERVICE PROVIDERS

Sec.
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Authority

The provisions of this Chapter 216 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 216 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 218.1 (relating to purpose and scope); and 25 Pa. Code § 220.1 (relating to purpose and scope).

§ 216.1. Purpose and scope.

(a) This chapter establishes requirements for the registration of radiation-producing machines and radiation-producing machine service providers. A person who possesses a radiation-producing machine or provides services described in this chapter shall comply with this chapter.

(b) A person possessing an accelerator as defined in § 228.2 (relating to definitions) is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines). Accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators) and license fees are specified in § 218.11(d) (relating to registration, renewal of registration and license fees).

Authority

The provisions of this § 216.1 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S.§ 510-20).

Source

The provisions of this § 216.1 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282339).

§ 216.2. Registration of radiation-producing machines.

(a) A person possessing a radiation-producing machine shall:

(1) Register with the Department within 30 days after acquisition. Registration shall be completed on forms furnished by the Department and shall contain information required on the form and accompanying instructions.

(2) Designate on the registration form an individual to be responsible for radiation protection.

(3) Notify the Department in writing within 30 days of a change of address, owner or radiation safety officer or number of machines.

(b) The registration becomes valid upon receipt of the properly completed registration form and the fee required under Chapter 218 (relating to fees).

(c) A certificate of registration will be issued by the Department to a person whose registration becomes valid under subsection (b).

(d) A registrant shall have the currently valid certificate of registration available for inspection by the Department.

(e) A certificate of registration issued under this chapter may not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, to any person without submitting a written request by the registrant to the Department.

Authority

The provisions of this § 216.2 amended under sections 301, 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.301, 7110.302 and 7110.401); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.2 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended January 1, 1988, effective January 2, 1988, 18 Pa.B. 11; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282339) to (282340).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration); 25 Pa. Code § 216.7 (relating to out-of-State radiation-producing machines); and 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees).

§ 216.2a. Registration of radiation-producing machine service providers.

After July 17, 2004, a person who engages in the business of assembling or installing radiation-producing machines or who offers to assemble or install

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radiation-producing machines or who is in the business of furnishing or offering to furnish radiation-producing machine servicing or services or who is in the business of selling, leasing or lending radiation-producing machines in this Commonwealth shall apply for registration of the activities with the Department prior to furnishing or offering to furnish those services.

(1) Registration is for 12 months and is renewable.

(2) An application for registration or renewal will not be accepted unless accompanied by the appropriate fee specified in § 218.11(h) (relating to registration, renewal of registration and license fees). Fees are not refundable after issuance of a registration.

(3) An application for registration shall be submitted on forms provided by the Department. The Department will issue a certificate of registration for radiation-producing machine services to the applicant when the application is complete, contains all the information required by the Department and when the appropriate fee specified in § 218.11(h) has been paid.

(4) A person who, on July 17, 2004, is currently in the business of providing radiation-producing machine services shall apply for registration by September 15, 2004.

Authority

The provisions of this § 216.2a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.2a adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

Cross References

This section cited in 25 Pa. Code § 216.3 (relating to exemptions); and 25 Pa. Code 216.4a (relating to expiration and termination of certificates of registration).

§ 216.2b. Reporting and recordkeeping requirements for registered radiation-producing machine service providers.

(a) A radiation-producing machine service provider who installs, services, sells, leases or otherwise transfers a radiation producing-machine or major X-ray system component in this Commonwealth shall submit information to the Department and maintain records as described in this section.

(1) The following information shall be submitted in writing to the Department within 15 days of the action:

(i) The date of installation, service or transfer.

(ii) The name, address, telephone number and registration number, if registered, of the client facility.

(iii) The type of radiation-producing machine, the manufacturer's name, model number and control panel serial number of each radiation-producing machine, or major X-ray system components involved in the transaction.

(iv) A contact name of the individual for the service action.

(2) A copy of the assembler's report on United States Food and Drug Administration (FDA) Form 2579, prepared in compliance with the Federal diagnostic X-ray standard (21 CFR 1020.30(d)(1) (relating to diagnostic x-ray systems and their major components)), when completed in full and submitted to the Department within 15 days following the service, satisfies the requirements of paragraph (1) and subsection (d) for services provided under the assembler's report.

(b) Services performed under preventative maintenance that do not involve replacement or refurbishing of major X-ray system components are exempt from the reporting requirements specified in this section except subsection (d).

(c) A radiation-producing machine service provider shall maintain a log or other record of radiation-producing machines installed or serviced in this Commonwealth. The record shall be maintained for 5 years for inspection by the Department and shall list the following information:

(1) The date the machine was installed or service provided.

(2) The name of the customer, address, telephone number and customer's State registration number.

(3) The type of radiation-producing machine, the manufacturer's name, model number and control panel serial number of each radiation-producing machine or major X-ray system component involved.

(4) The name of the individual performing the service.

(d) A radiation-producing machine service provider who services a radiation-producing machine in a radiation installation in this Commonwealth that is not registered shall report the service to the Department. The report shall be submitted in writing within 15 days after the services and contain the following information:

(1) The date service was provided.

(2) The name, address and telephone number of the client.

(3) The type of radiation-producing machine, the manufacturer's name, model number and control panel serial number of each radiation-producing machine or major X-ray system component.

(4) The name of the individual performing the service.

Authority

The provisions of this § 216.2b issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.2b adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

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Cross References

This section cited in 25 Pa. Code § 216.6 (relating to transfer and disposal obligations).

§ 216.3. Exemptions.

The following radiation-producing machines or equipment are exempt from registration:

(1) Electrical equipment that produces radiation incidental to its operation for other purposes, if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed .5 mrem (.005 mSv) per hour at 5 centimeter from an accessible surface. The production, testing or factory servicing of the equipment are not exempt. Electron beam welders and electron microscopes are not exempt.

(2) Radiation-producing machines while in transit in the possession of a transport carrier.

(3) Radiation-producing machines in the possession of vendors, installers or persons engaged in the service or repair of the machines, if applicable persons who have these machines register their activities with the Department under § 216.6 (relating to transfer and disposal obligations).

(4) Accelerators are exempt from registration. Accelerators shall be licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Accelerator service providers are not exempt from registration of services under § 216.2a (relating to registration of radiation-producing machine service providers).

Authority

The provisions of this § 216.3 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.3 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282340).

§ 216.4. Renewal of certificate of registration.

(a) The Department will send an application for renewal of the certificate of registration to the registrant at least 2 months prior to the expiration date on the certificate of registration. The application for renewal will include references to the fee due under § 218.11 (relating to registration, renewal of registration and license fees).

(b) An applicant for renewal of a registration shall submit a signed application and the fee required under § 218.11 prior to the expiration date of the certificate of registration.

(c) The renewal becomes valid upon receipt of the properly completed application and the fee required under Chapter 218 (relating to fees).

Authority

The provisions of this § 216.4 amended under sections 301, 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.301, 7110.302 and 7110.401); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.4 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203806).

Cross References

This section cited in 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration); and 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees).

§ 216.4a. Expiration and termination of certificates of registration.

(a) A certificate of registration expires on the date specified on the certificate of registration. Expiration of the certificate of registration does not relieve the registrant from the requirements of this article.

(b) When a registrant decides to terminate all activities involving radiation-producing machines under the certificate of registration, the registrant shall notify the Department immediately, in writing, and request termination of the certificate of registration. This notification and request for termination of the certificate of registration shall be in accordance with subsection (c).

(c) If a registrant does not submit a renewal for a certificate of registration under § 216.4 (relating to renewal of certificate of registration), the registrant shall, on or before the expiration date specified in the certificate of registration, do the following:

(1) Terminate use of all radiation-producing machines subject to registration under § 216.2 (relating to registration of radiation-producing machines) or cease all radiation-producing machine services subject to registration under § 216.2a (relating to registration of radiation-producing machine service providers).

(2) Transfer or dispose of all radiation-producing machines subject to registration under § 216.2 in accordance with § 216.6 (relating to transfer and disposal obligations).

(3) Remit any outstanding registration or renewal of registration fees owed to the Department under § 218.11 (relating to registration, renewal of registration and license fees).

(4) Request termination of the certificate of registration in writing to the Department.

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Authority

The provisions of this § 216.4a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.4a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249211) to (249212).

§ 216.5. Approval not implied.

No person, in an advertisement, may refer to the fact that radiation-producing machines are registered by the Department nor state that an activity under the registration has been approved by the Department.

Source

The provisions of this § 216.5 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§ 216.6. Transfer and disposal obligations.

(a) A person, distributor, retailer or other agent who, by selling, leasing, lending or gifting, transfers possession of radiation-producing machines or major X-ray system components in this Commonwealth that are not otherwise reported under § 216.2b (relating to reporting and recordkeeping requirements for registered radiation-producing machine service providers), shall notify the Department within 30 days of the following information:

(1) The name and address of persons who have received the machines or components.

(2) The manufacturer, model and serial number of a machine or component transferred.

(3) The date of transfer of a radiation-producing machine or major X-ray system component.

(b) A person who disposes of a radiation-producing machine shall notify the Department within 15 days of the method of disposal used.

Authority

The provisions of this § 216.6 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.6 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249212) and (282341).

Cross References

This section cited in 25 Pa. Code § 216.3 (relating to exemptions); and 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration).

§ 216.7. Out-of-State radiation-producing machines.

(a) If a radiation-producing machine is brought into this Commonwealth for temporary use, the person proposing to do so or an authorized agent shall give written notice to the Department at least 2 working days before the machine enters this Commonwealth. The notice shall include the type of machine, the nature, duration and scope of use and the exact location where the machine is to be used. In addition, the person shall:

(1) Comply with this title.

(2) Supply the Department with other information as the Department may reasonably request.

(3) Not operate within this Commonwealth on a temporary basis in excess of 60 calendar days per year.

(b) If for a specific case, the 2-working-day period would impose an undue hardship, the person, upon application to the Department, may receive a waiver of this requirement.

(c) When a radiation-producing machine is brought into this Commonwealth for temporary use exceeding 60 days per year, a person possessing the machine shall register with the Department under § 216.2 (relating to registration of radiation-producing machines) within 15 days after the 60th day.

Authority

The provisions of this § 216.7 amended under sections 301, 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.301, 7110.302 and 7110.401); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.7 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282341).

Cross References

This section cited in 25 Pa. Code § 225.5a (relating to reciprocity).

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CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

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Authority

The provisions of this Chapter 217 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 217 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.27 (relating to vacating premises); 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 218.1 (relating to purpose and scope); 25 Pa. Code § 220.1 (relating to purpose and scope); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); 25 Pa. Code § 228.37 (relating to production of radioactive material); and 25 Pa. Code § 232.1 (relating to purpose and scope).

Subchapter A. GENERAL

Sec.
217.1. Purpose and scope.
217.2. Address for communications.

§ 217.1. Purpose and scope.

(a) This chapter establishes requirements for the licensing of radioactive material. Persons who use radioactive material shall comply with this chapter. A person may not receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued under this chapter or otherwise provided in this chapter.

(b) A licensee is subject to Chapters 215, 218—220 and 230. A licensee engaged in industrial uses and radiographic operations is subject to Chapter 225 (relating to radiation safety requirements for industrial radiographic operations). A licensee using radioactive material for human use is subject to Chapter 224 (relating to medical use of radioactive material). A licensee using sealed sources in well logging is subject to Chapter 226 (relating to licenses and radiation safety requirements for well logging). A licensee using sealed sources in irradiators is subject to Chapter 232 (relating to licenses and radiation safety requirements for irradiators). A licensee for the disposal of low-level radioactive wastes received from other persons is subject to Chapter 236 (relating to low-level radioactive waste management and disposal).

(c) The use of radioactive material in this Commonwealth under a license issued by the NRC is exempt from the licensing requirements of this chapter until the Commonwealth becomes an agreement state on the date published in the *Federal Register.*

Source

The provisions of this § 217.1 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203809) to (203810).

§ 217.2. Address for communications.

An application for a license, license renewal and license amendments and other communications under this chapter shall be addressed to the Bureau of Radiation Protection, Department of Environmental Protection, Post Office Box 8469, Harrisburg, Pennsylvania 17105-8469.

Source

The provisions of this § 217.2 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203810).

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

Sec.
217.11—217.18. [Reserved].
217.21—217.24. [Reserved].
217.31 and 217.32. [Reserved].
217.41—217.44. [Reserved].
217.45. [Reserved].
217.46—217.48. [Reserved].
217.49. [Reserved].
217.51. [Reserved].
217.52. [Reserved].

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217.53—217.56.	[Reserved].
217.57.	[Reserved].
217.61—217.64.	[Reserved].
217.65.	[Reserved].
217.71—217.73.	[Reserved].
217.74.	[Reserved].
217.81—217.83.	[Reserved].
217.84.	[Reserved].
217.85—217.87.	[Reserved].
217.88.	[Reserved].
217.89.	[Reserved].
217.90—217.92.	[Reserved].
217.93.	[Reserved].
217.101.	[Reserved].
217.111—217.114.	[Reserved].
217.121.	[Reserved].
217.122.	[Reserved].
217.131.	Incorporation by reference.
217.132.	Effect of incorporation of 10 CFR Part 30.
217.133.	Persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register*.
217.134.	Filing application for specific licenses.
217.135.	Renewal of licenses.
217.136.	Exempt concentrations.
217.137.	Exempt quantities.

Cross References

This subchapter cited in 25 Pa. Code § 217.153 (relating to licensing the incorporation of NARM into gas and aerosol detectors); and 25 Pa. Code § 217.203 (relating to reciprocity of licenses of naturally occurring and accelerator-produced radioactive material).

§§ 217.11—217.18. [Reserved].

Source

The provisions of these §§ 217.11—217.18 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203810) to (203817).

§§ 217.21—217.24. [Reserved].

Source

The provisions of these §§ 217.21—217.24 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203819) to (203821).

§§ 217.31 and 217.32. [Reserved].

Source

The provisions of these §§ 217.31 and 217.32 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203821) to (203823).

§§ 217.41—217.44. [Reserved].

Source

The provisions of these §§ 217.41—217.44 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203823) to (203828).

§ 217.45. [Reserved].

Source

The provisions of this § 217.45 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203829) to (203830).

§§ 217.46—217.48. [Reserved].

Source

The provisions of these § 217.46—217.48 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203830) to (203832) and (249215) to (249216).

§ 217.49. [Reserved].

Source

The provisions of this § 217.49 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249216).

§ 217.51. [Reserved].

Source

The provisions of this § 217.51 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249217).

§ 217.52. [Reserved].

Source

The provisions of this § 217.52 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249217) to (249218).

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§§ 217.53—217.56. [Reserved].

Source

The provisions of these §§ 217.53—217.56 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249218) to (249221).

§ 217.57. [Reserved].

Source

The provisions of this § 217.57 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249221).

§§ 217.61—217.64. [Reserved].

Source

The provisions of these § 217.61—217.64 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial pages (123549) to (123556).

§ 217.65. [Reserved].

Source

The provisions of this § 217.65 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249222) to (249233).

§§ 217.71—217.73. [Reserved].

Source

The provisions of these § 217.71—217.73 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249223) to (249226).

§ 217.74. [Reserved].

Source

The provisions of this § 217.74 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249226).

§§ 217.81—217.83. [Reserved].

Source

The provisions of these §§ 217.81—217.83 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249226) to (249230).

§ 217.84. [Reserved].

Source

The provisions of this § 217.84 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249230) to (249234).

§§ 217.85—217.87. [Reserved].

Source

The provisions of these §§ 217.85—217.87 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249234) to (249235).

§ 217.88. [Reserved].

Source

The provisions of this § 217.88 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249235) to (249237).

§ 217.89. [Reserved].

Source

The provisions of this § 217.89 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249237) to (249238).

§§ 217.90—217.92. [Reserved].

Source

The provisions of these §§ 217.90—217.92 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249238) to (249242).

§ 217.93. [Reserved].

Source

The provisions of this § 217.93 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249242) to (249244).

§ 217.101. [Reserved].

Source

The provisions of this § 217.101 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203863) to (203864).

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§§ 217.111—217.114. [Reserved].

Source

The provisions of these §§ 271.111—217.114 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206. Immediately preceding text appears at serial pages (170357) to (170360).

§ 217.121. [Reserved].

Source

The provisions of this § 217.121 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203864) to (203866).

§ 217.122. [Reserved].

Source

The provisions of this § 217.122 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203866) to (203867).

§ 217.131. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 30.5, 30.6, 30.8, 30.21(c), 30.34(d), (e)(1) and (3), 30.41(a)(6), 30.55, 30.63 and 30.64 are not incorporated by reference.

Source

The provisions of this § 217.131 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 217.132. Effect of incorporation of 10 CFR Part 30.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 30, the following words and phrases shall be substituted for the language in 10 CFR Part 30 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 217.132 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 217.133. Persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register.*

On the date the Commonwealth becomes an agreement state as published in the *Federal Register*, a person who possesses a general or specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass, is deemed to possess a like license issued under this chapter and the act. The license shall expire either 90 days after receipt from the Department of a notice of expiration of the license, or on the date of expiration specified in the NRC license, whichever is earlier.

Source

The provisions of this § 217.133 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Cross References

This section cited in 25 Pa. Code § 217.203 (relating to reciprocity of licenses for byproduct, source, naturally occuring and accelerator-produced radioactive material and special nuclear material in quantities not sufficient to form a critical mass).

§ 217.134. Filing application for specific licenses.

In addition to incorporation by reference, an application for a specific license shall be accompanied by the fee required under Chapter 218 (relating to fees).

Source

The provisions of this § 217.134 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Cross References

This section cited in 25 Pa. Code § 217.135 (relating to renewal of licenses).

§ 217.135. Renewal of licenses.

(a) An application for renewal of a specific license shall be filed under § 217.134 (relating to filing application for specific licenses).

(b) If a renewal application is filed prior to 30 days before the expiration of a license, the existing license does not expire until definitive notice has been given by the Department of its action on the renewal application. This subsection also applies to new license applications incorporating other licenses.

Source

The provisions of this § 217.135 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

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§ 217.136. Exempt concentrations.

In addition to the parts of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) incorporated by reference, the following requirements apply:

(1) Except as provided in paragraph (2), a person may receive, possess, use, transfer, own or acquire products or materials containing radioactive material introduced in concentrations less than those listed in Table 1 without possession of a license under this chapter.

(2) Except under a specific license issued under Subchapter D (relating to specific licenses to manufacture or transfer certain items containing radioactive material), or the general license under Subchapter F (relating to specific domestic licenses of broad scope for radioactive material), a person may not introduce radioactive material into a product or material for distribution to persons exempt under paragraph (1) or equivalent regulations of the NRC, an agreement state or licensing state.

TABLE 1
EXEMPT CONCENTRATIONS

Note: Some of the values in Table A-1 are presented in the computer "E" notation. In this notation, a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600 and 6E+0 represents 6×10^{0} or 6.

Element (atomic number)	*Isotope*	*Column I Gas concentration μCi/ml*	*Column II Liquid and solid concentration μCi/ml*
Actinium (89)	Ac-228		9E-04
Cesium (55)	Cs-129		3E-03
Europium (63)	Eu-154		2E-04
Gallium (31)	Ga-67		2E-03
Germanium (32)	Ge-68		9E-03
Gold (79)	Au-195		1E-02
Indium (49)	In-111		1E-03
Iodine (53)	I-123		3E-04
	I-124		4E-06
	I-125		2E-06
Lead (82)	Pb-212		2E-04
Phosphorus (15)	P-33		3E-04
Potassium (19)	K-43		2E-04
Protactinium (91)	Pa-230		2E-03
Radium (88)	Ra-223		7E-06
	Ra-224		2E-05
	Ra-228		3E-07

Element (atomic number)	*Isotope*	*Column I Gas concentration μCi/ml*	*Column II Liquid and solid concentration μCi/ml*
Radon (86)	Rn-220	1E-07	
	Rn-222	3E-08	
Sodium (11)	Na-22		4E-04
Technetium (43)	Tc-97m		4E-03
Xenon (54)	Xe-127	4E-06	
Yttrium (39)	Y-88		8E-04

Source

The provisions of this § 217.136 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282351) to (282352).

§ 217.137. Exempt quantities.

In addition to the parts of 10 CFR 30 incorporated by reference, the following requirements apply:

(1) A person may receive, possess, use, transfer, own or acquire radioactive material in individual quantities each of which is less than those listed in Table 2 if the person does not produce, package or repackage radioactive material for purposes of commercial distribution or incorporate radioactive material into products intended for commercial distribution.

(2) Except under a specific license issued by the Department or the NRC under 10 CFR 32.18 (relating to manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license), a person may not, for purposes of commercial distribution, transfer radioactive material for distribution to persons exempt under paragraph (1) or equivalent regulations of the NRC, an agreement state or licensing state.

TABLE 2

EXEMPT QUANTITIES

Radioactive Material	*Microcuries*
Actinium-228 (Ac 228)	1
Beryllium-7 (Be 7)	10
Bismuth-207 (Bi 207)	10
Cesium-129 (Cs 129)	100
Cobalt-57 (Co 57)	100
Gallium-67 (Ga 67)	100
Germanium-68	10
Gold-195 (Au 195)	10

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Radioactive Material	*Microcuries*
Gold-196 (Au 196)	1
Indium-111 (In 111)	100
Iodine-123 (I 123)	100
Iodine-124 (I 124)	1
Iridium-190 (Ir 190)	100
Lead-203 (Pb 203)	100
Lead-210 (Pb 210)	0.1
Lead-212 (Pb 212)	10
Phosphorus-33 (P 33)	10
Potassium-43 (K 43)	10
Protactinium-230 (Pa 230)	10
Protactinium-231 (Pa 231)	0.1
Radium-223 (Ra 223)	1
Radium-224 (Ra 224)	1
Radium-226 (Ra 226)	0.1
Radium-228 (Ra 228)	0.1
Radon-220 (Rn 220)	1
Radon-222 (Rn 222)	1
Rhenium-183 (Re 183)	100
Rhenium-187 (Re 187)	100
Rubidium-81 (Rb 81)	10
Scandium-46 (Sc 46)	10
Sodium-22 (Na 22)	10
Technetium-96m (Tc 96m)	100
Xenon-127 (Xe 127)	1,000
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10

Source

The provisions of this § 217.137 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

Sec.
217.141. Incorporation by reference.
217.142. Effect of incorporation of 10 CFR Part 31.
217.143. Certain measuring, gauging or controlling devices.
217.144. Incidental radioactive material produced by a particle accelerator.

Source

The provisions of this Subchapter C adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.203 (relating to reciprocity of licenses of naturally occurring and accelerator-produced radioactive material).

§ 217.141. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 31 (relating to general domestic licenses for byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 31.4 and 31.14 (relating to information collection requirements: OMB approval; and criminal penalties) are not incorporated by reference.

Source

The provisions of this § 217.141 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282354).

§ 217.142. Effect of incorporation of 10 CFR Part 31.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 31 (relating to general domestic licenses for byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 31 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

§ 217.143. Certain measuring, gauging or controlling devices.

In addition to the parts of 10 CFR 31.5 (relating to certain detecting measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere) incorporated by reference, general licensees subject to registration under 10 CFR 31.5(c)(13)(i) or possessing general licensed devices containing 37 MBq (1 mCi) or more of accelerator-produced material, as determined on the date of manufacture, or 3.7 MBq (0.1 mCi) or more of radium-226 shall also comply with the following:

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(1) Conduct a physical inventory every 6 months to account for all sources or devices, or both, received and possessed under this section and do the following:

(i) Maintain the physical inventory records for 3 years from the date of each inventory.

(ii) Furnish a report to the Department annually showing to the extent practicable, the make, model, serial number, isotope, source activity and location of each device. The report shall list an individual to contact regarding questions about this report.

(2) For portable devices, also comply with the following:

(i) A person who initiates acquisition, transfer or disposal of a portable device shall notify the Department within 15 days of the action. Sending a portable device for calibration, maintenance or source replacement does not constitute transfer.

(ii) Portable devices may only be used by or under the direct supervision of individuals who have been instructed in the operating and emergency procedures necessary to ensure safe use.

(iii) For each individual that the licensee permits to use a portable device, the licensee shall maintain a record showing the type of device use permitted and the basis, such as training certificates, for that authorization. An individual's record shall be kept for at least 3 years after the individual terminates association with the licensee.

(iv) Portable devices shall be secured from access by unauthorized personnel whenever the device is not under the direct surveillance of an individual authorized to use the device.

(v) The licensee shall maintain a current sign out log at the permanent storage location of the portable device. Log entries shall be available for inspection by the Department for 3 years from the date of entry. The following information shall be recorded for each portable device:

(A) The model and serial number of the device.

(B) The name of the assigned user.

(C) The locations and dates of use.

(vi) Emergency instructions shall accompany each portable device taken off the premises of the licensee.

Source

The provisions of this § 217.143 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282354) to (282355).

Cross References

This section cited in 25 Pa. Code Chapter 218, Appendix A (relating to fees for radioactive material licenses).

§ 217.144. Incidental radioactive material produced by a particle accelerator.

A general license is issued to possess radioactive material produced incidentally to the operation of a particle accelerator. The general license is also subject to the applicable provisions of this chapter and Chapters 215, 219 and 220 (relating to general provisions; standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations). A licensee may transfer this radioactive material only under Subchapter I and Chapter 230 (relating to transfer of radioactive material; and packaging and transportation of radioactive material). A licensee may dispose of this radioactive material only with Department approval.

Cross References

This section cited in 25 Pa. Code § 228.37 (relating to production of radioactive materials).

Subchapter D. SPECIFIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING RADIOACTIVE MATERIAL

Sec.
217.151. Incorporation by reference.
217.152. Effect of incorporation of 10 CFR Part 32.
217.153. Licensing the incorporation of NARM into gas and aerosol detectors.
217.154. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226.
217.155. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

Source

The provisions of this Subchapter D adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.136 (relating to exempt concentrations).

§ 217.151. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29 and 32.40 are not incorporated by reference.

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§ 217.152. Effect of incorporation of 10 CFR Part 32.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 32 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to byproduct material includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

§ 217.153. Licensing the incorporation of NARM into gas and aerosol detectors.

An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subchapter B (relating to general provisions for radioactive material) will be approved if the application satisfies requirements equivalent to those in 10 CFR 32.26—32.29. The maximum quantity of radium-226 may not exceed 0.1 microcuries (3.7 kBq).

§ 217.154. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226.

In addition to the incorporation by reference of requirements in 10 CFR 32.57 (relating to calibration sources containing americium-241), applicants using plutonium and radium-226 in the manufacture of calibration or reference sources shall comply with 10 CFR 32.57.

§ 217.155. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

(a) In addition to the incorporation by reference of requirements in 10 CFR 32.71 (relating to manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license), applicants using cobalt-57 shall prepare for distribution the cobalt-57 in prepackaged units that do not exceed 10 microcuries (370 kBq) of cobalt-57.

(b) A prepackaged unit shall bear a durable, clearly visible label identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) cobalt-57.

Subchapter F. SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR RADIOACTIVE MATERIAL

Sec.
217.161. Incorporation by reference.
217.162. Effect of incorporation of 10 CFR Part 33.
217.163. Types of specific licenses of broad scope.

Source

The provisions of this Subchapter F adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.136 (relating to exempt concentrations).

§ 217.161. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 33 (relating to specific domestic licenses of broad scope for byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 33.8, 33.21 and 33.23 (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

§ 217.162. Effect of incorporation of 10 CFR Part 33.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 33, the following words and phrases shall be substituted for the language in 10 CFR Part 33 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to byproduct material includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

§ 217.163. Types of specific licenses of broad scope.

In addition to the incorporation by reference of 10 CFR 33.11 (relating to types of specific licenses of broad scope), the following requirements for licensees using NARM also apply:

(1) A Type A specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the act.

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The quantities specified exceed those specified in Column I, Table 3 and are usually in the multicurie range.

(2) A Type B specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in Table 3, for an authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I, Table 3. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column I, Table 3, for that radionuclide; the sum of the ratios for radionuclides possessed under the license may not exceed unity.

(3) A Type C specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in Table 3, for an authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column II, Table 3. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Column II, Table 3, for that radionuclide; the sum of the ratios for radionuclides possessed under the license may not exceed unity.

TABLE 3

LIMITS FOR BROAD LICENSES

Radioactive Material	*Col. I curies*	*Col. II curies*
Beryllium-7	10	0.1
Cobalt-57	10	0.1
Radium-226	0.01	0.0001
Scandium-46	1	0.01
Sodium-22	0.1	0.001

Subchapter G. LICENSING OF SOURCE MATERIAL

Sec.
217.171. Incorporation by reference.
217.172. Effect of incorporation of 10 CFR Part 40.

Source

The provisions of this Subchapter G adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

§ 217.171. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 40 (relating to domestic licensing of source material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated by reference.

Source

The provisions of this § 217.171 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282359).

§ 217.172. Effect of incorporation of 10 CFR Part 40.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 40 (relating to domestic licensing of source material), the following words and phrases shall be substituted for the language in 10 CFR Part 40 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Subchapter H. LICENSING OF SPECIAL NUCLEAR MATERIAL

Sec.
217.181. Incorporation by reference.
217.182. Effect of incorporation of 10 CFR Part 70.

Source

The provisions of this Subchapter H adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

§ 217.181. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 70 (relating to domestic licensing of special nuclear material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 70.1(c), (d) and (e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1),

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(c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b), 70.23a, 70.24, 70.25(a), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7) and (b)(1), (3) and (4) and (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55(c)(1), (2) and (3), 70.56(c) and (d), 70.57, 70.58, 70.59, 70.62, 70.71 and 70.72 are not incorporated by reference.

§ 217.182. Effect of incorporation of 10 CFR Part 70.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 70 (relating to domestic licensing of special nuclear material), the following words and phrases shall be substituted for the language in 10 CFR Part 70 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Subchapter I. TRANSFER OF RADIOACTIVE MATERIAL

Sec.
217.191. Transfer of material.

Source

The provisions of this Subchapter I adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator).

§ 217.191. Transfer of material.

The requirements of 10 CFR 30.41 (relating to transfer of byproduct material) also apply to NARM.

Subchapter J. RECIPROCITY

Sec.
217.201. Incorporation by reference.
217.202. Effect of incorporation of 10 CFR Part 150.
217.203. Reciprocity of licenses for byproduct source, naturally occurring and accelerator-produced radioactive material and special nuclear material in quantities not sufficient to form a critical mass.

Source

The provisions of this Subchapter J adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

§ 217.201. Incorporation by reference.

Except as provided in this subchapter, the requirements of 10 CFR 150.1, 150.2, 150.3, 150.11 and 150.20 are incorporated by reference.

Source

The provisions of this § 217.201 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282361).

§ 217.202. Effect of incorporation of 10 CFR Part 150.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 150 (relating to exemptions and continued regulatory authority in agreement states and in offshore waters under section 274), the following words and phrases shall be substituted for the language in 10 CFR Part 150:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 217.202 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282362).

§ 217.203. Reciprocity of licenses for byproduct, source, naturally occurring and accelerator-produced radioactive material and special nuclear material in quantities not sufficient to form a critical mass.

(a) Subject to this article, a person who holds a specific license from the NRC or a state where the licensee maintains an office, issued by the agency hav-

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ing jurisdiction to direct the licensed activity and to maintain radiation safety records, is granted a general license to conduct the activities authorized in the licensing document within this Commonwealth, except for areas of exclusive Federal jurisdiction, for a period not in excess of 180 days in a calendar year if:

(1) The licensing document does not limit the activity authorized by the document to specified installation or locations.

(2) The out-of-State licensee notifies the Department in writing at least 3 days prior to engaging in the activity. The notification shall indicate the location, period and type of proposed possession and use within this Commonwealth, and shall be accompanied by a copy of the pertinent licensing document. If for a specific case the 3-day period would impose an undue hardship on the out-of-State licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection.

(3) The out-of-State licensee complies with this title and with the terms and conditions of the licensee's document, except terms and conditions which may be inconsistent with this title.

(4) The out-of-State licensee supplies other information as the Department may request.

(5) The out-of-State licensee does not transfer or dispose of radioactive material possessed or used under the general license provided in this subsection except by transfer to a person who is one of the following:

(i) Specifically licensed by the Department, the NRC or by another state to receive the material.

(ii) Exempt from the requirements for a license for the material under Subchapter B (relating to general provisions for radioactive material).

(b) Notwithstanding the provisions of subsection (a), a person who holds a specific license issued by the NRC or a state authorizing the holder to manufacture, transfer, install or service a device described in Subchapter C (relating to general licenses for radioactive material) within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate or service the device in this Commonwealth subject to the following conditions:

(1) The person files a report with the Department within 30 days after the end of a calendar quarter in which a device is transferred to or installed in this Commonwealth. The report shall identify the general licensee to whom the device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device.

(2) The device has been manufactured, labeled, installed and serviced in accordance with the specific license issued to the person by the NRC or a state.

(3) The person assures that labels required to be affixed to the device, under regulations of the authority which licensed manufacture of the device, bear a statement that "Removal of this label is prohibited."

(4) The holder of the specific license or his intermediary shall provide a copy of the conditions of general license contained in Subchapter C to the general licensee upon transfer of the radioactive material or installation of a device containing the radioactive material.

(c) The Department may withdraw, limit or qualify its acceptance of a specific license or equivalent licensing document issued by another agency, or product distributed under the licensing document, upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

(d) When a person is granted a general license under subsection (a) and subsequently exceeds the prescribed 180-day period, the person shall file a license application with the Department under Subchapter B within 30 days after the end of the 180-day period.

(e) Implementation of the requirements of this section regarding byproduct, source and special nuclear material is subject to § 217.133 (relating to persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register*).

Source

The provisions of this § 217.203 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282362) to (282363).

APPENDIX A. [Reserved]

Source

The provisions of this Appendix A reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203868) to (203873).

APPENDIX B. [Reserved]

Source

The provisions of this Appendix B reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203874) to (203879).

APPENDIX C. [Reserved]

Source

The provisions of this Appendix C adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135. Immediately preceding text appears at serial pages (123598) to (123600).

APPENDIX D. [Reserved]

Source

The provisions of this Appendix D reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203879) to (203884).

[Next page is 218-1.]

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CHAPTER 218. FEES

GENERAL

Sec.
218.1. Purpose and scope.

PAYMENT OF FEES

218.11. Registration, renewal of registration and license fees.
218.12. Failure by registrant or licensee to pay required fee.

Authority

The provisions of this Chapter 218 issued under sections 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.302 and 7110.401), unless otherwise noted.

Source

The provisions of this Chapter 218 adopted December 31, 1987, effective January 2, 1988, 18 Pa.B. 11, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 216.2 (relating to registration); 25 Pa. Code § 216.4 (relating to renewal of certificate of registration); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.134 (relating to filing applications for specific licenses); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 232.1 (relating to purpose and scope).

GENERAL

§ 218.1. Purpose and scope.

(a) This chapter establishes fees for registration and licensing and provides for their payment. For the purpose of this chapter, radiation-producing machines under the same administrative control in a single building are registered or licensed as a single facility. Radiation-producing machines under the same administrative control at the same address or in a contiguous group of buildings may be registered or licensed as a single facility if the Department determines that it is appropriate.

(b) Except as otherwise specifically provided, this chapter applies to a person who:

(1) Is required to register or renew registration for radiation-producing machines or radiation-producing machine service providers under Chapter 216 (relating to registration of radiation-producing machines and radiation-producing machine service providers).

(2) Is an applicant for or holder of a radioactive material license issued under Chapter 217 (relating to licensing of radioactive material).

(3) Is an applicant for or holder of an accelerator license issued under Chapter 228 (relating to radiation safety requirements for particle accelerators).

Authority

The provisions of this § 218.1 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 218.1 amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285659) to (285660).

PAYMENT OF FEES

§ 218.11. Registration, renewal of registration and license fees.

(a) Annual registration fees for radiation-producing machines, other than accelerators, are the sum of an annual administrative fee and an annual fee for each X-ray tube or radiation generating device as follows:

Type Facility	*Annual Administrative Fee*	*Annual Fee per X-ray Tube or Radiation Generating Device*
Dentists, podiatrists, veterinarians	$ 70	$35
Hospitals	$520	$35
Other Facilities	$250	$35

(b) A registrant filing an initial registration under § 216.2 (relating to registration of radiation-producing machines) or an application for renewal of a certificate of registration under § 216.4 (relating to renewal of certificate of registration) shall remit the appropriate fee calculated by using the information on the registration or application form and the fee schedule in subsection (a). Fees for any initial registration under § 216.2 are payable upon the filing of the registration. Fees for the renewal of a certificate of registration are payable upon the submission of an application for a renewal of a certificate of registration. If the number of tubes increases after an initial registration or after an application for renewal has been filed with the Department, no additional fee is required until the time of the next registration. Likewise, if the number of tubes decreases during the year, no refund will be made for that year.

(c) Annual license fees for radioactive material are set forth in Appendix A (relating to fees for radioactive material licenses).

(1) No refund will be made for termination of a license.

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(2) If, by amendment or otherwise, a license changes to another fee category, the fee for the new category will take effect on the anniversary date of the license.

(d) Particle accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Annual fees are as follows:

(i) Accelerators, below 50 MeV, other than for ion implantation—$1,500 for the first accelerator at the facility plus $500 for each additional unit at that facility.

(ii) Accelerators used for ion implantation—$500 plus $50 for each additional unit at the same facility.

(iii) Accelerators above 50 MeV—full cost of staff time to review license applications and conduct inspections as needed. (Hourly rate is $50 per hour). For the purpose of anticipating costs and compliance with subsections (e) and (f), a minimum annual fee of $1,500 for the first accelerator at the facility plus $500 for each additional unit is established. Additional invoices will be issued by the Department at regular intervals at least quarterly when net costs are incurred above the minimum annual fee.

(e) An initial application for a license or reciprocity shall be accompanied by a check payable to the Department in accordance with the fee schedules in subsections (c) and (d). Thereafter, the Department will issue an annual fee invoice in accordance with the appropriate fee schedule at least 2 months prior to the license expiration. Fees are payable by the last day of the license expiration month as shown on the license fee invoice. This provision is not applicable to full cost recovery licenses specified in Appendix A.

(f) The Department will not accept an initial application for a license prior to payment of the fees required by subsections (c) and (d).

(g) If the registration involves more than one of the facilities in subsection (a), or if a license involves more than one of the categories in subsection (c), the highest applicable fee applies.

(h) A radiation-producing machine service provider shall pay an annual registration fee of $100.

Authority

The provisions of this § 218.11 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 218.11 adopted December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended May 3, 1991, effective May 4, 1991, 21 Pa.B. 2005; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285660) to (285661).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.2a (relating to registration of radiation-producing machine service providers); 25 Pa. Code § 216.4 (relating to renewal of certificate of registration); 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration); and 25 Pa. Code § 228.21a (relating to notification and license requirements).

§ 218.12. Failure by registrant or licensee to pay required fee.

(a) A registrant or licensee who fails to pay an annual fee required under this chapter shall be subject to the civil and criminal penalties provided under the act.

(b) Nonpayment of fees required by this chapter shall be cause for revocation of licenses or registrations issued by the Department under the act.

Authority

The provisions of this § 218.12 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 218.12 amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280. Immediately preceding text appears at serial page (249247).

APPENDIX A

Fees for Radioactive Material Licenses

Fee Category[5,6]	*Description*	*Annual Fee ($)*[1,2,3,4,7]
1C	Special Nuclear Material Sealed Source Gauges (X-Ray Fluorescence)	875
1D	Special Nuclear Material—Other	2,475
2B	Source Material as Shielding	450
2C	Source Material—Other (not 11e2)	8,650
3A1	Manufacturing & Distribution Commercial Broad Scope—10 CFR 30, 33	19,875
3A2	Manufacturing & Distribution Commercial Broad Scope—NARM Only	4,000
3B1	Manufacturing & Distribution Commercial Specific License—10 CFR 30	4,650
3B2	Manufacturing & Distribution Commercial Specific License—NARM Only	2,000
3C1	Manufacturing & Distribution Pharmaceuticals—10 CFR 32.72—32.74	11,650

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Fee Category[5,6]	*Description*	*Annual Fee ($)*[1,2,3,4,7]
3C2	Manufacturing & Distribution Pharmaceuticals—NARM Only	4,000
3D1	Pharmaceuticals—Distribution Only—10 CFR 32.7x	2,825
3D2	Pharmaceuticals—Distribution Only—NARM Only	2,000
3E	Irradiator—Shielded Source	2,575
3F	Irradiator—Unshielded < 10kCi	4,300
3G	Irradiator—Unshielded >= 10kCi	10,750
3I	Distribution As Exempt—No Review of Device	3,525
3J	Distribution—SSD Devices to Part 31 GLs	1,550
3K	Distribution—No Review-Exempt Sealed Source	1,300
3L1	Research & Development Broad Scope	8,300
3L2	Research & Development Broad Scope—NARM Only	2,000
3M1	Research & Development	3,650
3M2	Research & Development—NARM Only	750
3N	Services other than Leak Testing, Waste Disposal or Calibration	3,875
3O	Radiography	10,850
3P1	Other Byproduct Material	1,900
3P2	NARM Licenses not covered elsewhere	750
3Q	Generally licensed devices under § 217.143 (relating to certain measuring, gauging or controlling devices)	315
4A	Waste Storage, Processing or Disposal	Full Cost *
4B	Waste Packaging or Repackaging	8,175
4C	Waste Receipt of Prepackaged for Disposal	6,125
5A	Well Logging & Non Field Flood Tracers	7,500
5B	Well Logging Field Flood Tracer Studies	Full Cost *
6A	Nuclear Laundry	14,250

Fee Category[5,6]	*Description*	*Annual Fee ($)*[1,2,3,4,7]
7A	Human Use—Teletherapy	11,275
7B1	Human Use—Broad Scope (except Teletherapy)	19,975
7B2	Human Use—Broad Scope (except Teletherapy)—NARM Only	2,000
7C1	Human Use—Specific License (except Teletherapy)	4,300
7C2	Human Use—Specific License (except Teletherapy)—NARM Only	750
8A1	Specifically licensed sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	875
8A2	Specifically licensed NARM sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	200
14	Decontamination, Decommissioning, Reclamation or Site Restoration	Full Cost *
16A	Reciprocity (180 days/year)	900
16B	Reciprocity—NARM (180 days/year)	300
$SB1_5$	Small Business—Category 1	2,100
$SB2_6$	Small Business—Category 2	400

[1] A license may include as many as four noncontiguous sites at the base fee. Sites that are within 5 miles of the main Radiation Safety Office where the license records are kept will be considered contiguous. An additional fee of 25% of the base fee will be added for each noncontiguous site above four.

[2] All fees for NARM licenses will be effective upon publication of the final rules in the *Pennsylvania Bulletin*. The fees for NRC licenses that are transferred to the Commonwealth will be effective on the next license anniversary date. NARM licenses will be changed to the corresponding category of byproduct material license on the next license anniversary date after achievement of Agreement State status and fees adjusted at that time. The NARM license categories will cease to exist one year after Agreement State status is achieved.

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[3] Annual fees for categories of NRC licenses that are not included in this table will be calculated as follows: PA Fee = 0.7 (NRC Annual Fee + 0.10 NRC Application or Renewal fee).

[4] Annual fees charged to holders of transferred NRC licenses with multiple sites will not exceed the fees charged by the NRC for the same licenses in the year of transfer, provided the number of noncontiguous sites remains constant.

[5] Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of more than $350,000 and less than $5 million; Manufacturing Entities that have an average of 35—500 employees with Gross Annual Receipts of more than $350,000 and less than $5 million; Small Government Jurisdictions (including publicly supported, nonmedical educational institutions) with a population between 20,000 and 50,000; and nonmedical Educational Institutions that are not state or publicly supported and have 35—500 employees.

[6] Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of less than $350,000; Manufacturing Entities that have an average of less than 35 employees and less than $350,000 in Gross Annual Receipts; Small Government Jurisdictions (including publicly supported nonmedical educational institutions) with a population less than 20,000; and nonmedical Educational Institutions that are not state or publicly supported and have less than 35 employees.

[7] Full cost recovery licensees and licensees required to provide financial assurance for decommissioning are not eligible for reduced fees under category SB1 or SB2.

* Full cost recovery consists of a professional fee, to cover the activities and support of Department personnel, and any other additional incidental charges incurred, such as related contracted services or laboratory costs. The professional fee component (Hourly Rate) is $50 per hour. Other costs are recovered at 100% of actual cost. Invoices shall be issued by the Department at regular intervals but at least quarterly when net costs are incurred.

Authority

The provisions of this Appendix A issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administration Code of 1929 (71 P. S. 510-20).

Source

The provisions of this Appendix A adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285662) to (285664).

Cross References

This appendix cited in 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees).

[Next page is 219-1.]

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CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subch.		Sec.
A.	GENERAL PROVISIONS	219.1
B.	[Reserved]	219.21
C.	[Reserved]	219.31
D.	RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC	219.51
E.	TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES	219.61
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G.	[Reserved]	219.91
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I.	STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION	219.131
J.	PRECAUTIONARY PROCEDURES	219.151
K.	[Reserved]	219.181
L.	[Reserved]	219.201
M.	REPORTS	219.221
N.	[Reserved]	219.241

Authority

The provisions of this Chapter 219 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 219 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 220.2 (relating to posting of notices to workers); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 225.74 (relating to training and testing); 25 Pa. Code § 225.84 (relating to operating and emergency procedures); 25 Pa. Code § 225.91 (relating to radiation survey meter requirements); 25 Pa. Code § 226.1 (relating to purpose and scope); 25 Pa. Code § 228.31a (relating to limitations); 25 Pa. Code § 228.33a (relating to facility and shielding requirements); 25 Pa. Code § 228.38 (relating to radiation safety surveys); 25 Pa. Code § 232.1 (relating to purpose and scope); 25 Pa. Code § 236.15 (relating to protection of individuals during operations); 25 Pa. Code § 236.208 (relating to specific technical information); 25 Pa. Code § 236.209 (relating to technical analyses); 25 Pa. Code § 236.225 (relating to requirements for issuance of license); and 25 Pa. Code § 236.403 (relating to facility operation plan).

Subchapter A. GENERAL PROVISIONS

Sec.
219.1. Purpose.
219.2. Scope.
219.3. Definitions.
219.4. [Reserved].
219.5. Incorporation by reference.
219.6. Effect of incorporation of 10 CFR Part 20.
219.7. Effect of incorporation of 10 CFR 20.1403 "Criteria for license termination under restricted conditions."
219.8. Requirement for a Radiation Safety Committee.
219.11—219.15. [Reserved].

GENERAL PROVISIONS

§ 219.1. Purpose.

(a) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted under licenses or registrations issued by the Department. Licensees and registrants shall comply with this chapter.

(b) The requirements of this chapter are designed to control the receipt, possession, use, transfer and disposal of sources of radiation by a licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter. This chapter does not limit actions that may be necessary to protect health and safety.

Source

The provisions of this § 219.1 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial page (170385).

§ 219.2. Scope.

Except as specifically provided in other chapters of this article, this chapter applies to persons licensed or registered by the Department to receive, possess, use, transfer or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy or to voluntary participation in medical research programs.

Source

The provisions of this § 219.2 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170385) to (170386).

§ 219.3. Definitions.

The following term, when used in this subchapter, has the following meaning, unless the context clearly indicates otherwise:

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Medical reportable event for radiation-producing machine therapy—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a therapeutic radiation dose to the wrong individual.

(ii) An administration of a dose for therapy when the result is an increase in the total expected doses inside or outside of the intended treatment volume for organs, tissue or skin that exceeds 20% of the total prescribed dose for the intended target volume.

(iii) A total dose delivered to the treatment site identified in a written directive for therapy that is outside the prescribed dose range or differs from the total prescribed dose by more than 20%, or for a fractionated dose, when the weekly administered dose differs from the weekly prescribed dose by more than 30%.

Source

The provisions of this § 219.3 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282368) to (282369).

Cross References

This section cited in 25 Pa. Code § 228.35 (relating to operating procedures).

§ 219.4. [Reserved].

Source

The provisions of this § 219.4 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204037).

§ 219.5. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 20 (relating to standards for protection against radiation) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated by reference.

Source

The provisions of this § 219.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 219.6. Effect of incorporation of 10 CFR Part 20.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 20 (relating to standards for protection against radiation), the following words and phrases shall be substituted for the language in 10 CFR Part 20 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) A reference to "licensee" includes registrant.

(4) A reference to "license" includes registration.

(5) A reference to "licensed" includes registered.

(6) A reference to "Department" in 10 CFR means the United States Department of Energy.

(7) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

(8) 10 CFR Part 20, notwithstanding, exposures involving the use of X-rays may be weighted, in a manner specified by the Department, so that, with Department approval, the effective dose equivalent may be substituted for the deep dose equivalent in determining compliance with occupational exposure limits for specified groups of individuals.

Source

The provisions of this § 219.6 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282369) to (282370).

§ 219.7. Effect of incorporation of 10 CFR 20.1403 "Criteria for license termination under restricted conditions."

The Department will not terminate a license under the conditions of restricted release as provided for in 10 CFR 20.1403 (relating to criteria for license termination under restricted conditions) until a license termination plan (LTP), approved by the Department, has been in effect for a period of time sufficient to demonstrate to the Department that continued implementation of the plan will be effective in maintaining compliance with the required conditions of the plan. The Department may choose to implement the license termination process in one or more of the following steps:

(1) The license is amended to authorize activities necessary to begin decommissioning under the LTP.

(2) After decommissioning activities are complete and the provisions of 10 CFR 20.1403 are in effect under the LTP, the license may be amended to end authorization of licensed activities. The license shall remain in effect for up to 5 years being limited to ownership/possession of the decommissioned material.

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(3) At the end of the period prescribed in paragraph (2), the Department will make a determination of the effectiveness of the LTP as enacted. If the LTP has demonstrated the ability to maintain compliance with 10 CFR 20.1403, the license will be terminated subject to the revisitation provision of 10 CFR 20.1401(c) (relating to general provision and scope) regarding new evidence of a significant threat to health and safety. Otherwise, the licensee will be directed by the Department to take corrective actions as necessary to conform to 10 CFR 20.1403 and the process shall revert back to paragraph (2).

Source

The provisions of this § 219.7 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 219.8. Requirement for a Radiation Safety Committee.

The requirements of 10 CFR 35.24 (relating to authority and responsibilities for the radiation protection program) apply to registrants as well as licensees. For the purpose of this requirement, facilities that utilize two or more modalities in which patients are likely to receive, or will receive a dose to an organ in excess of 200 rads (2.0 gray), shall have a radiation safety committee.

Source

The provisions of this § 219.8 adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

§§ 219.11—219.15. [Reserved].

Source

The provisions of these §§ 219.11—219.15 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170386) to (170393).

Subchapter B. [Reserved]

§ 219.21. [Reserved].

Source

The provisions of this § 219.21 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204038) and (249251).

§ 219.22. [Reserved].

Source

The provisions of this § 219.22 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170394) to (170396).

Subchapter C. [Reserved]

§§ 219.31—219.33. [Reserved].

Source

The provisions of these §§ 219.31—219.33 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249251) to (249252) and (204041) to (204042).

§§ 219.34—219.38. [Reserved].

Source

The provisions of these §§ 219.34—219.38 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204042), (249253) to (249254) and (204045) to (204048).

§§ 219.41—219.49. [Reserved].

Source

The provisions of these §§ 219.41—219.49 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170398) to (170404).

Subchapter D. RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

Sec.
219.51. Dose limits for individual members of the public.
219.52. [Reserved].

§ 219.51. Dose limits for individual members of the public.

In addition to incorporation by reference of 10 CFR Part 20 Subpart D (relating to dose limits for individual members of the public), registrants who met the previous limit (5 mSv or 0.5 REM in 1 year) for locations having existing radiation-producing machines or equipment or other registered radiation sources will not be required to retrofit installations existing before November 18, 1995. The Department does not require the retrofitting of shielding for the replacement of equipment in the facility as long as the equipment is being replaced with similar equipment.

Source

The provisions of this § 219.51 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204048) and (249255).

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Cross References

This section cited in 25 Pa. Code § 223.7 (relating to structural shielding).

§ 219.52. [Reserved].

Source

The provisions of this § 219.52 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249256).

Subchapter E. TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

Sec.
219.61. Testing for leakage or contamination of sealed sources.
219.62—219.66. [Reserved].

§ 219.61. Testing for leakage or contamination of sealed sources.

(a) In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), a licensee possessing a sealed source shall assure that:

(1) Except as specified in subsection (b), each sealed source is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee.

(2) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals specified in the Sealed Source and Device Registry approved by the Department, a state or the NRC.

(3) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals specified in the Sealed Source and Device Registry approved by the Department, a state or the NRC.

(4) For each sealed source that is required to be tested for leakage or contamination, the sealed source is tested for leakage or contamination before further use at any time there is reason to suspect that the sealed source might have been damaged or might be leaking.

(5) Except for brachytherapy sources manufactured to contain radium, tests for leakage for sealed sources shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination

to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

(6) The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its progeny has been determined with respect to collection method, volume and time.

(7) Tests for contamination from radium progeny shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μCi) of any radium progeny which has a half-life greater than 4 days.

(b) A licensee need not perform tests for leakage or contamination on the following sealed sources:

(1) Sealed sources containing only radioactive material with a half-life of less than 30 days.

(2) Sealed sources containing only radioactive material as a gas.

(3) Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material.

(4) Sealed sources containing only hydrogen-3.

(5) Seeds of iridium-192 encased in nylon ribbon.

(6) Sealed sources, which are stored, are not being used, and are identified as in storage. The licensee shall test each of these sealed sources for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

(c) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Department, an agreement state, a licensing state or the NRC to perform these services.

(d) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Department.

(e) The following shall be considered evidence that a sealed source is leaking:

(1) The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample.

(2) Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

(3) The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

(f) The licensee shall immediately withdraw a leaking sealed source from use and take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this article.

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(g) Reports of test results for leaking or contaminated sealed sources shall be made under § 219.227 (relating to reports of leaking or contaminated sealed sources).

Source

The provisions of this § 219.61 adopted June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceding text appears at serial pages (282373) to (282374).

Cross References

This section cited in 25 Pa. Code § 219.227 (relating to reports of leaking or contaminated sealed sources).

§§ 219.62—219.66. [Reserved].

Source

The provisions of these §§ 219.62—219.66 adopted June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170407) to (170410).

Subchapter F. [Reserved]

§ 219.71. [Reserved].

Source

The provisions of this § 219.71 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 3135; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204053).

§ 219.72. [Reserved].

Source

The provisions of this § 219.72 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204054).

§ 219.73. [Reserved]

Source

The provisions of this § 219.73 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204054) and (249257).

§§ 219.74—219.76. [Reserved].

Source

The provisions of these §§ 219.74—219.76 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170414) to (170415).

§ 219.81. [Reserved].

Source

The provisions of this § 219.81 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170415) to (170417).

Subchapter G. [Reserved]

§§ 219.91—219.93. [Reserved].

Source

The provisions of these §§ 219.91—219.93 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249257) to (249258) and (204057) to (204059).

Subchapter H. [Reserved]

§§ 219.111—219.113. [Reserved].

Source

The provisions of these §§ 219.111—219.113 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204060) to (204062).

Subchapter I. STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

Sec.
219.131. Security of stored sources of radiation.
219.132. Control of sources of radiation not in storage.

Source

The provisions of this Subchapter I adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted. Immediately preceding text appears at serial page (204062).

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§ 219.131. Security of stored sources of radiation.

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), the licensee or registrant shall secure from unauthorized removal or access radiation sources that are in storage.

§ 219.132. Control of sources of radiation not in storage.

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), the licensee or registrant shall maintain control of radiation producing machines that are not in storage.

Subchapter J. PRECAUTIONARY PROCEDURES

Sec.
219.151—219.158. [Reserved].
219.159. Posting of radiation-producing machines.
219.160. Exceptions to posting requirements.
219.161. Exemptions from labeling requirements.
219.162. Procedures for receiving and opening packages.

Source

The provisions of this Subchapter J adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085, unless otherwise noted.

§§ 219.151—219.158. [Reserved].

Source

The provisions of these §§ 219.151—219.158 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249259) to (249260) and (204065).

§ 219.159. Posting of radiation-producing machines.

The registrant or licensee shall ensure that each radiation producing machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized. For example:

**"CAUTION—RADIATION
THIS EQUIPMENT PRODUCES RADIATION
WHEN ENERGIZED."**

Source

The provisions of this § 219.159 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204065).

§ 219.160. Exceptions to posting requirements.

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), a room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

Source

The provisions of this § 219.160 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204065) to (204066).

§§ 219.161 and 219.162. [Reserved].

Source

The provisions of these §§ 219.161 and 219.162 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204066) to (204068).

Subchapter K. [Reserved]

§§ 219.181—219.186. [Reserved].

Source

The provisions of these §§ 219.181—219.186 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204068) to (204070) and (249261).

Subchapter L. [Reserved]

§§ 219.201—219.211. [Reserved].

Source

The provisions of these §§ 219.201—219.211 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249261) to (249266).

Subchapter M. REPORTS

Sec.
219.221. Reports of stolen, lost or missing licensed or registered sources of radiation.
219.222. Notification of incidents and reportable events.
219.223—219.226. [Reserved].
219.227. Reports of leaking or contaminated sealed sources.

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219.228. Reports of medical reportable events for radiation-producing machine therapy.
219.229. Other medical reports.

Source

The provisions of this Subchapter M adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085, unless otherwise noted.

§ 219.221. Reports of stolen, lost or missing licensed or registered sources of radiation.

In addition to incorporation by reference of the requirements in 10 CFR Part 20 (relating to standards for protection against radiation) covering the reporting requirements associated with reports of theft or loss of licensed material, the following reporting requirements apply to radiation-producing machines:

(1) *Telephone reports.* Each licensee or registrant shall report to the Department by telephone immediately, after its occurrence becomes known, a stolen, lost or missing radiation producing machine.

(2) *Written reports.* Each licensee or registrant required to make a report under paragraph (1) shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

(i) A description of the licensed or registered source of radiation involved, including, for radiation producing machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted.

(ii) A description of the circumstances under which the loss or theft occurred.

(iii) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved.

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred and the possible total effective dose equivalent to persons in unrestricted areas.

(v) Actions that have been taken, or will be taken, to recover the source of radiation.

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(3) *Additional information.* Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of the information.

(4) *Detachable reports.* The licensee or registrant shall prepare a report filed with the Department under this section so that the names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

Source

The provisions of this § 219.221 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249266) to (249267) and (204077).

Cross References

This section cited in 25 Pa. Code § 225.76 (relating to reporting requirements).

§ 219.222. Notification of incidents and reportable events.

In addition to incorporation by reference of the requirements in 10 CFR 20.2202 and 20.2203 (relating to notification of incidents; and reports of exposures, radiation levels and concentrations of radioactive material exceeding the constraints or limits), those notification requirements, as well as written 30-day reports under 10 CFR 20.2203(a), also apply to radiation-producing machines and NARM.

Source

The provisions of this 219.222 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204077) to (204078).

Cross References

This section cited in 25 Pa. Code § 225.76 (relating to reporting requirements).

§§ 219.223—219.226. [Reserved].

Source

The provisions of these §§ 219.223—219.226 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204078) to (204080) and (249269).

§ 219.227. Reports of leaking or contaminated sealed sources.

If the test for leakage or contamination, required under § 219.61 (relating to testing for leakage or contamination of sealed sources), indicates a sealed source is leaking or contaminated, a report of the test shall be filed within 5 days with the Department describing the equipment involved, the test results and the corrective action taken.

Cross References

This section cited in 25 Pa. Code § 219.61 (relating to testing for leakage or contamination of sealed sources).

§ 219.228. Reports of medical reportable events for radiation-producing machine therapy.

(a) For a medical reportable event for radiation-producing machine therapy, the licensee or registrant shall do the following:

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(1) Notify the Department by telephone within 24 hours after discovery of the event.

(2) Submit a written report to the Department within 15 days after discovery of the event. The written report shall include the licensee's or registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee or registrant notified the patient, or the patient's responsible relative or guardian (for notification purposes under this section, this person will be included in subsequent references to "the patient"), and if not, why not; and if the patient was notified, what information was provided to the patient. The report may not include the patient's name or other information that could lead to identification of the patient.

(3) Notify the referring physician and also notify the patient of the event within 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee or registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee or registrant shall notify the patient as soon as possible thereafter. The licensee or registrant may not delay appropriate medical care for the patient, including necessary remedial care, because of delay in notification.

(4) If the patient was notified, the licensee or registrant shall also furnish, within 15 days after discovery of the event, a written report to the patient by sending one of the following:

(i) A copy of the report that was submitted to the Department.

(ii) A brief description of both the event and the consequences, as they may affect the patient, if a statement is included that the report submitted to the Department can be obtained from the licensee or registrant.

(b) The licensee or registrant shall retain a record of each medical reportable event for radiation-producing machine therapy for 5 years. The record shall contain the names of the individuals involved (including the prescribing physician, allied health personnel, the patient and the patient's referring physician), the patient's Social Security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, this section does not affect rights or duties of licensees or registrants and physicians in relation to each other, patients or the patient's responsible relatives or guardians.

Source

The provisions of this § 219.228 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceding text appears at serial pages (282380) to (282381).

Cross References

This section cited in 25 Pa. Code § 219.229 (relating to other medical reports); and 25 Pa. Code § 228.35 (relating to operating procedures).

§ 219.229. Other medical reports.

Within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological system of a patient exposed to therapeutic or diagnostic radiation from a radiation-producing machine, the registrant or licensee shall document the finding and provide a report to the Department and provide a clinical summary to the prescribing physician and the patient. The report shall be retained for at least 5 years. Exempt from this reporting requirement are any events already reported under § 219.228 (relating to reports of medical reportable events for radiation-producing machine therapy) and any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed.

Source

The provisions of this § 219.229 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceding text appears at serial pages (282381) to (282382).

Subchapter N. [Reserved]

§ 219.241. [Reserved].

Source

The provisions of this § 219.241 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249270).

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APPENDIX A. [Reserved]

Source

The provisions of this Appendix A amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204084) to (204087).

APPENDIX B. [Reserved]

Source

The provisions of this Appendix B amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204088) to (204161).

APPENDIX C. [Reserved]

Source

The provisions of this Appendix C adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1987, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204162) to (204169).

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CHAPTER 220. NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS AND INVESTIGATIONS

Sec.
220.1. Purpose and scope.
220.2. Posting of notices to workers.
220.3—220.5. [Reserved].
220.6—220.8. [Reserved].
220.9. Incorporation by reference.
220.10. Effect of incorporation of 10 CFR Part 19.

Authority

The provisions of this Chapter 220 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 220 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 225.74 (relating to training and testing); 25 Pa. Code § 226.1 (relating to purpose and scope); 25 Pa. Code § 228.31a (relating to limitations); 25 Pa. Code § 232.1 (relating to purpose and scope); and 25 Pa. Code § 240.401 (relating to inspection).

§ 220.1. Purpose and scope.

This chapter establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration. This chapter also establishes options available to the individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the act and regulations, orders and licenses issued thereunder regarding radiological working conditions. This chapter applies to persons who receive, possess, use, own or transfer radiation sources licensed by or registered with the Department under Chapters 216 and 217 (relating to registration of radiation-producing machines and radiation-producing machine service providers; and licensing of radioactive material).

§ 220.2. Posting of notices to workers.

(a) A licensee or registrant shall post current copies of the following documents:

(1) This chapter and Chapter 219 (relating to standards for protection against radiation).

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto.

(3) The operating procedures applicable to activities under the license or registration.

(4) A notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued under Chapter 215 (relating to general provisions) and response from the licensee or registrant.

(b) If posting of a document specified in subsection (a)(1), (2) or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Department Form 2900-FM-RP0003, "Notice to Employees," shall be posted by a licensee or registrant as required by this article.

(d) Department documents posted under subsection (a)(4) shall be posted within 2 working days after receipt of the documents from the Department; the licensee's or registrant's response shall be posted within 2 working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

(e) Documents, notices or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from the particular work location to which the document applies. The documents, notices or forms shall be conspicuous and shall be replaced if defaced or altered.

Source

The provisions of this § 220.2 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceding text appears at serial pages (282385) to (282386).

§§ 220.3—220.5. [Reserved].

Source

The provisions of these §§ 220.3—220.5 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249272) and (203895).

§§ 220.6—220.8. [Reserved].

Source

The provisions of these §§ 220.6—220.8 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203895) to (203897).

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§ 220.9. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 19 (relating to notices, instructions and reports to workers; inspections and investigations) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated by reference.

Source

The provisions of this § 220.9 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 220.10. Effect of incorporation of 10 CFR Part 19.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 19 (relating to notices, instructions and reports to workers; inspections and investigations), the following words and phrases shall be substituted for the language in 10 CFR Part 19 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) A reference to "license," "licenses," "licensed" and "licensed radioactive material" also include "registration," "registrant" "registered," and "registered source of radiation," respectively.

(4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 220.10 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

[Next page is 221-1.]

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CHAPTER 221. X-RAYS IN THE HEALING ARTS

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221.204. Radiation measurements and performance evaluations.
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Authority

The provisions of this Chapter 221 issued under section 301 of the The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed), unless otherwise noted.

Source

The provisions of this Chapter 221 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL

§ 221.1. Purpose and scope.

This chapter establishes requirements for the use of X-ray equipment by or under the supervision of a licensed practitioner of the healing arts. A registrant who uses X-rays in the healing arts shall comply with this chapter. This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

Authority

The provisions of this § 221.1 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (117772), (42615) and (4877) to (4880).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

AAPM—American Association of Physicists in Medicine.

ACR—American College of Radiology.

Aluminum equivalent—The thickness of type 1100 aluminum alloy—the nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, .12% copper—affording the same attenuation, under specified conditions, as the material in question.

Automatic exposure control—A device which automatically controls one or more technique factors in order to obtain at preselected locations a desired quantity of radiation.

Beam axis—A line from the source through the centers of the X-ray fields.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

Cephalometric device—A device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components—Components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C.A. §§ 263b—263n).

Certified system—An X-ray system which has one or more certified components.

Changeable filter—A filter, exclusive of inherent filtration, which can be added to or removed from the useful beam through an electronic, mechanical or physical process.

Coefficient of variation (C)—The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}} \left[\sum_{i=1}^{n} \frac{(X_i - \overline{X})^2}{n-1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population.

$\overline{X}$ = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample; $n>1$.

Contact therapy system—An X-ray system used for therapy with the X-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

Control panel—The part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

Dead-man switch—A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Dental panoramic system—A device intended to produce a radiographic image of both dental arches on one film.

Diagnostic source assembly—The tube housing assembly with a beam-limiting device attached.

Diagnostic X-ray system—An X-ray system designed for irradiation of a part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation—The scattered radiation coming directly from material irradiated by the useful beam and not scattered by other material.

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Entrance exposure rate—The exposure in air per unit time at the point where the center of the useful beam enters the patient.

Field emission equipment—Equipment using an X-ray tube in which electrons are emitted from the cathode solely by the force between an electric field and the electrons.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and preferentially absorb selected radiation.

Filtration—The amount of material placed in the useful beam to modify the radiation's characteristics, typically expressed in terms of millimeters of aluminum or copper equivalent.

Fluoroscopic imaging assembly—A subsystem in which X-ray photons produce a fluoroscopic image. The term includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic system—See fluoroscopic imaging assembly.

Focal spot—The area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

Half-value layer (HVL)—

(i) The thickness of specified material which attenuates the exposure rate by 1/2 when introduced into the path of a given beam of radiation. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(ii) The term is used to describe the penetrating ability of the radiation.

Healing arts screening—The testing of human beings using X-ray machines for the detection or evaluation of health indications when the tests are not specifically and individually ordered for the purpose of diagnosis or treatment by a licensed practitioner of the healing arts legally authorized to prescribe the X-ray tests.

Image intensifier—A device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

Image receptor—A device, such as a fluorescent screen or radiographic film, which 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.

Intensifying screen—A fluorescent screen which transforms incident X-ray photons into a visible image.

Intraoral dental radiography—A modality of dental radiography in which the image receptor is placed inside a patient's oral cavity.

kV—Kilovolts

kVp—Peak tube potential (see kilovolts peak).

Kilovolts peak (kVp)—The maximum value of the potential difference across the X-ray tube during an exposure.

Lead equivalent—The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation—Radiation emanating from the diagnostic or therapeutic source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors—The technique factors associated with the tube housing assembly which are used in measuring leakage radiation defined as follows:

(i) For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the charge per exposure being 10 millicoulombs—10 milliampere seconds—or the minimum charge obtainable from the unit, whichever is larger.

(ii) For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(iii) For other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Licensed practitioner of the healing arts—An individual licensed by the Commonwealth to practice the healing arts, which for the purposes of this article shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

Light field—The area defined by the intersection of the light beam with a plane parallel with the plane of the image receptor. The edge of the field is defined by the points at which the light intensity is 25% of the maximum light intensity in the plane.

Line-voltage regulation—The difference between the no-load and the load line potentials expressed as a percent of the load line potential calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100\ (V_n - V_l)/V_l$$

where

V_n = No-load line potential and

V_l = Load line potential.

mA—Milliampere.

mAs—Milliampere second.

mR—Milliroentgen.

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Maximum line current—The root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

Mobile X-ray system—see X-ray equipment.

Patient—An individual subjected to healing arts examination, diagnosis or treatment.

Peak tube potential—The maximum value of the potential difference across the X-ray tube during an exposure.

Phototimer—A method for controlling the radiation exposures to an image receptor by measuring the radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated.

Portable radiation system—See X-ray equipment.

Position indicating device (PID)—A device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance.

Positive beam limitation—The automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby an X-ray exposure cannot be made without an adjustment.

Protective apron—An apron incorporating radiation absorbing materials.

Protective barrier—A barrier of radiation absorbing material used to reduce radiation exposure. The term includes the following types:

(i) *Primary protective barrier*—Material used to reduce radiation exposure from the useful beam.

(ii) *Secondary protective barrier*—Material used to reduce exposure from stray, leakage or scattered radiation.

Protective glove—A glove incorporating radiation absorbing materials.

Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Radiation therapy simulation system—A radiographic or fluoroscopic 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.

Radiograph—An image receptor on which an image is created directly or indirectly by an X-ray pattern and results in a permanent record.

Radiographic imaging system—A system whereby an image is produced on an image receptor by the action of ionizing radiation.

Rating—The operating limits specified by the component manufacturer.

Registrant—A person who is legally obligated to register with the Department under this article and the act.

Research—One of the following:

(i) Theoretical analysis, exploration or experimentation.

(ii) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental testing of models, devices, equipment, materials and processes. The term includes the external administration of X-ray radiation to human beings for diagnostic or therapeutic purposes or in an equivalent manner as a diagnostic or therapeutic procedure.

Response time—The time required for an instrument system to reach 90% of its final reading when the instrument system is exposed to a step change from zero radiation flux to a flux sufficient to provide a steady state midscale reading.

SSD—The distance between the source and the skin of the patient.

SID—Source-image receptor distance—The distance from the source to the center of the input surface of the image receptor.

Scattered radiation—Radiation that, during passage through matter, has been deviated in direction.

Screening—See the definition of "healing arts screening."

Serial radiography—Radiographic images produced in regular sequence.

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

Source—The focal spot of the X-ray tube.

Specific prescription—A written or oral directive authorizing a radiographic or fluoroscopic examination of a specified individual.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Spot film—A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device—A device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. The term includes a device intended to hold a cassette in front of the input end of an image intensifier for the purpose of making a radiograph.

Stray radiation—The sum of leakage and scattered radiation.

Technique factors—The following conditions of operation:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, number of X-ray pulses and either tube current or product of tube current and time.

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(iii) For other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

Therapeutic X-ray system—A system design for irradiation of a part of the human body for the purpose of treatment or alleviation of symptoms of disease.

Timer—An electronic device which is capable of measuring an X-ray exposure.

Tube—An X-ray tube, unless otherwise specified.

Tube housing assembly—The tube housing with the X-ray tube installed. The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device—A beam-limiting device which has capacity for stepless adjustment of the X-ray field size.

Visible area—The portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray control—A device which controls input power to the X-ray high-voltage generator or the X-ray tube, or both. The term includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.

X-ray equipment—An X-ray system, subsystem or component thereof. Types of X-ray equipment are as follows:

(i) *Mobile X-ray equipment*—X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(ii) *Portable X-ray equipment*—X-ray equipment designed to be hand-carried.

(iii) *Stationary X-ray equipment*—X-ray equipment which is installed in a fixed location or vehicle.

X-ray field—The area defined by the intersection of the useful beam with a plane parallel with the plane of the image receptor. The edge of the field is defined by the points at which the exposure rate is 25% of the maximum exposure rate in the plane.

X-ray high-voltage generator—A device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential.

X-ray subsystem—A combination of two or more components of an X-ray system.

X-ray system—An assembly of components for the controlled production of X-rays. The term includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary

supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray tube—An electron tube which is designed to be used primarily for the production of X-rays.

Authority

The provisions of this § 221.2 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282389) to (282390) and (249277) to (249282).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.201 (relating to definitions).

§ 221.3. Sale and installation.

No person may sell or install a radiation–producing machine that does not meet the provisions of this article.

Authority

The provisions of this § 221.3 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4881).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

(a) The registrant is responsible for directing the operation of X-ray systems under his administrative control and shall assure that the requirements of this article are met in the operation of the X-ray systems.

(b) An individual who operates an X-ray system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include items included in Appendix A (relat-

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ing to determination of competence) and there shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

(c) A chart, which specifies the techniques for examinations performed with the system, shall be provided in the vicinity of each diagnostic X-ray system's control panel. This chart shall include information pertinent to the particular examination, such as:

(1) The patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized.

(2) The type and size of the film or film-screen combination.

(3) The type of grid, if any.

(4) The type and location of placement of patient shielding-for example, gonad, and the like.

(5) For mammography, indication of kVp/target/filter combination.

(6) Source to image receptor distance to be used, except for dental intraoral radiography.

(d) Written safety procedures and rules shall be available at a facility including restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with the rules.

(e) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. The following apply for individuals other than the patient being examined:

(1) Individuals shall be positioned so that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material. The lead equivalent of the material is to be determined at 60 kV.

(2) All persons required for the medical procedure shall be protected from the stray radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be so positioned that the persons are not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(3) A patient who cannot be removed from the room shall be protected from the stray radiation by protective barriers of at least 0.25 millimeter lead equivalent material unless the shield would compromise the health of the individual or shall be so positioned that the patient is not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(4) No individual, other than the patient being examined, may be in the useful beam, unless required to conduct the procedure.

(f) During diagnostic procedures in which the gonads are in the useful beam, gonad shielding of at least 0.5 millimeter lead equivalent shall be used for patients except for cases in which this would interfere with the diagnostic procedure.

(g) An individual may not be exposed to the useful beam except for healing arts purposes or under § 221.15 (relating to use of X-rays in research on humans). An exposure shall be authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration or other nonhealing arts purposes.

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Department. When requesting authorization, the registrant shall submit the information outlined in § 221.13 (relating to information to be submitted by persons requesting approval to conduct healing arts screening).

(h) If a patient or image receptor requires auxiliary support during a radiation exposure the following apply:

(1) Mechanical holding devices shall be used when the technique permits.

(2) The human holder shall be protected as required by subsection (e).

(3) An individual may not be used routinely to hold image receptors or patients.

(i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(j) The screen and film system used shall be spectrally compatible. Defective screens may not be used for diagnostic radiological imaging.

(k) With the exception of intraoral dental radiography, film may not be used without intensifying screens for routine diagnostic radiological imaging.

(l) The registrant shall have a quality assurance program. This quality assurance program shall be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address repeat rate; image recording, processing and viewing; and maintenance and modifications to the quality assurance program. Records shall be maintained by the registrant for inspection by the Department for 3 years. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

(m) Neither the X-ray tube housing nor the collimating device may be handheld during the exposure.

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Authority

The provisions of this § 221.11 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249282), (285667) to (285669).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.42a (relating to control of scattered radiation).

§ 221.12. Records, maintenance and associated information.

The registrant shall maintain records of surveys, calibrations, maintenance and modifications performed on the X-ray systems including the names of persons who performed the services. The registrant shall keep these records for inspection by the Department for 5 years.

Authority

The provisions of this § 221.12 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123681).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.13. Information to be submitted by persons requesting approval to conduct healing arts screening.

(a) The Department will consider efficacy as a factor in evaluating healing arts screening procedures. In its review, the Department will consider National medical organization consensus statements as well as peer reviewed scientific and medical literature that addresses the efficacy of the proposed screening procedures. The review may also consider relevant information from appropriate Federal agencies. For procedures that result in an individual organ dose or deep dose equivalent greater than 1 mSv (100 mrem) to a screened individual the Department will consult with the Department of Health (DOH) for assistance in review-

ing the efficacy of the proposed procedures but the final decision will remain that of the Department. The DOH will have access to all relevant materials when rendering its review.

(b) A person requesting that the Department approve a healing arts screening program shall submit in writing the following information for evaluation by the Department. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) The diseases or conditions for which the X-ray examinations are to be used.

(3) The description in detail of the X-ray examinations proposed in the screening program.

(4) A description of the population to be examined in the screening program—age, sex, physical condition and other appropriate information.

(5) An evaluation of all known alternate methods that could achieve the goals of the screening program and why these methods are not used in preference to the proposed X-ray examinations.

(6) An evaluation by a qualified expert of the X-ray systems to be used in the screening program. The evaluation shall show that the systems satisfy the requirements of this article. The evaluation shall include a measurement of patient entrance exposures and calculation of the maximum shallow dose, deep dose equivalent and organ dose from the X-ray examinations to be performed.

(7) A description of the diagnostic X-ray quality control program.

(8) A copy of the technique chart for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(9) The qualifications of all individuals who will be operating the X-ray systems.

(10) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(11) The name, address and qualifications of the individual who will interpret the screening procedure results.

(12) A description of the information and procedure for advising the individuals screened of the potential for false positive or negative results and the implications for the patient; the procedure for recording informed consent for the procedure following disclosure of this information; and the procedure for advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and further medical needs indicated.

(13) A description of the procedures for the retention or disposition of the diagnostic images, data and other records pertaining to the X-ray examination.

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(14) Mammography facilities shall comply with 21 CFR Part 900 (relating to mammography).

(15) An approximation of the frequency of screening activities and duration of the entire screening program.

Authority

The provisions of this § 221.13 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285669) to (285670).

Cross References

This section cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities); and 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.14. [Reserved].

Source

The provisions of this § 221.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

§ 221.15. Use of X-rays in research on humans.

(a) Registrants conducting research using X-rays involving human subjects are exempted from the requirements of this section if the research is conducted, funded, regulated or supported by a Federal agency which has implemented the Federal policy for the protection of human subjects or if the research is carried out in an institution which conducts other Federally funded or supported human research and follows all Federal requirements for protocol review and research subject protection.

(b) If not exempted under subsection (a), a person shall submit, in writing, the following information and evaluation to the Department and receive approval by the Department before conducting the research. If the information submitted to the Department becomes invalid or outdated, the person shall immediately, in writing, notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) A description of the population to be examined in the research program, age, sex, physical condition and other appropriate information.

(3) An evaluation of all known alternate methods that could achieve the goals of the research program and why these methods are not used in preference to the X-ray examinations.

(4) An evaluation by a qualified expert of the X-ray system to be used in the research program. This evaluation shall show that the system satisfies the requirements of this article. The evaluation shall include a projected measurement of individual and cumulative patient exposures from the X-ray examinations to be performed.

(5) A description of the diagnostic X-ray quality control program.

(6) A copy of the technique chart which specifies the information for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(7) The qualifications of all individuals who will be operating the X-ray system.

(8) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(9) The name, address and qualifications of the individual who will interpret the data.

(10) A copy of the research protocol authorized by a committee consisting of at least three qualified persons. At least one of the committee members shall be knowledgeable in radiation effects on humans.

(11) The provisions for independent institutional review.

(c) Proposed subjects or their legal representative shall sign a statement acknowledging that they have been informed of their anticipated radiation exposure and possible consequences arising from this exposure.

Authority

The provisions of this § 221.15 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.15 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3238. Immediately preceeding text appears at serial pages (249287) to (249288).

Cross References

This section cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities); and 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

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DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.21. Diagnostic equipment requirements.

Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30—1020.33.

Authority

The provisions of this § 221.21 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123683).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.22. Battery charge indicator.

On battery-powered X-ray generators, the control panel shall have means to indicate visually whether the battery is adequately charged for proper operation.

Authority

The provisions of this § 221.22 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.23. Leakage radiation from the diagnostic source assembly.

The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Authority

The provisions of this § 221.23 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.24. Radiation from components other than the diagnostic source assembly.

The radiation emitted by a component other than the diagnostic source assembly may not exceed 2 milliroentgens (.516 μC/kg) in 1 hour at 5 centimeters from an accessible surface of the component when it is operated in an assembled X-ray system under conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Authority

The provisions of this § 221.24 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4882) to (4883).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.25. Beam quality.

(a) Diagnostic X-ray systems shall have filtration that satisfies the requirements of Table I. The requirements of this section shall be considered to have been met if it can be demonstrated that the half value layer of the primary beam is not less than that shown in Table II.

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TABLE I

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	*Total Filtration (inherent plus added) (millimeters aluminum equivalent)*
Below 50	5 millimeters
50—70	1.5 millimeters
Above 70	2.5 millimeters

TABLE II

Design operating range (Kilovolts peak)	*Measured potential (Kilovolts peak)*	*Minimum half-value layer (millimeters of aluminum)*	
		Specified dental systems*	All other X-ray systems
Below 51	30	1.5	0.3
	40	1.5	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

Note: Half-value layers for kilovoltages not listed in Table II may be determined by interpolation or extrapolation.

* Dental systems manufactured after December 1, 1980, designed for use with intraoral image receptors.

(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(c) For capacitor energy storage equipment, compliance with this section shall be determined with the maximum quantity of charge per exposure.

(d) The required minimal aluminum equivalent filtration shall include the filtration contributed by materials which are always present between the source and the patient.

(e) For X-ray systems having variable filtration in the useful beam, a means shall be provided to prohibit exposure unless the filtration requirements of subsection (a) are met for the kVp selected.

Authority

The provisions of this § 221.25 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.25 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3238. Immediately preceeding text appears at serial pages (249290) and (285671).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.26. Multiple tubes.

If two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

Authority

The provisions of this § 221.26 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.26 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.27. Mechanical support of tube head.

The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

Authority

The provisions of this § 221.27 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

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Source

The provisions of this § 221.27 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.28. Technique indicators.

(a) The technique factors for radiographic systems shall be indicated before exposure except for units utilizing automatic exposure controls, in which case the maximum mAs shall be indicated.

(b) The requirement of subsection (a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by a fluoroscopist.

Authority

The provisions of this § 221.28 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.27 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123686).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.29. Kilovoltage (kV) accuracy.

(a) For variable kV units, the kV output may not vary from the set-indicated value by more than 10% over the range of technique factors normally used. Discrepancies of more than 10% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

(b) For fixed kV units, the kV output may not vary from the set-indicated value by more than 20% over the range of technique factors normally used. Discrepancies of more than 20% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

Authority

The provisions of this § 221.29 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.29 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285672) to (285673).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.30. Exposure reproducibility.

The coefficient of variation of exposure reproducibility may not exceed 0.10 when technique factors are held constant. This requirement shall be deemed to have been met when four exposures are made. This requirement applies when either manual techniques or automatic exposure control is used.

Authority

The provisions of this § 221.30 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.30 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.31. [Reserved].

Source

The provisions of this § 221.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123686) to (123688).

§ 221.31a. Locks.

Position locking, holding and centering devices on X-ray systems shall function as intended.

Authority

The provisions of this § 221.31a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.31a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

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Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.32. [Reserved].

Source

The provisions of this § 221.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123688).

§ 221.32a. Radiographic beam limitation.

(a) The useful beam shall be limited to the area of clinical interest.

(b) The beam limiting device shall do one of the following:

(1) Indicate numerically the field size in the plane of the image receptor to which it is adjusted to within 2% of the SID.

(2) Provide for visually defining the perimeter of the X-ray field except for systems designed for one image receptor size. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field may not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

(c) A means shall be provided for stepless (continuous) adjustment of the size of the X-ray field except for systems which use removable fixed operation beam limiting devices.

(d) A means shall be provided to:

(1) Indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor if the angle between the axis of the X-ray beam and the plane of the image receptor is variable. This paragraph does not apply to portable, mobile or intraoral dental units.

(2) Align the center of the X-ray field with respect to the center of the image receptor to within 2% of the SID.

(3) Indicate the SID to within 2%.

(e) Intraoral dental X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than either of the following:

(1) Eighteen centimeters if operable above 50 kVp.

(2) Ten centimeters if not operable above 50 kVp.

(f) Indication of field size dimensions and SIDs shall be specified so that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(g) Intraoral dental systems designed for use with an intraoral image receptor shall be provided with a means to limit the X-ray beam so that:

(1) Eighteen centimeters or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

(2) Less than 18 centimeters, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(h) When positive beam limitation is used, the following conditions shall be met:

(1) The radiation beam may not be larger than the linear dimensions of the image receptor being used.

(2) The positive beam limitation device shall allow the operator to further reduce the size of the radiation field.

(i) Mobile or portable radiographic systems, other than intraoral dental X-ray systems, shall be provided with a means to limit the source-to-skin distance to at least 30 centimeters.

(j) Radiographic equipment designed for one or more image receptor sizes at a fixed SID shall be provided with a means to accomplish one of the following:

(1) Limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and align the center of the X-ray field with the center of the image receptor to within 2% of the SID.

(2) The X-ray field shall be sized and aligned so that at the plane of the image receptor, it does not extend beyond the edge of the image receptor by more than 2% of the SID.

Authority

The provisions of this § 221.32a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.32a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (254508) and (249295).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.33. [Reserved].

Source

The provisions of this § 221.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123688) to (123689).

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§ 221.33a. Radiation from capacitor energy storage equipment in standby status.

Radiation emitted from an X-ray tube when the exposure switch or timer in not activated may not exceed a rate of 2 milliroentgens (0.516 μC/kg) per hour at 5 centimeters from an accessible surface of a fully charged diagnostic source assembly, with the beam-limiting device fully open.

Authority

The provisions of this § 221.33a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.33a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (249295) to (249296).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.34. [Reserved].

Source

The provisions of this § 221.34 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123690).

§ 221.34a. Radiation exposure control.

(a) *Radiation exposure control.* A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure may not be initiated without such an action.

(b) *Visual indication and audible signal.* A means shall be provided for visual indication observable from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) *Termination of exposure.* A means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the time to its initial setting or to "zero."

(d) *Manual exposure control.* An X-ray control shall be incorporated into each X-ray system which allows the operator to terminate an exposure at any time except for one or more of the following:

(1) Exposure of 1/2 second or less.

(2) During serial radiography in which case a means shall be provided to permit completion of any single exposure of the series in process.

(e) *Automatic exposure control.*

(1) Indication shall be made on the control panel when this mode of operation is selected.

(i) A means shall be provided to terminate irradiation at an appropriate exposure for the projection if the automatic exposure control fails to terminate irradiation.

(ii) A visible signal shall indicate when an exposure has been terminated at the limits required by subparagraph (i), and manual resetting shall be required before further automatically timed exposures can be made.

(2) For X-ray systems operating in automatic exposure control mode, and which lack engineered safeguards that prevent exposure in the event of either a malfunction or a mispositioned X-ray beam with respect to film cassette sensors, the back-up or default mAs shall be set by the operator to an appropriate maximum value for the projection.

(3) X-ray systems utilizing automatic exposure control, in which the back-up mAs values are preset and cannot be selected by the operator, shall prominently indicate the preset mAs value on the console, along with an appropriate warning notice to the operator.

(f) *Exposure control location.*

(1) Stationary X-ray systems shall have X-ray controls permanently mounted in a protected area and situated so that the operator is required to remain in that protected area during the entire exposure.

(2) For mobile and portable X-ray systems the exposure switch shall be arranged so that the operator can stand at least 2 meters from the patient and from the tube head and away from the direction of the useful X-ray beam.

Authority

The provisions of this § 221.34a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.34a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.35. [Reserved].

Source

The provisions of this § 221.35 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123690) to (123691).

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§ 221.35a. Fluoroscopic X-ray systems.

Fluoroscopic X-ray systems shall use an image intensifier and in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

Authority

The provisions of this § 221.35a issued under sections 301 and 302 of the Radiation Protection Act (31 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.35a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.36. [Reserved].

Source

The provisions of this § 221.36 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123691).

§ 221.36a. Limitation of useful beam of fluoroscopic equipment.

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

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless a barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(c) A means shall be provided for stepless (continuous) adjustment of the field size.

(d) The minimum field size at the greatest source to image receptor distance shall be containable in a square of 5 centimeters by 5 centimeters unless otherwise provided in 21 CFR 1020.32(b) (relating to fluoroscopic equipment).

(e) Equipment may not be operated at a source to skin distance less than 30 centimeters or as required under 21 CFR 1020.32(g).

(f) The width of the X-ray field in the plane of the image receptor may not exceed that of the visible area of the image receptor by more than 3% of the source to image receptor distance. The sum of the excess length and the excess width may not be greater than 4% of the source to image receptor distance.

(g) For rectangular X-ray fields used with a circular image receptor, the error in alignment shall be determined along the length and width dimensions of the X-ray field which passes through the center of the visible area of the image receptor.

(h) Compliance with subsections (a)—(g) shall be determined with the beam axis perpendicular to the plane of the image receptor.

(i) Spot-film devices shall meet the following additional requirements:

(1) A means shall be provided between the source and the patient for adjustment of the X-ray field size to the size of the portion of film which has been selected on the spot-film selector.

(2) The adjustments shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the film.

(3) The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor may not exceed 3% of the source-to image receptor when adjusted for full coverage of the selected portion of the image receptor.

(4) The sum, without regard to sign, of the misalignment along any two orthogonal dimensions, may not exceed 4% of the source to image receptor distance.

(5) The center of the X-ray field in the plane of the film shall be aligned with the center of the film within 2% of the source to image receptor distance.

Authority

The provisions of this § 221.36a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.36a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285678) to (285679).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.37. [Reserved].

Source

The provisions of this § 221.37 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123691) to (123692).

§ 221.37a. Activation of fluoroscopic tube.

X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of the exposure (dead-man switch). When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate X-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

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Authority

The provisions of this § 221.37a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.37a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.38. [Reserved].

Source

The provisions of this § 221.38 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123692).

§ 221.38a. Entrance exposure rate.

(a) *Fluoroscopic systems without high level control.* The exposure rate may not exceed 10 roentgens (2.58 mC/kg) per minute except during recording of fluoroscopic images.

(b) *Fluoroscopic systems with high level control.*

(1) When the high level control is activated, the maximum exposure rate shall be 20 roentgens (5.16 mC/kg) per minute.

(2) When the high level control is not activated, the maximum exposure rate shall be 10 roentgens (2.58 mC/kg) per minute.

(3) Special means of activation of high level controls are required. The high level control shall only be operable when continuous manual activation is provided by the operator.

(4) There shall be an indication to the fluoroscopist that the high level control is being used.

(c) *Frequency of output measurements.* Output measurements to show compliance with this section shall be made at least annually and after maintenance that could affect the output of the machine.

(d) *Compliance requirements.* Compliance with subsections (a)—(c) shall be determined as follows:

(1) If the source is below the table, the exposure rate shall be expressed for the center of the useful beam 1 centimeter above the tabletop or cradle with the image intensifier 30 centimeters above the tabletop or cradle.

(2) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(3) In a c-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source at its closest possible position of operation.

(4) The tube potential and current shall be set to give the maximum exposure possible from the X-ray system. For systems with automatic exposure control, at least 3 millimeters of lead shall be placed between the measuring device and image receptor.

(5) The measurement shall be made at the center of the useful beam.

Authority

The provisions of this § 221.38a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.38a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.39. [Reserved].

Source

The provisions of this § 221.39 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123692) to (123693).

§ 221.39a. Barrier transmitted radiation rate limits.

The protective barrier may not transmit more than 2 milliroentgens (.516 μmC/kg) per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly for each roentgen per minute of entrance exposure rate.

Authority

The provisions of this § 221.39a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.39a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.40. [Reserved].

Source

The provisions of this § 221.40 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123693).

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§ 221.40a. Indication of tube voltage and current.

During fluoroscopy and cinefluorography, the voltage and the current shall be continuously indicated.

Authority

The provisions of this § 221.40a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.40a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.41. [Reserved].

Source

The provisions of this § 221.41 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123693).

§ 221.41a. Fluoroscopic timer.

A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

Authority

The provisions of this § 221.41a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.41a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.42. [Reserved].

Source

The provisions of this § 221.42 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123694).

§ 221.42a. Control of scattered radiation.

(a) Fluoroscopic table designs when combined with normal operating procedures shall be of a type so no unprotected part of the staff or an ancillary individual's whole body is exposed to unattenuated scattered radiation which originates from under the table. The attenuation required may be not less than .25 millimeter lead equivalent.

(b) Equipment configuration when combined with normal operating procedures shall be of a type so that no portion of the staff or an ancillary individual's whole body, except the extremities, is exposed to the unattenuated scattered radiation emanating from above the table top unless one of the following criteria is met:

(1) The individual is at least 120 centimeters from the center of the useful beam.

(2) The radiation has passed through at least .25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover (film-tray cover panel), sliding or folding panel or self supporting curtains—in addition to lead equivalency provided by the protective apron referred to in § 221.11(e) (relating to registrant responsibilities).

Authority

The provisions of this § 221.42a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.42a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.43. [Reserved].

Source

The provisions of this § 221.43 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123694) to (123695).

§ 221.43a. Mobile fluoroscopes.

In addition to the other requirements of §§ 221.35a—221.42a, mobile fluoroscopes shall provide image intensification.

Authority

The provisions of this § 221.43a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.43a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

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§§ 221.44—221.49. [Reserved].

Source

The provisions of these §§ 221.44—221.49 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123694) to (123698).

§§ 221.51—221.55. [Reserved].

Source

The provisions of these §§ 221.51—221.55 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123698) to (123701).

§ 221.56. [Reserved].

Source

The provisions of this § 221.56 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (249304) and (254511).

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

(a) Fluoroscopic systems used solely for radiation therapy simulations shall comply with §§ 221.35a, 221.37a, 221.40a and 221.41a. The requirements in § 221.41a (relating to fluoroscopic timer) may also be satisfied if a means is provided to indicate the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.

(b) CT units used solely for therapy simulations shall comply with §§ 221.202(f)(1), (7) and (8) and 221.203 (relating to equipment requirements; and facility design requirements).

Authority

The provisions of this § 221.61 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.61 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (285683).

§ 221.62. [Reserved].

Source

The provisions of this § 221.62 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123701) to (123702).

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.71. Equipment requirements.

(a) When the tube is operated at its leakage technique factors, the leakage radiation may not exceed:

(1) One hundred milliroentgens (25.8μC/kg) per hour at 5 centimeters from the surface of the tube housing assembly for contact therapy systems.

(2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured or installed prior to December 19, 1987.

(3) One hundred milliroentgens (25.8μC/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured on or after December 19, 1987.

(4) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 151 to 500 kVp systems.

(5) One-tenth percent of the exposure rate of the useful beam 1 meter from the source for 501 to 999 kVp systems at 1 meter from the source.

(b) Fixed diaphragms or cones used for limiting the useful beam shall provide at least the same protection as required by the tube housing assembly.

(c) Beam limiting devices may, for the portion of the useful beam blocked by these devices, transmit not more than 5% of the original X-ray beam intensity at the maximum voltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(d) The filter system shall be designed so that:

(1) Filters cannot be accidentally displaced from the useful beam at any possible tube orientation.

(2) The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under operating conditions.

(3) A filter is marked as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.

(4) On equipment purchased after January 1, 1971, a filter indication system shall be used on therapy machines using changeable filters. The system shall indicate from the control panel the presence or absence of a filter and shall be designed to permit easy recognition of an added filter in place.

(5) An X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(e) The tube housing assembly shall be immobilized during stationary treatments.

(f) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and the marking shall be readily accessible for use during calibration procedures.

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(g) Contact therapy tube housing assemblies shall have a removable shield of at least .5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(h) Systems of greater than 150 kVp manufactured after December 19, 1987, shall have a beam monitor system which shall meet the following requirements:

(1) Not allow irradiation until a preselected value of exposure has been made at the treatment control panel.

(2) Independently terminate irradiation when the preselected exposure has been reached.

(3) Be designed so that, in the event of a system malfunction or electrical power failure or other interruption, the dose administered to a patient prior to the interruption can be accurately determined.

(4) Have a control panel display which maintains the reading until intentionally reset to zero.

(5) Have a control panel display which does not have scale multiplying factors and utilizes a design so that increasing dose is displayed by increasing numbers.

(i) The following apply to times on the equipment:

(1) A timer shall be provided which has a display at the control panel. The timer shall be graduated in minutes and fractions of minutes. The timer shall have a preset time selector and an elapsed time indicator.

(2) The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer to zero.

(3) The timer shall terminate irradiation when a preselected time has elapsed if a dose monitoring system present has not previously terminated irradiation.

(4) The timer shall permit accurate presetting and determination of exposure time as short as 1 second.

(5) The timer may not permit an exposure if set at zero.

(6) The timer may not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

(j) The control panel, in addition to the displays required in this section, shall have:

(1) An indication of power status.

(2) An indication of X-ray production.

(3) The means of indicating X-ray tube current and voltage.

(4) The means of terminating an exposure.

(k) When a control panel may energize more than one X-ray tube, the following requirements shall be met:

(1) It shall be possible to activate only one X-ray tube at one time.

(2) There shall be an indication at the control panel identifying which X-ray tube is energized.

(3) There shall be an indication at the tube housing assembly when that tube is energized.

(l) There shall be a means of determining the SSD to within 5 millimeters.

(m) Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

(1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

(2) An indication of shutter position shall appear at the control panel.

Authority

The provisions of this § 221.71 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.71 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§ 221.72. Facility design requirements for systems capable of operating above 50 kVp.

(a) Provision shall be made to permit continuous observation of and communication with the patient during irradiation.

(b) Windows, mirror systems or closed-circuit television viewing screens used for observing the patient shall be so located that the operator can maintain direct surveillance over both the control panel and the patient.

(c) Treatment rooms which contain an X-ray system capable of operating above 150 kVp shall meet the following additional requirements:

(1) Necessary shielding, except for a beam interceptor, shall be provided by fixed barriers.

(2) The control panel shall be outside the treatment room or in a shielded booth.

(3) Doors of the treatment room shall be electrically interlocked to the control panel so that X-ray production cannot occur unless entrance doors are closed.

(4) Interlocks shall be provided so that, when a door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than two milliroentgens (.52 μC/kg) per hour and a maximum of ten milliroentgens (2.58 μC/kg) per hour at a distance of 1 meter in any direction from the target; or interlocks shall energize a conspicuous visible or audible alarm signal so that the individual entering and the operator are made aware of the entry. After a shut-off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

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(5) Treatment room entrances shall be provided with warning lights, which will indicate when the useful beam is on, in a readily observable position near the outside of access doors.

Authority

The provisions of this § 221.72 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.72 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§ 221.73. Surveys.

(a) A facility shall have a survey made by, or under the direction of, a qualified expert. The survey shall also be done after a change in the facility or equipment which might cause a change in radiation levels.

(b) The qualified expert or radiological physicist shall report the survey results in writing to the individual in charge of the facility and a copy of the report shall be maintained by the registrant for inspection by the Department. The facility shall be operated in compliance with limitations indicated by the survey.

Authority

The provisions of this § 221.73 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.73 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (249309).

§ 221.74. Calibration.

(a) The calibration of an X-ray system shall be performed at intervals not to exceed 1 year and after a change of replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation output of the X-ray system shall be performed by or under the direction of a qualified expert for radiation therapy calibration who is physically present at the facility during the calibration.

(c) The calibration of the radiation output of an X-ray system shall be performed with a calibrated instrument. The calibration of the instrument shall be traceable to a National standard. The instrument shall have been calibrated within the preceding 2 years.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

(e) The calibration of the X-ray system shall include, but is not limited to, the following determinations:

(1) The exposure rates for each combination of field size, technique factors, filter and treatment distance used.

(2) The degree of congruence between the radiation field and the field indicated by the localizing device if a device is present.

(3) An evaluation of the uniformity of the largest radiation field used.

(f) Records of calibration performed under this section shall be maintained by the registrant for at least 5 years after completion of the calibration.

(g) A copy of the most recent X-ray system calibration shall be available at the control panel.

Authority

The provisions of this § 221.74 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.74 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249309) to (249310).

Cross References

This section cited in 25 Pa. Code § 221.75 (relating to spot checks).

§ 221.75. Spot checks.

Spot checks shall be performed on X-ray systems capable of operation at greater than 150 kVp. The spot checks shall meet the following requirements:

(1) The procedures shall be in writing and shall have been developed by a qualified expert for radiation therapy calibration.

(2) If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within 15 days.

(3) The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the X-ray system.

(4) The spot-check procedure shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in § 221.74 (relating to calibration).

(5) The procedure shall also note conditions which require that the system be recalibrated under § 221.74.

(6) Records of spot-check measurements performed under this section shall be maintained by the registrant for 5 years following the measurement.

(7) Spot check measurements shall be performed using a dosimetry system that has been calibrated under § 221.74(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated under § 221.74(c). The alternative calibration method shall have been performed within the previous year and after each servicing that may have affected the system calibration.

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Authority

The provisions of this § 221.75 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.75 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249310) to (249311).

§ 221.76. Operating procedures.

(a) Therapeutic X-ray systems shall be secured to prevent unauthorized use whenever the system is unattended.

(b) If a patient is held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(c) The tube housing assembly may not be held by an individual during exposures.

(d) No individual other than the patient may be in the treatment room during irradiation unless protected by a shielded booth.

(e) Interlocks, on-off beam control mechanisms and safety and warning devices shall be checked and appropriately serviced at least once in a calendar year.

Authority

The provisions of this § 221.76 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.76 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§§ 221.81—221.102. [Reserved].

Source

The provisions of these §§ 221.81—221.102 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123709) to (123726).

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

In addition to the definitions in §§ 215.2 and 221.2 (relating to definitions), the following words and terms when used in this section and §§ 221.202—221.205, have the following meanings, unless the context clearly indicates otherwise:

CS—Contrast scale—The change in the linear attenuation coefficient per CT number relative to water; that is:

$$CS = (U_x - U_w)/((CT)_x - (CT)_w)$$

Where:
U_x = Linear attenuation coefficient of the material of interest
U_w = Linear attenuation coefficient of water
$(CT)_x$ = CT number of the material of interest
$(CT)_w$ = CT number of water

CT number—The number used to represent the X-ray attenuation associated with each elemental area of the CT image.

CT—Computed tomography—The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

CTDI—Computed tomography dose index—The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

CT conditions of operation—The selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration and the technique factors as defined in this chapter.

Elemental area—The smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted.

Gantry—The tube housing assemblies, beam-limiting devices, detectors, transformers, if applicable, and the supporting structures and frames which hold these components.

Lux—A unit illumination equivalent to 1 lumen per square centimeter or .0929 foot-candles.

MSAD—Multiple scan average dose—The calculated average dose to the tissue within each slice in a series utilizing an ion chamber. The MSAD is calculated using the following equation:

$$MSAD = (F \times K \times L \times E)/(T \times N)$$

Where
F = Factor to convert exposure in air to absorbed dose in lucite in RADS/mR
K = Calibration factor to account for the ion chamber's response and volume.
L = Effective length of ion chamber in millimeters (mm)
E = Exposure reading in milliroentgen (mR)
T = Nominal slice thickness in millimeters (mm) and
N = Number of slices per scan

Multiple tomogram system—A computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise—The standard deviation of the fluctuations in the CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = 100 \times CS \times S/U_w$$

Where:
CS = Contrast scale

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U_w = Linear attenuation coefficient of water.

S = Estimated standard deviation of the CT number of picture elements in a specified area of the CT image.

Nominal tomographic section thickness—The full-width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

Performance phantom—A phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the CT system for low and high contrast objects, and measuring the mean CT number for water or other reference materials.

Picture element—See elemental area.

Pixel—See elemental area.

Reference plane—A plane which is at a known fixed distance—which could be zero—to the tomographic plane and parallel to it.

Scan—The complete process of collecting X-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan increment—The amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of the displacement.

Scan sequence—A preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan time—The period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

Sensitivity profile—The relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

Single tomogram system—A CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

Technique factors—The conditions of operation, specified as follows:

(i) For CT equipment designed for pulsed operations, peak tube potential, scan time in seconds, X-ray pulse width in seconds and the number of X-ray pulses per second or per mAs.

(ii) For CT equipment not designed for pulsed operation, peak tube potential, and either tube current and scan time in seconds or the product of tube current and exposure time in mAs.

Tomogram—The depiction of the X-ray attenuation properties of a section through a body.

Tomographic plane—The geometric plane which is identified as corresponding to the output tomogram.

Tomographic section—The volume of an object whose X-ray attenuation properties are imaged in a tomogram.

Authority

The provisions of this § 221.201 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.201 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.204 (relating to radiation measurements and performance evaluations).

§ 221.202. Equipment requirements.

(a) *Termination of exposure.* The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under X-ray system control, of greater than 0.5 second duration. Termination of the X-ray exposure shall necessitate resetting of the conditions of operation prior to initiation of another scan.

(b) *Tomographic plane indication and alignment.*

(1) For any single tomogram system, a means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, a means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic plane.

(c) *Status indicators and control switches.*

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) The emergency buttons or switches shall be clearly labeled as to their function.

(3) Each individual scan or series of scans shall require initiation by the operator.

(d) *Indication of CT conditions of operation.* The CT X-ray system shall be designed so that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(e) *Leakage radiation.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is

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operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(f) *Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.*

(1) The total error in the indicated location of the tomographic plane or reference plane by the light field or laser indicator may not exceed 5 millimeters.

(2) If the X-ray production period is less than 0.5 second, the indication of X-ray production shall be actuated for at least 0.5 second. Beam-on and shutter status indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The CT X-ray system shall be normalized to water.

(4) The CT number for water for a region of interest, not exceeding 100 square millimeters, shall be 0 ± 10.0 CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the qualified expert, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the qualified expert may establish and maintain an equivalent value.

(5) With the performance phantom, the mean CT number of water of one group of pixels may not differ from the mean CT number of water of a second group of pixels equal size within the same image by more than the manufacturer's published specifications.

(6) The noise, utilizing the facility's performance phantom, may not exceed the manufacturer's published specifications.

(7) The total error between the indicated and actual slice thickness may not exceed 2.0 millimeters.

(8) A distance of at least 100 millimeters measured in a CT image shall agree with the actual distance to within ± 5%.

(9) Premature termination of the X-ray exposure by the operator shall necessitate resetting the CT conditions of operation prior to the initiation of another scan.

Authority

The provisions of this § 221.202 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.202 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285686) to (285688).

Cross References

This section cited in 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems); 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 221.204 (relating to radiation measurements and performance evaluations).

§ 221.203. Facility design requirements.

(a) *Oral communication.* Provision shall be made for oral communication between the patient and the operator at the control panel.

(b) *Viewing systems.*

(1) A means shall be provided to permit continuous observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

(2) If the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

Authority

The provisions of this § 221.203 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.203 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems); and 25 Pa. Code § 221.201 (relating to definitions).

§ 221.204. Radiation measurements and performance evaluations.

(a) *Radiation measurements.*

(1) The CTDI or MSAD along the two axes specified in paragraph (2)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry at the point of maximum surface exposure identified. The CT conditions of operation shall be reproducible and correspond to typical values used by the registrant. If the point of maximum surface exposure constantly changes due to system design, then measurements shall be taken at four different locations-top left, top right, bottom left, bottom right—1 centimeter from the outer surface of the phantom.

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(2) CT dosimetry phantoms shall be used in determining the radiation output of a CT X-ray system. The phantoms shall meet the definition for a CT dosimetry phantom under 21 CFR 1020.33(b)(6) (relating to computed tomography (CT) equipment).

(i) The phantoms shall be specifically designed for CT dosimetry and deemed appropriate by the facility's qualified expert and the Department.

(ii) CT dosimetry phantoms shall provide a means for the placement of dosimeters along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. The means for the placement of dosimeters or alignment devices at other locations may be provided.

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(iv) Dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(3) In addition to the items in subsection (b), the following items shall be evaluated annually or after any component repair or change which in the opinion of the qualified expert may effect the performance of the CT unit:

(i) HVL (half value layer) determination at the most commonly used kVp or 120 kVp.

(ii) CTDI or MSAD as specified in § 221.201 (relating to definitions) for commonly used techniques.

(iii) Tomographic plane indication (light/laser alignment).

(iv) Slice thickness as specified in § 221.202(g)(7) (relating to equipment requirements).

(v) Distance readout calibration.

(4) The measurement of the radiation output of a CT X-ray system shall be performed with a dosimetry system that has calibration traceable to National Institute of Standards and Technology. The calibration of the system shall be in accordance with an established calibration protocol. The calibration protocol published by the AAPM is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent.

(5) An mR/mAs value shall be determined at least annually for the head and body.

(6) Procedures and results shall be maintained for 5 years and be available for review by the Department.

(b) *Performance evaluations.*

(1) Written performance evaluation procedures shall be developed by a qualified expert. These procedures shall be available for review by the Department.

(2) The performance evaluation procedures shall include at least the following using the facility's performance phantom:

(i) Noise.

(ii) Contrast scale.

(iii) Spatial resolution (low and high contrast).

(iv) Mean CT number for water.

(v) Acceptable tolerances.

(3) The performance evaluation shall be performed at intervals not to exceed 3 months by the qualified expert or an individual designated by the qualified expert.

(4) The qualified expert need not be present during the performance evaluation, but shall be informed within 48 hours of any problems or unacceptable deviations.

(5) Performance evaluations shall include acquisition of images obtained with the performance phantom using the same processing mode and CT conditions of operation as are used to perform the measurements required by subsection (a).

(6) Records of the performance evaluations shall be maintained for inspection by the Department for at least 4 years.

Authority

The provisions of this § 221.204 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.204 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285688) and (249317) to (249318).

Cross References

This section cited in 25 Pa. Code § 221.201 (relating to definitions).

§ 221.205. Operating procedures.

(a) Information shall be available at the control panel regarding the operation and performance evaluations of the system. The information shall include the following:

(1) The dates of the latest radiation measurements and performance evaluation and the location within the facility where the results of those tests may be obtained.

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(2) Instructions on the use of the CT phantoms including a schedule of performance evaluations appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent performance evaluation conducted on the system.

(3) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(b) If the radiation measurements and performance evaluation of the CT X-ray system indicates that a system operating parameter has exceeded a tolerance established by the qualified expert, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

Authority

The provisions of this § 221.205 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.205 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249318) to (249319).

Cross References

This section cited in 25 Pa. Code § 221.201 (relating to definitions).

APPENDIX A
DETERMINATION OF COMPETENCE

The registrant shall ensure that individuals who operate diagnostic X-ray equipment have received training on the subjects listed in this appendix. The individual shall be trained and competent in the general operation of the X-ray equipment, and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

(1) Basic properties of radiation.
(2) Units of measurement.
(3) Sources of radiation exposure.
(4) Methods of radiation protection.
(5) Biological effects of radiation exposure.
(6) X-ray equipment.
(7) Image recording and processing.
(8) Patient exposure and positioning.
(9) Procedures.
(10) Quality assurance.
(11) Regulations.

Authority

The provisions of this Appendix A issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this Appendix A adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (249320).

Cross References

This appendix cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities).

[Next page is 222-1.]

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CHAPTER 223. VETERINARY MEDICINE

GENERAL PROVISIONS

Sec.
223.1. Purpose and scope.
223.2. [Reserved].
223.2a. Definitions.
223.3—223.6. [Reserved].
223.7. Structural shielding.
223.8. Operating procedures.

X-RAYS

223.11. Radiographic equipment.
223.12. [Reserved].
223.12a. Fluoroscopic equipment.
223.13. [Reserved].
223.13a. Therapeutic systems.

RADIOACTIVE MATERIAL

223.21. In vitro testing.
223.22. Sealed sources.

Authority

The provisions of this Chapter 223 issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 223 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL PROVISIONS

§ 223.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons utilizing radiation sources in veterinary medicine. Persons who use radiation sources for veterinary medicine shall comply with this chapter. The requirements of this chapter are in addition to and not in substitution for other applicable requirements of this article.

Source

The provisions of this § 223.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119229).

§ 223.2. [Reserved].

Source

The provisions of this § 223.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119229).

§ 223.2a. Definitions.

As used in this chapter, the following words and terms have the following meanings, unless the context clearly indicates otherwise:

C—Coefficient of variation—The ratio of the standard deviation to the mean value of a population of observations.

Dead-man switch—A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Fluoroscopic imaging assembly—A subsystem in which X-ray photons produce a fluoroscopic image. The term includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Image receptor—A device, such as a fluorescent screen or radiographic film, which 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.

Leakage radiation—Radiation emanating from the diagnostic or therapeutic source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

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Authority

The provisions of this § 223.2a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.2a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§§ 223.3—223.6. [Reserved].

Source

The provisions of these §§ 223.3—223.6 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119230).

§ 223.7. Structural shielding.

Facilities regularly used for diagnostic or therapeutic veterinary X-ray procedures shall have protective barriers sufficient to assure compliance with § 219.51 (Reserved).

Authority

The provisions of this § 223.7 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110-301 and 7110-302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.7 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 223.8. Operating procedures.

(a) Individuals, whose presence is not necessary to conduct the X-ray procedures, shall be located in a shielded area or at least 2 meters from the primary X-ray beam and X-ray tubehead.

(b) Mechanical supporting or restraining devices shall be used during X-ray procedures to hold the animal patient or films in position, when the technique permits.

(c) Individuals whose presence is necessary to conduct X-ray procedures and who are not located behind protective barriers or at least 2 meters from the X-ray tubehead and primary X-ray beam shall be protected with appropriate shielding devices such as lead aprons and gloves, and be positioned so that no part of their body except hands and forearms will be exposed to the primary beam. Appropriate shielding devices shall have a lead equivalent at least 0.25 millimeters of lead.

(d) X-ray exposures shall be authorized by a veterinarian.

Authority

The provisions of this § 223.8 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.8 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 223.12a (relating to fluoroscopic equipment).

X-RAYS

§ 223.11. Radiographic equipment.

(a) *Leakage radiation.*

(1) The leakage radiation from the tube housing assembly with a beam-limiting device attached measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is operated at its maximum technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) The radiation emitted by a component other than the tube housing assembly with a beam-limiting device attached may not exceed 2 milliroentgens (0.516 μC/kg) in 1 hour at 5 centimeters from an accessible surface of the component when it is operated in an assembled X-ray system under conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(b) *X-ray beam restriction.*

(1) The primary X-ray beam shall be restricted to the area of clinical interest and equal to or smaller than the image receptor.

(2) Collimating devices capable of limiting the primary beam to the appropriate image receptor to within 2% of the source to image distance shall be provided and used. They shall provide the same degree of protection as is required in subsection (a)(1) for a diagnostic source assembly.

(3) A means shall be provided to align the center of the X-ray field to the center of the image receptor to within 2% of the source to image distance.

(c) *X-ray beam filtration.* The total filtration permanently in the useful beam may not be less than .5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50—70 kVp and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(d) *Exposure control devices.*

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(1) An exposure control device shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to zero. It may not be possible to initiate an exposure with the exposure control device in the zero or off position, if either position is available, unless equipped for current adjustment.

(2) A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator such as the depression of a switch. The switch shall be of the dead man type.

(e) The coefficient of variation for exposure may not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure (a) is greater than or equal to 5 times the maximum exposure (e(max)) minus the minimum exposure (e(min)).

(f) Veterinary portable X-ray units shall be supported by a tube stand when the technique permits unless the unit is designed to be hand held during X-ray procedures.

(g) The X-ray control shall provide indication of the production of X-rays that is observable from the operator's position. The technique factors that are set prior to the exposure shall be indicated on the X-ray control and shall be visible to the operator from the operator's position.

Authority

The provisions of this § 223.11 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.11 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203901).

Cross References

This section cited in 25 Pa. Code § 223.12a (relating to fluoroscopic equipment).

§ 223.12. [Reserved].

Source

The provisions of this § 223.11 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203901).

§ 223.12a. Fluoroscopic equipment.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the primary beam at the maximum source to image receptor distance.

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless the primary barrier is in position to intercept the entire primary beam.

(c) X-ray production in the fluoroscopic mode shall be controlled by a deadman switch for the duration of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposures at any time. A means may be provided to permit completion of a single exposure of the series in process.

(d) The protective barrier may not transmit more than 2 milliroentgens (.516 μC/kg) per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly for each roentgen per minute of entrance exposure rate.

(e) During fluoroscopy and cinefluorography, the voltage and the current shall be continuously indicated.

(f) A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

(g) Fluoroscopic table designs when combined with normal operating procedures shall be of a type that no unprotected part of the staff or an ancillary individual's whole body is exposed to unattenuated scattered radiation which originates from under the table. The attenuation required may be not less than 0.25 millimeter lead equivalent.

(h) Equipment configuration when combined with normal operating procedures shall be of a type that no portion of the staff or an ancillary individual's whole body, except the extremities, is exposed to the unattenuated scattered radiation emanating from above the tabletop unless one of the following criteria is met:

(1) The individual is at least 120 centimeters from the center of the primary beam.

(2) The radiation has passed through at least 0.25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover (film-tray cover panel), sliding or folding panel or self-supporting curtains—in addition to the lead equivalency provided by the protective apron referred to in § 223.8(c) (relating to operating procedures).

(i) In addition to the other requirements of this section, mobile fluoroscopes shall have image intensification.

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Authority

The provisions of this § 223.12a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.12a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 223.13. [Reserved].

Source

The provisions of this § 223.13 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203902).

§ 223.13a. Therapeutic systems.

(a) When the tube is operated at its maximum technique factors, the leakage radiation may not exceed any of the following:

(1) One hundred milliroentgens (25.8 μC/kg) per hour at 5 centimeters from the surface of the tube housing assembly for contact therapy systems.

(2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-500 kVp systems.

(3) One-tenth percent of the exposure rate of the primary beam at 1 meter from the source for 501-999 kVp systems.

(b) Beam limiting devices used for limiting the primary beam shall provide at least the same protection as required by the tube housing assembly.

(c) Therapeutic X-ray systems shall be secured to prevent unauthorized use whenever the system is unattended.

(d) Interlocks shall be provided so that, when a door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than 2 milliroentgens (0.516 μC/kg) per hour and a maximum of 10 milliroentgens (2.58 μC/kg) per hour at a distance of 1 meter in any direction from the target; or interlocks will energize a conspicuous visible or audible alarm signal so that the individual entering and the operator are made aware of the entry. After a shut-off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

(e) Interlocks, on-off beam control mechanisms and safety and warning devices shall be checked and appropriately serviced at least once in a calendar year.

(f) Treatment room entrances shall be provided with warning lights, which will indicate when the primary beam is on, in a readily observable position near the outside of access doors.

(g) Exposure factors shall be displayed on the control panel.

(h) Provision shall be made to permit continuous observation of the animal patient from the control panel during irradiation.

(i) A registrant may not permit an individual to operate a therapeutic X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the system and has demonstrated understanding of the operating procedures and competence in the use of the system.

Authority

The provisions of this § 223.13a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.13a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

RADIOACTIVE MATERIAL

§ 223.21. In vitro testing.

A veterinarian who uses radioactive material for in vitro testing shall comply with 10 CFR 31.11 (relating to general license for use of by-product material for certain in vitro clinical or laboratory testing) but is exempt from 10 CFR Part 20 Subpart K (relating to waste disposal).

Authority

The provisions of this § 223.21 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.906); and sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.21 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282396).

§ 223.22. Sealed sources.

A veterinarian who uses sealed sources for therapeutic treatment of animals shall comply with 10 CFR Part 35, Subparts F, G, H and K but is exempt from 10 CFR 35.632—35.645 and 35.2632—35.2645.

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Authority

The provisions of this § 223.22 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.906); and sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.22 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282396) and (249329).

[Next page is 224-1.]

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CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

Subch.		Sec.
A.	GENERAL	224.1
B.	OTHER REQUIREMENTS	224.21
C.	[Reserved]	224.101
D.	[Reserved]	224.151
E.	[Reserved]	224.201
F.	[Reserved]	224.251
G.	[Reserved]	224.301
H.	[Reserved]	224.351
I.	[Reserved]	224.401
J.	[Reserved]	224.451
K.	[Reserved]	224.501

Authority

The provisions of this Chapter 224 issued under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.906); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 224 adopted June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); and 25 Pa. Code § 217.1 (relating to purpose and scope).

Subchapter A. GENERAL

Sec.	
224.1.	Purpose and scope.
224.2—224.9.	[Reserved].
224.10.	Incorporation by reference.
224.11.	Effect of incorporation of 10 CFR Part 35.

§ 224.1. Purpose and scope.

This chapter prescribes requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of radioactive material. These requirements and provisions provide for the protection of the public health and safety. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements in this article. Unless specifically exempted, the requirements of Chapters 215, 217—220 and 230 apply to applicants and licensees subject to this article.

Source

The provisions of this § 224.1 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206. Immediately preceding text appears at serial page (170454).

§§ 224.2—224.9. [Reserved].

Source

The provisions of these §§ 224.2—224.9 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203906) to (203910).

§ 224.10. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 35 (relating to medical use of byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 35.8, 35.4001 and 35.4002 (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

Authority

The provisions of this § 224.10 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 224.10 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282398).

§ 224.11. Effect of incorporation of 10 CFR Part 35.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 35 (relating to medical use of byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 35 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) A reference to "byproduct material" includes NARM.

(4) The definition of "sealed source" includes NARM.

(5) A reference to the Advisory Committee on the Medical Uses of Isotopes is synonymous with the Department's Radiation Protection Advisory Committee.

(6) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 224.11 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

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Subchapter B. OTHER REQUIREMENTS

Sec.
224.21. [Reserved].
224.22. Authorization for calibration, transmission and reference sources.
224.23. Decay-in-storage.
224.51—224.60. [Reserved].

§ 224.21. [Reserved].

Source

The provisions of this § 224.21 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; reserved July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282399).

§ 224.22. Authorization for calibration, transmission and reference sources.

Notwithstanding the incorporation by reference of 10 CFR 35.65 (relating to authorization for calibration, transmission, and reference sources), a licensee authorized for medical use radioactive materials may not receive, possess or use radium in total quantity of 3.7 MBq (100 μci) or more for check, calibration, transmission and reference use except as specifically authorized by the Department.

Authority

The provisions of this § 224.22 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 224.22 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282399).

§ 224.23. Decay-in-storage.

Notwithstanding the incorporation by reference of 10 CFR Part 35 (relating to medical use of byproduct material), a licensee may hold sealed sources of radioactive material with a physical half-life of up to 300 days for decay-in-storage before disposal in ordinary trash.

Authority

The provisions of this § 224.23 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 224.23 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282399).

§§ 224.51—224.60. [Reserved].

Source

The provisions of these §§ 224.51—224.60 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203910) to (203915).

Subchapter C. [Reserved]

§§ 224.101—224.111. [Reserved].

Source

The provisions of these §§ 224.101—224.111 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203916) to (203924).

§ 224.112. [Reserved].

Source

The provisions of this § 224.112 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203924).

Subchapter D. [Reserved]

§§ 224.151 and 224.152. [Reserved].

Source

The provisions of these §§ 224.151 and 224.152 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203924) to (203925).

Subchapter E. [Reserved]

§§ 224.201 and 224.202. [Reserved].

Source

The provisions of these §§ 224.201 and 224.202 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203925) to (203926).

§ 224.203. [Reserved].

Source

The provisions of this § 224.203 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203926).

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§ 224.204. [Reserved].

Source

The provisions of this § 224.204 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203927).

Subchapter F. [Reserved]

§§ 224.251 and 224.252. [Reserved].

Source

The provisions of these §§ 224.251 and 224.252 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203927) to (203928).

§ 224.253. [Reserved].

Source

The provisions of this § 224.253 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203928) to (203929).

§ 224.254. [Reserved].

Source

The provisions of this § 224.254 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203929).

Subchapter G. [Reserved]

§§ 224.301—224.304. [Reserved].

Source

The provisions of these §§ 224.301 and 224.304 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203929) to (203931).

§ 224.305. [Reserved].

Source

The provisions of this § 224.305 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203931) to (203932).

§ 224.306. [Reserved].

Source

The provisions of this § 224.306 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203932).

Subchapter H. [Reserved]

§§ 224.351 and 224.352. [Reserved].

Source

The provisions of these §§ 224.351 and 224.352 reserved September 14, 2001, reserved September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203932) to (203933).

Subchapter I. [Reserved]

§§ 224.401—224.411. [Reserved].

Source

The provisions of these §§ 224.401 and 224.411 reserved September 14, 2001, reserved September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203933) to (203942).

§ 224.412. [Reserved].

Source

The provisions of this § 224.412 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203942).

§§ 224.413 and 224.414. [Reserved].

Source

The provisions of these §§ 224.413 and 224.414 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203942) to (203943).

Subchapter J. [Reserved]

§§ 224.451—224.465. [Reserved].

Source

The provisions of these §§ 224.451 and 224.465 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203944) to (203953).

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Subchapter K. [Reserved]

§ 224.501. [Reserved].

Source

The provisions of this § 224.501 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (903953) to (203954).

[Next page is 225-1.]

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CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subch.		Sec.
A.	GENERAL PROVISIONS	225.1
B.	RADIATION-PRODUCING MACHINES	225.71

Authority

The provisions of this Chapter 225 issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed); and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 225 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 78.111 (relating to abandonment); 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 228.45 (relating to portable or mobile accelerators); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

Subchapter A. GENERAL PROVISIONS

Sec.	
225.1.	Purpose and scope.
225.2.	[Reserved].
225.2a.	Incorporation by reference.
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225.4.	[Reserved].
225.4a.	Radiation safety program.
225.5.	[Reserved].
225.5a.	Reciprocity.
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225.7.	[Reserved].
225.8.	[Reserved].
225.9.	[Reserved].
225.11—225.13.	[Reserved].
225.14.	[Reserved].
225.15—225.18.	[Reserved].
225.21.	[Reserved].
225.22.	[Reserved].
225.23.	[Reserved].
225.31—225.33.	[Reserved].
225.34—225.36.	[Reserved].
225.41—225.43.	[Reserved].

225.44. [Reserved].
225.51—225.53. [Reserved].
225.54—225.65. [Reserved].

§ 225.1. Purpose and scope.

(a) This chapter establishes radiation safety requirements for persons utilizing radiation sources for industrial radiography. Licensees and registrants who use radiation sources for industrial radiography shall comply with this chapter. The requirements of this chapter are in addition to and not in substitution for other applicable requirements in this article, in particular, the requirements and provisions of Chapters 215, 217—220, 228 and 230.

(b) Persons using only radiation-producing machines for industrial radiographic operations need not comply with § 225.2a (relating to incorporation by reference) unless otherwise specified in Subchapter B (relating to radiation-producing machines).

(c) This chapter does not apply to the use of radiation sources for medical diagnosis or therapy.

Source

The provisions of this § 225.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282406).

§ 225.2. [Reserved].

Source

The provisions of this § 225.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203957) to (203958).

§ 225.2a. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 34 (relating to licenses for industrial radiography and radiation safety requirements for industrial radiographic operations) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 34.5, 34.8, 34.121 and 34.123 are not incorporated by reference.

Source

The provisions of this § 225.2a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Cross References

This section cited in 25 Pa. Code § 225.1 (relating to purpose and scope).

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§ 225.3. [Reserved].

Source

The provisions of this § 225.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4895) to (4896).

§ 225.3a. Effect of incorporation of 10 CFR Part 34.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 34, the following words and phrases shall be substituted for the language in 10 CFR Part 34 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 225.3a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 225.4. [Reserved].

Source

The provisions of this § 225.4 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4896).

§ 225.4a. Radiation safety program.

(a) A person who intends to use radiation-producing machines for industrial radiography shall have a program for training personnel, written operating procedures and emergency procedures, an internal review system and an organizational structure for radiographic operations which includes specified delegations of authority and responsibility for operation of the program. This program shall be approved by the Department before commencing industrial radiographic operations.

(b) The registrant shall notify the Department of intended changes to the registrant's radiation safety program and obtain Departmental approval.

Source

The provisions of this § 225.4a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282407).

Cross References

This section cited in 25 Pa. Code § 225.102 (relating to shielded room X-ray radiography).

§ 225.5. [Reserved].

Source

The provisions of this § 225.5 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4896).

§ 225.5a. Reciprocity.

Out-of-State users of radiation producing machines shall meet the requirements of § 216.7 (relating to out-of-State radiation-producing machines).

Source

The provisions of this § 225.5a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 225.6. [Reserved].

Source

The provisions of this § 225.6 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4896).

§ 225.6a. Prohibitions.

Use of radiation sources covered under this chapter for diagnosis or therapy on humans or animals is not permitted.

Source

The provisions of this § 225.6a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 225.7. [Reserved].

Source

The provisions of this § 225.7 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4896) to (4897).

§ 225.8. [Reserved].

Source

The provisions of this § 225.8 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4897).

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§ 225.9. [Reserved].

Source

The provisions of this § 225.9 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4897).

§§ 225.11—225.13. [Reserved].

Source

The provisions of these § 225.11—225.13 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203959) to (203960).

§ 225.14. [Reserved].

Source

The provisions of this § 225.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203960) to (203961).

§§ 225.15—225.18. [Reserved].

Source

The provisions of these §§ 225.15—225.18 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial text pages (203962) to (203964).

§ 225.21. [Reserved].

Source

The provisions of this § 225.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203964).

§ 225.22. [Reserved].

Source

The provisions of this § 225.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203965).

§ 225.23. [Reserved].

Source

The provisions of this § 225.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203965) to (203966).

§§ 225.31—225.33. [Reserved].

Source

The provisions of these §§ 225.31—225.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203966) to (203967).

§§ 225.34—225.36. [Reserved].

Source

The provisions of these §§ 225.34—225.36 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (4902) to (4904).

§§ 225.41—225.43. [Reserved].

Source

The provisions of these §§ 225.41—225.43 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203968) to (203970).

§ 225.44. [Reserved].

Source

The provisions of this § 225.44 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203970) to (203971).

§§ 225.51—225.53. [Reserved].

Source

The provisions of these §§ 225.51—225.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203971) to (203972).

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§§ 225.54—225.65. [Reserved].

Source

The provisions of these §§ 225.54—225.65 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4908) to (4916).

Subchapter B. RADIATION-PRODUCING MACHINES

GENERAL ADMINISTRATIVE REQUIREMENTS

Sec.
225.71. Definitions.
225.72. Duties of personnel.
225.73. Training of personnel.
225.74. Training and testing.
225.75. Audits and safety reviews of radiographers and radiographer's assistants.
225.76. Reporting requirements.

GENERAL TECHNICAL REQUIREMENTS

225.81. Permanent radiographic installations.
225.82. Operating requirements.
225.83. Records required at field radiography sites.
225.84. Operating and emergency procedures.
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RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

225.91. Radiation survey meter requirements.
225.92. Radiation survey meter calibration requirements.
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RADIATION-PRODUCING MACHINE REQUIREMENTS

225.101. Cabinet X-ray systems and baggage/package X-ray systems.
225.102. Shielded room X-ray radiography.
225.103. Field site radiography.
225.104. X-ray detection systems for explosives, weapons and illegal items.

Source

The provisions of this Subchapter B adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 225.1 (relating to purpose and scope).

GENERAL ADMINISTRATIVE REQUIREMENTS

§ 225.71. Definitions.

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

Cabinet radiography—Industrial radiography conducted in an enclosure or cabinet (not a room) so shielded that doses to individual members of the public at every location on the exterior meet the limitations specified in 10 CFR 20.1301 (relating to dose limits for individual members of the public).

Cabinet X-ray system—An X-ray system with the X-ray tube installed in an interlocked enclosure or cabinet, designed to exclude personnel from its interior during operation.

(i) Included are all X-ray systems designed primarily for the inspection of baggage or packages.

(ii) An X-ray tube used within a shielded part of a building or X-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet X-ray system.

Certified cabinet X-ray system—An X-ray system which has been certified under 21 CFR 1010.2 (relating to certification) as being manufactured and assembled under 21 CFR 1020.40 (relating to cabinet x-ray systems).

DRD—Direct reading dosimeter—

(i) As used in this subchapter, means an "individual monitoring device" (see 10 CFR 20.1003 (relating to definitions)) that does not require additional processing to measure an individual's dose.

(ii) The term also includes the direct reading personnel (individual) monitoring devices known as pocket dosimeter, pocket ionization chamber and electronic personal dosimeter (EPD).

Field radiography—A location where radiographic operations are conducted (onsite or offsite) other than those designated as a permanent radiographic facility.

Industrial radiography—An examination of the structure of materials by nondestructive methods, including fluoroscopy, which utilizes radiation producing machines to make radiographic images.

NVLAP—National Voluntary Laboratory Accreditation Program.

Permanent radiographic installation—A shielded installation or structure designed or intended for radiography in which radiography is regularly performed.

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Personal supervision—The provision of guidance and instruction to a radiographer's assistant given by a radiographer who is:

(i) Physically present at the site.

(ii) In visual contact with the radiographer's assistant while the assistant is using radiation sources.

(iii) In proximity so that immediate assistance can be given if required.

Personnel dosimeter—As used in this subchapter, means any of the "individual monitoring devices" (see 10 CFR 20.1003) that shall be processed and evaluated to generate a permanent record of an individual's dose, for example, a film badge, thermoluminescent dosimeter (TLD) or optically stimulated luminescent dosimeter (OSLD).

RSO—radiation safety officer—An individual who ensures that, in the daily operation of the registrant's or licensee's radiation safety program, activities are being performed in accordance with approved procedures and are in compliance with Department requirements.

Radiographer—An individual who performs radiographic operations or an individual in attendance at a site where radiation producing machines are being used who personally supervises industrial radiographic operations.

Radiographer's assistant—An individual who, under the personal supervision of a radiographer, uses radiation producing machines or radiation survey instrumentation.

Radiographer trainee—An individual who is in the process of becoming a radiographer's assistant or a radiographer.

Radiographic operations—The activities associated with a radiation producing machine during use of the machine, to include surveys to confirm adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

Safety device—As applied to radiation-producing machines in this subchapter, a device or component that causes the unit to de-energize or interrupt the beam.

Shielded room radiography—Industrial radiography that is conducted in an enclosed room, the interior of which is not occupied during radiographic operations.

Source

The provisions of this § 225.71 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282412) to (282413).

§ 225.72. Duties of personnel.

(a) The RSO shall assure that the radiation safety program of the registrant or licensee is implemented and suspend or terminate operations that are not being conducted in accordance with approved procedures or the Department's requirements.

(b) The radiographer is responsible to the registrant or licensee for following the procedures of the registrant or licensee and for complying with the Department's requirements while industrial radiographic operations are being conducted.

(c) The radiographer's assistant shall only use radiation producing machines or radiation survey instrumentation under the personal supervision of a radiographer.

(d) The radiographer trainee is not permitted to operate radiation producing machines or radiation survey instrumentation.

§ 225.73. Training of personnel.

(a) A registrant may not allow an individual to act as a radiographer or radiographer's assistant unless that individual meets the requirements of § 225.74 (relating to training and testing).

(b) Persons performing field radiography shall comply with the training requirements in Appendix A (relating to subjects to be covered during the instruction of radiographers).

Source

The provisions of this 225.73 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282414).

§ 225.74. Training and testing.

(a) The registrant may not permit an individual to act as a radiographer until that individual has:

(1) Been instructed in the subjects outlined in Appendix A.

(2) Received copies of this chapter, Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations), and copies of the license or certificate of registration and the operating and emergency procedures of the registrant or licensee.

(3) Received instruction covering regulatory requirements, operating and emergency procedures and the use of radiation-producing machines and radiation survey instruments of the registrant or licensee.

(4) Demonstrated competency and understanding of the information in this subsection to the satisfaction of the registrant or licensee as evidenced by the successful completion of a written test and a field examination.

(b) The registrant or licensee may not permit an individual to act as a radiographer's assistant until that individual has:

(1) Received copies of, and instruction in, the applicable operating and emergency procedures and has been instructed in the use of sources of radiation and radiation survey instruments of the registrant or licensee.

(2) Demonstrated that, under direct personal supervision of a radiographer, the individual is competent to use sources of radiation and radiation survey

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instruments as evidenced by the successful completion of a written or oral test and a field examination on the subjects relevant to being an assistant radiographer.

(c) Records of the training required under subsections (a) and (b), including copies of written tests, dates of oral tests and field examinations, shall be maintained for inspection by the Department for 3 years following termination of employment by the individual or until the registration or license is terminated.

Cross References

This section cited in 25 Pa. Code § 225.73 (relating to training and testing).

§ 225.75. Audits and safety reviews of radiographers and radiographer's assistants.

(a) The registrant or licensee shall review and provide for the safety and ongoing training needs of radiographers and radiographer's assistants at least once during each calendar year.

(b) The registrant or licensee shall conduct an annual inspection program of the job performance of each radiographer and radiographer's assistant to ensure that operating and emergency procedures and this article and registration or license requirements for the registrant or licensee are followed. This audit program shall:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed 1 calendar year.

(2) Provide that, if a radiographer or radiographer's assistant has not participated in a radiographic operation for more than 6 months since the last annual inspection, the individual's performance shall be observed and recorded when the individual next participates in a radiographic operation.

(c) The registrant or licensee shall maintain records of the training set forth in subsection (b) to include certification documents, written and field examinations, annual safety reviews and annual audits of job performance. Records shall be available for inspection by the Department for 3 years following the termination of employment of the individual or until the registration or license is terminated.

§ 225.76. Reporting requirements.

(a) In addition to the reporting requirements in §§ 219.221 and 219.222 (relating to reports of stolen, lost or missing licensed or registered sources of radiation; and notification of incidents and reportable events), each registrant or licensee shall provide to the Department, within 30 days of its occurrence, a written report on any of the following incidents involving machines or equipment used in radiographic operations:

(1) The inability to terminate irradiation from a radiation producing machine.

(2) An interlock failure during shielded room radiography.

(b) The registrant or licensee shall include the following information in each report submitted under subsection (a):

(1) A description of the equipment problem.

(2) The cause of the incident, if known or determined.

(3) The manufacturer and model number of the equipment involved.

(4) The place, date and time of the incident.

(5) Actions taken to reestablish normal operations.

(6) Corrective actions taken or planned to prevent reoccurrence.

(7) The names and qualifications of personnel involved.

(c) Reports of overexposures, required under 10 CFR 20.2202 (relating to notification of incidents) or of excessive exposures, required under 10 CFR 20.2203 (relating to reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits) which involve the failure of safety components of radiography equipment shall also include, to the extent known, the information specified under subsection (b). Complete information required in subsection (b) shall be available in the 30-day follow-up report rule under 10 CFR 20.2203(a).

GENERAL TECHNICAL REQUIREMENTS

§ 225.81. Permanent radiographic installations.

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in 10 CFR 20.1601 and 20.1902 (relating to control of access to high radiation areas; and posting requirements) shall also meet the following requirements.

(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the X-ray source is energized. The audible signal shall be actuated when an attempt is made to enter the installation while the X-ray source is energized.

(2) The entrance control device or alarm system shall be tested for proper function prior to beginning operations on each day of use.

(3) The radiographic exposure system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used provided that the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.52 (relating to surveillance; posting), § 225.83 (relating to records required at field radiography sites) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the radiation safety officer or an individual designated by the radiation safety officer shall validate the repair.

(b) Records of the tests performed under subsection (a) shall be maintained for inspection by the Department for 3 years.

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§ 225.82. Operating requirements.

(a) When radiographic operations are performed at a location other than a permanent radiographic installation, a minimum of two radiographic personnel shall be present to operate the X-ray device. At least one of the radiographic personnel shall be qualified as a radiographer. The other individual may be either a radiographer, a radiographer's assistant or a radiographer trainee.

(b) Other than a radiographer, or a radiographer's assistant who is under the personal supervision of a radiographer, an individual may not manipulate the controls or operate the equipment used in industrial radiographic operations.

(c) At each job site, the following shall be supplied by the registrant or licensee:

(1) The appropriate barrier ropes and warning signs.

(2) At least one operable, calibrated radiation survey instrument.

(3) For each worker requiring monitoring, an individual personnel dosimeter that is processed and evaluated by an NVLAP processor.

(4) An operable, calibrated direct reading dosimeter with a range of zero to 51.6 μC/kg (200 milliroentgen) for each worker requiring monitoring.

(d) An industrial radiographic operation may not be performed if any of the items in subsection (c) is not available at the job site or is inoperable.

Source

The provisions of this § 225.82 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282416) to (282417).

§ 225.83. Records required at field radiography sites.

Each registrant or licensee conducting radiographic operations at a field radiography site shall maintain and have available for inspection by the Department at that job site, the following records or documents:

(1) The certificate of registration, license or equivalent document which authorizes radiographic operations, and radiographic personnel certifications.

(2) Operating and emergency procedures.

(3) Relevant regulations of the Department.

(4) Survey records required under this chapter for the period of operation at the site.

(5) Daily direct reading dosimeter records for the period of operation at the site.

(6) The current radiation survey meter calibration records for meters in use at the site. Acceptable records include tags or labels that are affixed to the survey meter.

Source

The provisions of this § 225.83 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282417).

Cross References

This section cited in 25 Pa. Code § 225.81 (relating to permanent radiographic installations).

§ 225.84. Operating and emergency procedures.

The operating and emergency procedures of the registrant or licensee shall include instruction in at least the following:

(1) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation in excess of the limits established in Chapter 219 (relating to standards for protection against radiation).

(2) Methods and occasions for conducting radiation surveys and the proper use of survey meters.

(3) Methods for controlling access to areas where radiographic operations are being conducted.

(4) Methods and occasions for locking and securing sources of radiation.

(5) Personnel monitoring and the use of individual monitoring devices, including steps that are to be taken immediately by radiographic personnel when a direct reading dosimeter is found to be off-scale.

(6) Methods and procedures for minimizing exposure to individuals in the event of an accident.

(7) The procedure for notifying proper personnel in the event of an accident.

(8) Maintenance of records required by the Department.

(9) The inspection and maintenance of radiation-producing machines and survey meters.

Cross References

This section cited in 25 Pa. Code § 225.102 (relating to shielded room X-ray radiography).

§ 225.85. Surveys and survey records.

(a) A survey with a calibrated radiation survey instrument shall be made after each radiographic exposure to determine that the emission of radiation has terminated.

(b) Records of the surveys required by subsection (a) shall be maintained (for inspection by the Department) for 3 years. If the survey has been used to determine an individual's exposure, the records of the survey shall be maintained until the Department terminates the registration or license.

§ 225.86. Utilization logs.

A registrant or licensee shall maintain current logs, which shall be kept available for inspection by the Department for 3 years from the date of the event, showing for each radiation-producing machine, the following applicable information:

(1) The identity (name and signature) of the operator to whom the radiation-producing machine is assigned.

(2) The model and serial number of the radiation-producing machine.

(3) The locations and dates of use.

(4) The technique factors (tube kilovoltage, tube current, exposure time) used for each radiographic exposure.

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§ 225.87. Security.

During each radiographic operation, the radiographer or radiographer's assistant shall maintain direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except when one of the following exists:

(1) The high radiation area is equipped with a control device or an alarm system as described in 10 CFR 20.1601 and 20.1902(b) (relating to control of access to high radiation areas; and posting of high radiation areas).

(2) The high radiation area is locked to protect against unauthorized or accidental entry.

§ 225.88. Posting.

Areas in which radiographic operations are being performed shall be conspicuously posted as required by 10 CFR 20.1902 (relating to posting requirements).

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

§ 225.91. Radiation survey meter requirements.

(a) A registrant or licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this chapter and Chapter 219 (relating to standards for the protection against radiation).

(b) A radiographic operation may not be conducted unless calibrated and operable radiation survey instrumentation is available and used at each site where radiographic operations are conducted.

(c) Immediately prior to first use at a site where radiographic operations are conducted and at the beginning of work shift changes thereafter, a radiation survey instrument shall be checked to ensure that it is operating properly by exposing the instrument to a reference source of radiation and observing its response. Instruments that fail to respond as expected may not be used.

Cross References

This section cited in 25 Pa. Code § 225.92 (relating to radiation survey meter calibration requirements).

§ 225.92. Radiation survey meter calibration requirements.

(a) In addition to the requirements of § 225.91 (relating to survey meter requirements), instruments required by this chapter shall have a range so that 0.516 μC/kg (2 mR) per hour through 258 μc/kg (1 R) per hour can be measured.

(b) Each radiation instrument shall be calibrated:

(1) At energies appropriate for use.

(2) At intervals not to exceed 6 months.

(3) After each instrument servicing, other than battery replacement.

(4) To within an accuracy of +/- 20%.

(5) At two points located approximately one-third and two-thirds of full scale on each scale of linear scale instruments; at mid-range of each decade and at two points of at least 1 decade for logarithmic scale instruments; and for digital instruments, at three points between 0.516 μC/kg (2 mR) and 258 μC/kg (1000 mR) per hour.

(6) By a person authorized by the Department, the NRC or an agreement state.

(c) Calibration records shall be maintained for inspection by the Department for 3 years after the date of calibration.

§ 225.93. Personnel monitoring control.

(a) The registrant or licensee may not permit an individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each individual wears a direct reading dosimeter and a personnel dosimeter that is processed and evaluated by an NVLAP processor.

(1) Personnel monitoring devices used to determine compliance with dose limits for the whole body shall be worn on the trunk of the body over the area most likely to receive exposure.

(2) This does not relieve the registrant or licensee from providing peripheral monitoring devices such as ring finger TLDs when appropriate.

(3) Each personnel monitoring device shall be assigned to and worn by only one individual.

(b) Film badges shall be replaced at intervals not to exceed 1 month. Other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at intervals not to exceed 3 months.

(c) Direct reading dosimeters shall meet the criteria as in ANSI N13.5-1972, "Performance Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma-Radiation" published in 1972, exclusive of subsequent amendments or additions.

(d) The use of DRDs is subject to the following requirements:

(1) DRDs shall have a range of zero to 51.6 μC/kg (200 mR) and shall be rezeroed at the start of each work shift.

(2) As a minimum, at the beginning and the end of each worker's shift involving the use of a source of radiation, DRDs shall be read and the exposure values recorded.

(3) Direct reading dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. A dosimeter may not be used for personnel monitoring unless the response is accurate within +/- 20% of the true radiation exposure. Records of dosimeter response checks shall be maintained for inspection by the Department for 3 years.

(4) If an individual's DRD indicates exposure that is "off-scale" beyond the range it can measure, industrial radiographic operations by that individual

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shall cease immediately and the individual's personnel dosimeter shall be sent immediately for processing. The individual may not use any sources of radiation until the individual's radiation dose has been determined.

(e) Data on personnel exposure reported or recorded from personnel monitoring devices shall be kept for inspection by the Department until the certificate of registration or license is terminated or until the Department authorizes their disposition, in writing, following a determination by the Department that the records contain inaccurate personnel monitoring information.

RADIATION-PRODUCING MACHINE REQUIREMENTS

§ 225.101. Cabinet X-ray systems and baggage/package X-ray systems.

(a) Cabinet and baggage/package X-ray systems that are certified under 21 CFR Chapter I, Subchapter J (relating to radiological health) shall also meet the requirement of 21 CFR 1020.40 (relating to cabinet X-ray systems).

(b) A cabinet X-ray system may not be energized unless all openings are securely closed and exposure to radiation from the system does not exceed the limits in 10 CFR 20.1301 (relating to dose limits for individual members of the public). Each access door to the cabinet shall have an interlock that terminates the exposure whenever the door is opened. The enclosure shall be shielded so that every location on the exterior meets the conditions for an unrestricted area.

(c) A registrant may not permit an individual to operate a cabinet X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the X-ray system and has demonstrated competency in the use of the cabinet X-ray system and an understanding of the operating procedures.

(d) The registrant shall perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 and maintain records of these surveys for inspection by the Department for 3 years:

(1) Upon installation of the equipment.

(2) Following a change in the initial arrangement, relocation of the unit, or following any maintenance requiring the disassembly or removal of any shielding component.

(3) When a visual inspection reveals an abnormal condition.

(e) The registrant shall test on-off switches, interlocks and safety devices at intervals not exceeding 1 year, and make repairs as necessary to maintain all safety features including warning labels. Records of these tests shall be maintained for inspection by the Department for 3 years.

(f) Cabinet X-ray systems and baggage/package X-ray systems are exempt from all other provisions of this chapter.

Source

The provisions of this § 225.101 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282421).

Cross References

This section cited in 25 Pa. Code § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items).

§ 225.102. Shielded room X-ray radiography.

(a) A room used for shielded room X-ray radiography shall be shielded so that every location on the exterior meets conditions for an unrestricted area and the only access to the room is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

(b) The operator shall conduct a physical radiation survey to determine that the radiation source is deenergized prior to each entry into the radiographic exposure area.

(c) As an alternative to subsection (b), the registrant may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels.

(d) With the exception of the provisions of §§ 225.4a and 225.84 (relating to radiation safety program; and operating and emergency procedures), shielded room radiography is exempt from all other provisions of this chapter.

Source

The provisions of this § 225.102 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282421) to (282422).

§ 225.103. Field site radiography.

(a) The operator shall conduct a physical radiation survey to determine that the radiation source is de-energized prior to each entry into the radiographic exposure area. Survey results and records of the boundary location shall be maintained and kept available for inspection by the Department for 3 years.

(b) Mobile or portable radiation producing machines shall be physically secured to prevent tampering or removal by unauthorized personnel.

Source

The provisions of this § 225.103 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282422).

§ 225.104. X-ray detection systems for explosives, weapons and illegal items.

(a) This section applies to X-ray systems that produce an image that may be used to screen for the presence of explosive devices or components, weapons, contraband or prohibited items. This section does not apply to cabinet and baggage/package X-ray systems covered under § 225.101 (relating to cabinet X-ray systems and baggage/package X-ray systems).

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(b) An X-ray system used for detection of explosives, weapons or illegal items may not be used on human beings or animals without specific permission of the Department. X-ray systems that irradiate human beings for medical diagnosis are covered under Chapter 221 (relating to human use of X-ray machines). X-ray systems that irradiate animals for diagnosis or therapy are covered under Chapter 223 (relating to veterinary medicine).

(c) Radiographic X-ray detection systems shall conform to the following:

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) Portable X-ray systems shall be equipped with collimators which are capable of restricting the useful beam to the area of interest. Collimators shall provide the same degree of protection required in paragraph (1).

(3) A means shall be provided to terminate the exposure after a preset time, a preset to image receptor or a preset product of exposure time and tube current.

(4) The X-ray control shall have a dead-man type exposure switch.

(5) The X-ray controls shall indicate the technique factors, (that is, kilovoltage, tube current and exposure time or the product of tube current and exposure time).

(6) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the words, "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.

(7) For fixed radiographic equipment, an easily visible warning light shall be located adjacent to the X-ray tube and labeled with the words "X-RAY ON" or words having a similar intent. The warning light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(d) Fluoroscopic X-ray detection systems shall conform to the following:

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the words, "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.

(3) To the extent practicable, the X-ray system (X-ray tube, imaging system and the object being irradiated) shall be completely enclosed so that every location on the exterior meets conditions for an unrestricted area and the only

access to the room or enclosure is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

(4) The equipment shall be constructed so that, under conditions of normal use, the entire cross-section of the useful beam shall be attenuated by a primary protective barrier permanently incorporated into the equipment.

(5) The X-ray control shall have a dead-man type exposure switch. Activation of the X-ray beam shall be possible only by continuous pressure on the exposure switch.

(6) An easily visible warning light shall be located adjacent to the X-ray tube or on the outside of the enclosure and be labeled with the words "X-RAY ON" or words having a similar intent. This light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(e) Operating procedures for portable radiographic X-ray detection systems are as follows:

(1) To the extent practicable, portable X-ray tube heads shall be supported by a stand.

(2) To the extent practicable, supporting or positioning devices for the image receptor shall be used during radiation exposures.

(3) Individuals, other than those whose presence is necessary to conduct the X-ray procedure, shall be located at least 2 meters away from the X-ray tube and the object being irradiated during exposures.

(4) An individual may not be regularly employed to support the image receptor or object during radiation exposures.

(f) Operating procedures for fixed radiographic X-ray detection systems are as follows:

(1) A registrant shall test the safety and warning devices, including interlocks, at intervals not to exceed 12 months. Test records shall be maintained for inspection by the Department for 3 years after the test has been conducted.

(2) Safety or warning devices that do not function properly shall be repaired in a timely manner.

(3) If an X-ray detection system is required to be operated while in need of repair, procedures shall be modified to maintain the design level equivalent of safety or else the equipment may not be used.

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APPENDIX A

Subjects to be Covered During the
Instruction of Radiographers

I. *Fundamentals of Radiation Safety*
   A. Characteristics of radiation
   B. Units of radiation dose and quantity of radioactivity
   C. Significance of radiation dose
      1. Radiation protection standards
      2. Biological effects of radiation dose
   D. Levels of radiation from radiation sources
   E. Methods of controlling radiation dose
      1. Working time
      2. Working distances
      3. Shielding

II. *Radiation Detection Instrumentation to be Used*
   A. Use of radiation survey instruments
      1. Operation
      2. Calibration
      3. Limitations
   B. Survey techniques
   C. Use of personnel monitoring equipment
      1. Film badges
      2. Thermoluminescent dosimeters
      3. Pocket dosimeters

III. *Radiographic Equipment to be Used*
   A. Remote handling equipment
   B. Radiographic exposures devices and sealed sources
   C. Storage containers
   D. Operation and control of X-ray equipment

IV. *The Requirements of Pertinent Federal and State Regulations*

V. *The Licensee's or Registrant's Written Operating and Emergency Procedures*

VI. *Inspection and Maintenance Performed by the Radiographers*

VII. *Case Histories of Radiography Incidents*

Source

The provisions of this Appendix A adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This appendix cited in 25 Pa. Code § 225.73 (relating to training of personnel).

[Next page is 226-1.]

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CHAPTER 226. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

GENERAL

Sec.
226.1. Purpose and scope.
226.2. [Reserved].
226.3. [Reserved].
226.3a. Abandonment of a sealed source.
226.4. Incorporation by references.
226.5. Effect of incorporation of 10 CFR Part 39.
226.11. [Reserved].
226.12. [Reserved].
226.13. [Reserved].
226.14. [Reserved].
226.15—226.19. [Reserved].
226.21—226.23. [Reserved].
226.31—226.33. [Reserved].
226.34. [Reserved].
226.41—226.43. [Reserved].
226.51. [Reserved].

PARTICLE ACCELERATORS

226.61. Particle accelerators.

Authority

The provisions of this Chapter 226 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. § 7110.301 and § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 226 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 78.111 (relating to abandonment); 25 Pa. Code § 215.32 (relating to exemption qualifications); and 25 Pa. Code § 217.1 (relating to purpose and scope).

GENERAL

§ 226.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons using radiation sources for well logging in a single well, radioactive markers, uranium sinker bars and subsurface tracer studies. Persons who use radiation sources for well

logging operations shall comply with this chapter, which is in addition to and not in substitution for other applicable requirements of this article, in particular, the requirements of Chapters 215, 217—220, 228 and 230.

Source

The provisions of this § 226.1 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203978).

§ 226.2. [Reserved].

Source

The provisions of this § 226.2 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203978) to (203979).

§ 226.3. [Reserved].

Source

The provisions of this § 226.3 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203979).

§ 226.3a. Abandonment of a sealed source.

In addition to incorporation by reference of 10 CFR 39.15 and 39.77 (relating to agreement with well owner or operator; and notification of incidents and lost sources; abandonment procedures for irretrievable sources), the requirements of § 78.111 (relating to abandonment) shall also be met.

Source

The provisions of this § 226.3a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282428).

§ 226.4. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 39 (relating to licenses and radiation safety requirements for well logging) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 39.5, 39.8, 39.101 and 39.103 are not incorporated by reference.

Source

The provisions of this § 226.4 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 226.5. Effect of incorporation of 10 CFR Part 39.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 39, the following words and phrases shall be substituted for the language in 10 CFR Part 39 as follows:

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(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 226.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 226.11. [Reserved].

Source

The provisions of this § 226.11 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203979) to (203980).

§ 226.12. [Reserved].

Source

The provisions of this § 226.12 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203980).

§ 226.13. [Reserved].

Source

The provisions of this § 226.13 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203980).

§ 226.14. [Reserved].

Source

The provisions of this § 226.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203980) to (203981).

§§ 226.15—226.19. [Reserved].

Source

The provisions of these §§ 226.15—226.19 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203982) to (203984).

§§ 226.21—226.23. [Reserved].

Source

The provisions of these §§ 226.21—226.23 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203984) to (203985).

§§ 226.31—226.33. [Reserved].

Source

The provisions of these §§ 226.31—226.33 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203985).

§ 226.34. [Reserved].

Source

The provisions of this § 226.34 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203985) to (203986).

§§ 226.41—226.43. [Reserved].

Source

The provisions of these §§ 226.41—226.43 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203986) to (203987).

§ 226.51. [Reserved].

Source

The provisions of this § 226.51 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203987) to (203989).

PARTICLE ACCELERATORS

§ 226.61. *Particle accelerators.*

(a) A licensee or registrant may not permit aboveground testing of particle accelerators designed for use in well logging which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of 10 CFR 20.1301 (relating to radiation dose to dose limits for individual members of the public) are met.

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(b) The use of particle accelerators for well logging shall be conducted under the licensing provisions of Chapter 228 (relating to radiation safety requirements for particle accelerators).

Source

The provisions of this § 226.61 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

APPENDIX A. [Reserved]

Source

The provisions of this Appendix A reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203990).

APPENDIX B. [Reserved]

Source

The provisions of this Appendix B reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203991).

[Next page is 227-1.]

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CHAPTER 227. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT, X-RAY GAUGING EQUIPMENT, ELECTRON MICROSCOPES AND X-RAY CALIBRATION SYSTEMS

GENERAL PROVISIONS

Sec.
227.1. Purpose and scope.
227.2. Definitions.
227.3. [Reserved].

ANALYTICAL X-RAY EQUIPMENT

227.11. [Reserved].
227.11a. Equipment requirements.
227.12. [Reserved].
227.12a. Area requirements.
227.13. [Reserved].
227.13a. Operating requirements.
227.14. Personnel requirements.
227.15. [Reserved].

X-RAY GAUGING EQUIPMENT

227.21. Warnings.
227.22. Radiation levels.
227.23. Personnel requirements.
227.24. [Reserved].
227.25. [Reserved].

ELECTRON MICROSCOPES

227.31. Warnings.
227.32. Radiation levels.
227.33. Personnel requirements.
227.41—227.44. [Reserved].
227.51—227.53. [Reserved].
227.61—227.71. [Reserved].
227.81—227.85. [Reserved].
227.91—227.97. [Reserved].

X-RAY CALIBRATION SYSTEMS

227.101. Scope.
227.102. Area requirements.
227.103. Operating requirements.
227.104. Personal requirements.

Authority

The provisions of this Chapter 227 issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed); and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 227 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL PROVISIONS

§ 227.1. Purpose and scope.

This chapter establishes the requirements for the use of analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration sys-

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tems. Registrants who use analytical X-ray equipment, X-ray gauging equipment, electron microscopes or X-ray calibration systems shall comply with this chapter. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of this article.

Source

The provisions of this § 227.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249334).

§ 227.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Analytical X-ray machine—An assembly of components utilizing X-rays to determine the elemental or chemical composition or to examine the microstructure of materials usually by X-ray diffraction or fluorescence.

Electron microscope—Equipment utilizing the wave characteristics of electrons that have been accelerated by an electric field to visualize the microscopic structure of material.

Fail-safe characteristics—A design feature which causes X-ray production to cease, beam port shutters to close or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

Local components—Parts of an analytical X-ray system, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, that contain or are in the path of the X-ray beam. The term does not include power supplies, transformers, amplifiers, readout devices and control panels.

Open-beam configuration—An analytical X-ray system in which the beam is not enclosed or shielded so any portion of an individual's body could accidentally be placed in the beam path during normal operation.

Operating procedures—Step-by-step instructions necessary to accomplish the analysis.

Primary beam—Radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

X-ray calibration systems—Radiation-producing machines and equipment used to calibrate radiation detection or measuring devices.

X-ray gauging equipment—A machine utilizing X-rays to detect, measure, gauge or control thickness, density, level or interface location.

Source

The provisions of this § 227.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249335).

§ 227.3. [Reserved].

Source

The provisions of this § 227.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119234) and (4919).

ANALYTICAL X-RAY EQUIPMENT

§ 227.11. [Reserved].

Source

The provisions of this § 227.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203996).

§ 227.11a. Equipment requirements.

(a) Open-beam configurations shall have a safety device which either prevents the entry of any portion of an individual's body into the primary X-ray beam path, or causes the beam to be terminated or interrupted upon entry into the path. A registrant may apply to the Department for an exemption from the requirement of a safety device. The application for an exemption shall include the following:

(1) A description of the various safety devices that have been evaluated.

(2) The reason each of these safety devices cannot be used.

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Open-beam configurations shall be provided with a readily discernible indication of one or both of the following:

(1) X-ray tube status (on-off) located near the radiation source housing, if the primary beam is controlled in this manner.

(2) Shutter status (open-closed) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified. In addition, equipment manufactured after December 17, 1987, shall have fail-safe characteristics.

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(d) An easily visible warning light located immediately adjacent to the tube head or port and labeled with the words "X-ray on," or words containing a similar warning, shall be provided and shall be illuminated when the X-ray tube is energized.

(e) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(f) Analytical X-ray equipment shall be labeled with a readily discernible sign bearing the radiation symbol and both of the following:

(1) "CAUTION—HIGH INTENSITY X-RAY BEAM" or words having a similar intent on the X-ray source housing.

(2) "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X-ray tube.

(g) On equipment with an open-beam configuration manufactured and installed after December 19, 1987, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or coupling has been connected to the port.

(h) Equipment exclusively designed and exclusively used for vacuum spectroscopy where the tube housing and sample chamber is located behind all external surfaces of the unit shall be exempt from the requirements of this section, §§ 227.12a and 227.13a (relating to area requirements; and operating requirements), but shall meet the requirements of § 227.14 (relating to personnel procedures) and the following:

(1) The unit shall be designed so that when the unit is operating at the maximum kilovoltage and current ratings, the leakage radiation will not be in excess of 0.5 milliroentgens (.129 μC/kg) per hour at a distance of 4 centimeters from any external surface.

(2) Radiation surveys using appropriate radiation survey equipment shall be performed on the analytical X-ray unit upon installation, after moving the unit to a new location, and after maintenance or repair requiring the disassembly or removal of a local component or radiation shielding.

(3) Safety and warning devices shall be tested for proper operation at least annually. If the test reveals that a safety or warning device is not working properly, the unit may not be operated until the warning device is repaired or replaced.

(4) Records of all tests and surveys sufficient to show compliance with subsection (h) shall be maintained and kept available for inspection by the Department for 4 years.

(5) A sign bearing the radiation symbol and the words "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words of similar intent shall be placed next to any switch or device that activates the X-ray tube.

(6) A sign bearing the radiation symbol and the words "CAUTION—RADIATION," or words of similar intent shall be placed next to the opening of the sample chamber.

Authority

The provisions of this § 227.11a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.11a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285692) to (285693) and (282433).

§ 227.12. [Reserved].

Source

The provisions of this § 227.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203997).

§ 227.12a. Area requirements.

(a) The source housing construction shall be of a type that when all the shutters are closed and the source is in any possible operating mode, the leakage radiation will not be in excess of 2.5 milliroentgens (.645 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(b) The X-ray generator shall have a protective cabinet constructed so that the leakage radiation will not be in excess of 0.5 milliroentgen (.129 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(c) The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in 10 CFR 20.1301 (relating to dose limits for individual members of the public). For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.

(d) To show compliance with subsections (a)—(c), the registrant shall perform radiation surveys:

(1) Upon installation of the equipment and at least every 12 months thereafter.

(2) Following a change in the initial arrangement, number or type of local components in the system.

(3) Following maintenance requiring the disassembly or removal of a local component in the system.

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(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when a local component in the system is disassembled or removed.

(5) When a visual inspection of the local components in the system reveals an abnormal condition.

(6) When personnel monitoring devices show a significant increase in radiation exposure over the previous monitoring period or the readings are approaching the radiation dose limits.

(7) When the machine is operated in a manner other than the routine manner specified in § 227.13a (relating to operating requirements).

(e) The registrant shall test and inspect all safety and warning devices at least annually to insure their proper operation. If a safety or warning device is found to be malfunctioning, the machine shall be removed from service until repairs to the malfunctioning device are completed.

(f) Records of surveys and tests sufficient to show compliance with this chapter shall be maintained for 4 years and kept available for inspection by the Department.

(g) The equipment used to conduct the surveys and tests required in this chapter shall be adequate to measure the radiation produced by the radiation source.

Authority

The provisions of this § 227.12a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.12a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282434) and (249339).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements); and 25 Pa. Code § 227.14 (relating to personnel requirements).

§ 227.13. [Reserved].

Source

The provisions of this § 227.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (203997) to (203998).

§ 227.13a. Operating requirements.

(a) Operating procedures shall be written and available to the analytical X-ray equipment operators. These procedures shall include instructions for sample insertion and manipulation, equipment alignment, routine maintenance and data recording procedures which are related to radiation safety. An individual may not operate analytical X-ray equipment in a manner other than that specified in the operating procedures unless the individual has obtained written approval from the radiation safety officer.

(b) An individual may not bypass or otherwise circumvent a safety device unless the individual has obtained the prior written approval of the radiation safety officer. The radiation safety officer may grant the permission only if the following conditions are met:

(1) The radiation safety officer establishes administrative controls and procedures to assure the radiation safety of individuals working around the system.

(2) The period for the bypass of the safety device is not more than 30 days unless written permission is obtained from the Department for a longer period.

(3) A readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words containing a similar warning, is placed on the radiation source housing.

(c) Except as specified in subsection (b), an operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops may not be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Emergency procedures shall be written and posted near the equipment and shall list the names and telephone numbers of personnel to contact. The emergency procedures shall also provide information necessary to de-energize the equipment, such as location and operation of the power supply or circuit breakers.

Authority

The provisions of this § 227.13a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.13a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249339) to (249340).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements); and 25 Pa. Code § 227.12a (relating to area requirements).

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§ 227.14. Personnel requirements.

(a) An individual may not operate or maintain analytical X-ray equipment unless the individual has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment.

(2) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions necessary if the devices are absent or bypassed.

(3) Written operating and emergency procedures for the equipment.

(4) Symptoms of an acute localized radiation exposure.

(5) Procedures for reporting an actual or suspected exposure.

(6) Use of survey and personnel monitoring equipment.

(7) The applicable regulations of this article and those incorporated by reference.

(b) Finger or wrist personnel monitoring devices shall be provided to and shall be used by:

(1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device as described in § 227.12a(c) (relating to area requirements).

(2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when a local component in the analytical X-ray system is disassembled or removed or when safety devices are bypassed.

(c) Reported dose values may not be used for the purpose of determining compliance with 10 CFR 20.1201 (relating to occupational dose limits for adults) unless they are evaluated by a qualified expert.

(d) The registrant or licensee shall notify the Department within 5 days of a suspected radiation overexposure to an individual from analytical X-ray machines. This notification is required even if subsequent investigation reveals no actual over-exposure actually occurred.

Authority

The provisions of this § 227.14 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. 510-20).

Source

The provisions of this § 227.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249340) to (249341).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements).

§ 227.15. [Reserved].

Source

The provisions of this § 227.15 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (203999) to (204000).

X-RAY GAUGING EQUIPMENT

§ 227.21. Warnings.

X-ray gauging equipment shall be labeled with a readily discernable sign or signs bearing the radiation symbol and the words, "Caution Radiation—This Equipment Produces Radiation When Energized," or words containing a similar warning.

Source

The provisions of this § 227.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4922).

§ 227.22. Radiation levels.

An X-ray tube housing shall be constructed so that, with the unit in normal operation, the leakage radiation measured 5 centimeters from a surface is no more than 2.5 milliroentgens (645 nC/kg) per hour.

Source

The provisions of this § 227.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4922).

§ 227.23. Personnel requirements.

No registrant may permit an individual to operate or conduct maintenance upon X-ray gauging equipment until the individual has received a copy of and instruction in, and demonstrated an understanding of, the operating procedures necessary to ensure radiation safety.

Source

The provisions of this § 227.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4922) to (4923).

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§ 227.24. [Reserved].

Source

The provisions of this § 227.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4923) to (4924).

§ 227.25. [Reserved].

Source

The provisions of this § 227.25 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4924) to (4937).

ELECTRON MICROSCOPES

§ 227.31. Warnings.

An electron microscope shall be labeled with a readily discernable sign bearing the words, "Caution Radiation—This Equipment Produces Radiation When Energized," or words containing a similar warning.

Source

The provisions of this § 227.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4937).

§ 227.32. Radiation levels.

Radiation levels measured 5 centimeters from any accessible surface of an electron microscope may not exceed .5 milliroentgen (129 nC/kg) per hour.

Source

The provisions of this § 227.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4938).

§ 227.33. Personnel requirements.

A registrant may not permit an individual to operate or conduct maintenance upon any electron microscope until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to insure radiation safety.

Authority

The provisions of this § 227.33 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.33 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204002).

§§ 227.41—227.44. [Reserved].

Source

The provisions of these §§ 227.41—227.44 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4938) to (4941).

§§ 227.51—227.53. [Reserved].

Source

The provisions of these §§ 227.51—227.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4941) to (4942).

§§ 227.61—227.71. [Reserved].

Source

The provisions of these §§ 227.61—227.71 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4942) to (4948).

§§ 227.81—227.85. [Reserved].

Source

The provisions of these §§ 227.81—227.85 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4949) to (4951).

§§ 227.91—227.97. [Reserved].

Source

The provisions of these §§ 227.91—227.97 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4951) to (4955).

X-RAY CALIBRATION SYSTEMS

§ 227.101. Scope.

This section and §§ 227.102—227.104 apply to registrants who use X-ray producing machines to calibrate or test radiation detection or measuring devices.

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Authority

The provisions of this § 227.101 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.101 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

§ 227.102. Area requirements.

A room or enclosure used for testing or calibration shall be shielded so that every location on the exterior meets conditions for an unrestricted area, and the only access to the room or enclosure is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

Authority

The provisions of this § 227.102 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.102 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

§ 227.103. Operating requirements.

(a) The operator shall conduct a physical radiation survey to determine that the radiation machine X-ray tube is de-energized prior to each entry of any body part into the X-ray exposure area.

(b) As an alternative to subsection (a), the registrant may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels.

Authority

The provisions of this § 227.103 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.103 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

§ 227.104. Personnel requirements.

A registrant may not permit an individual to operate or conduct maintenance on any X-ray calibration system until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to ensure radiation safety.

Authority

The provisions of this § 227.104 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.104 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

[Next page is 228-1.]

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CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

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Authority

The provisions of this Chapter 228 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. § 7110.301 and § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 228 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.3 (relating to exemptions); 25 Pa. Code § 218.1 (relating to purpose and scope); 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 266.61 (relating to particle accelerators).

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GENERAL PROVISIONS

§ 228.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons utilizing particle accelerators for industrial, research or medical purposes. Persons who use particle accelerators shall comply with this chapter. The requirements in this chapter are in addition to and not in substitution for other applicable requirements of this article.

§ 228.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Accelerator or *particle accelerator*—A radiation-producing machine that imparts kinetic energies of one of the following:

(i) One-tenth of one MeV or greater to electrons if the electron beam is brought out of the evacuated region of the unit.

(ii) One MeV or greater to electrons if the electrons are utilized for X-ray production.

(iii) One-tenth of one MeV or greater to other particles.

Applicator—A structure which determines the extent of the treatment field at a given distance from the virtual source.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

Beam scattering filter—A filter used to scatter a beam of electrons.

Central axis of the beam—A line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

Dose monitoring system—A system of devices for the detection, measurement and display of quantities of radiation.

Dose monitor unit—A unit response from the dose monitoring system from which the absorbed dose can be calculated.

Existing equipment—Systems manufactured on or before October 3, 1998.

Field flattening filter—A filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

Field size—The configuration of the radiation field along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50% isodose line.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and remove radiation that does not contribute to the efficacy of the useful beam.

Isocenter—A fixed point in space located at the center of the smallest sphere through which the central axes of the beams pass.

Leakage radiation—Radiation emanating from the source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

Moving beam therapy—Radiation therapy with relative displacement of the useful beam and the patient during irradiation.

New equipment—Systems manufactured after January 1, 1985.

Normal treatment distance—

(i) For isocentric equipment, the isocenter.

(ii) For nonisocentric equipment, the target to patient skin distance along the central axis as specified by the manufacturer.

Particle accelerator—See the definition of "accelerator."

Phantom—A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Primary dose monitoring system—A system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been attained.

Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Radiation head—The structure from which the useful beam emerges.

Secondary dose monitoring system—A system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Shadow tray—A device attached to the radiation head to support auxiliary beam limiting material.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Stationary beam therapy—Radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subsystem—A combination of two or more components of an accelerator.

Target—The part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

Tube housing assembly—The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Virtual source—The nominal location of either the first scattering foil (for equipment providing electrons only) or the photon focal spot (for equipment capable of delivering both photons and electrons).

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.

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Source

The provisions of this § 228.2 amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249347) to (249349).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope).

§ 228.3. Sale and installation.

A person may not sell or install an accelerator that does not meet the provisions of this article.

Source

The provisions of this § 228.3 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

ADMINISTRATIVE CONTROLS

§ 228.11. [Reserved].

Source

The provisions of this § 228.11 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204010).

§ 228.11a. Licensee responsibilities.

(a) A person may not possess, operate or permit the operation of an accelerator unless the accelerator and installation meet the applicable requirements of this article.

(b) Written safety procedures and rules shall be available at a facility, including restrictions of the operating technique required for the safe operation of the particular accelerator. The operator shall be able to demonstrate familiarity with the rules.

(c) An individual may not be exposed to the useful beam except for healing arts purposes. An exposure shall be authorized by a licensed practitioner of the healing arts.

Source

The provisions of this § 228.11a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249349) to (249350).

§ 228.12. Information and maintenance record and associated information.

The licensee shall maintain records of surveys, calibrations, maintenance, machine malfunctions and modifications performed on the accelerators, including

the names of persons who performed the services. The licensee shall keep these records for inspection by the Department for 5 years.

Source

The provisions of this § 228.12 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (249530).

NOTIFICATION AND LICENSING PROCEDURES

§ 228.21. [Reserved].

Source

The provisions of this § 228.21 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204011).

§ 228.21a. *Notification and license requirements.*

(a) A person who intends to purchase, construct or acquire an accelerator shall notify the Department of this intent by filing an application for a specific license within 30 days after the initial order is issued to obtain any or all parts of the accelerator.

(1) The application shall be filed in duplicate on a form prescribed by the Department and shall be accompanied by the required fee as described in § 218.11(d) (relating to registration, renewal of registration and license fees).

(2) The application shall contain pertinent information to permit the Department to evaluate the accelerator facility for compliance with the act and this article.

(b) In addition to the notification requirement in subsection (a), a person who intends to install an accelerator shall notify the Department within 30 days after the initial construction or installation begins.

(c) Except as provided in subsection (d), a person may not operate a particle accelerator after October 3, 1998, without having obtained a license from the Department.

(d) A registrant possessing an accelerator before October 3, 1998, may continue to operate the accelerator provided an application for a license is filed in duplicate with the Department by October 4, 1999.

(e) The Department may, after the filing of an original application, and before the expiration of the license, require further information to enable the Department to determine whether the application will be granted or denied or whether a license will be modified or revoked.

(f) The application shall be signed by the applicant or licensee or an individual authorized by the applicant or licensee.

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(g) A license issued under this chapter may not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, to any person except through submission of a written request by the licensee to the Department for approval.

Source

The provisions of this § 228.21a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249350) and (285701).

Cross References

This section cited in 25 Pa. Code § 228.24a (relating to renewal of licenses); and 25 Pa. Code § 228.25a (relating to amendment of license at the request of the licensee).

§ 228.22. [Reserved].

Source

The provisions of this § 228.22 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204011).

§ 228.22a. Issuance of specific licenses.

(a) Upon determination that an application meets the requirements of the act and this article, the Department will issue a specific license authorizing the proposed activity and containing conditions and limitations as it deems appropriate or necessary.

(b) After the issuance of the license, the Department may, by appropriate regulations or order, incorporate additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of the accelerator subject to this chapter as it deems appropriate or necessary in order to:

(1) Protect the public health and safety or property.

(2) Prevent loss or theft of material subject to this chapter.

Source

The provisions of this § 228.22a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249351).

§ 228.23. [Reserved].

Source

The provisions of this § 228.23 amended November 17, 1995, effective November 28, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (204011) to (204012).

§ 228.23a. Expiration and termination of a license.

(a) Except as provided in § 228.24a (relating to renewal of licenses), and subject to subsection (d)(5)(ii), a specific license expires on the date specified in the license. A license is effective for 5 years.

(b) A licensee shall notify the Department in writing when the licensee decides to permanently discontinue activities involving the accelerator authorized under the license and request termination of the license. The notification and request for termination shall include the reports and information specified in subsection (d)(3)—(5). The licensee is subject to subsections (d) and (e), as applicable, until termination.

(c) At least 30 days before the expiration date specified in a specific license, the licensee shall do one of the following:

(1) Submit an application for license renewal under § 228.24a.

(2) Notify the Department in writing if the licensee decides not to renew the license.

(d) If the licensee does not submit an application for license renewal under § 228.24a on or before the expiration date specified in the license, the licensee shall:

(1) Terminate the use of, and transfer or dispose of the accelerator.

(2) Properly dispose of incidental radioactive material generated by the operation of the accelerator.

(3) Submit a completed Department Form 2900-PM-RP0314, "Certificate of Disposition of Materials," describing the disposition of materials in paragraph (2).

(4) Submit a radiation survey report to confirm the absence of radioactive materials or establish the levels of residual radioactive contamination unless the Department determines a radiation survey report is not necessary. This report shall include:

(i) The levels of beta and gamma radiation (in units of microrems or microsieverts, or in microrads or micrograys per hour) at 1 centimeter and gamma radiation at 1 meter from surfaces, levels of removable and fixed alpha, beta and gamma contamination on surfaces (in becquerels or microcuries per 100 square centimeters), and concentrations of contamination in soils (in units of picocuries or becquerels per gram) or in water (in units of picocuries or becquerels per liter) where soil and water concentrations are reported.

(ii) The survey instrumentation used to perform these surveys.

(5) Proceed with one of the following:

(i) Submit a certification that no detectable radioactive contamination was found if no residual contamination attributable to activities conducted

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under the license is detected. If the information submitted under this section is adequate, the Department will notify the licensee in writing that the license is terminated.

(ii) Continue the license in effect beyond the expiration date. If necessary, with respect to possession of residual radioactive material present as contamination if detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall comply with subsection (e), in addition to the information submitted under paragraphs (3) and (4) and this paragraph, the licensee shall submit a plan for decontamination, if necessary.

(e) A licensee who possesses residual radioactive material under subsection (d)(5)(ii) following the expiration date specified in the license, shall:

(1) Limit activities involving radioactive materials to those activities which are solely related to decontamination and other activities related to preparation for release for unrestricted use.

(2) Continue to control entry to restricted areas until the restricted areas are suitable for release for unrestricted use and until the Department notifies the licensee in writing that the license is terminated.

Source

The provisions of this § 228.23a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285702) and (249353).

§ 228.24. [Reserved].

Source

The provisions of this § 228.24 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204012).

§ 228.24a. Renewal of licenses.

(a) An application for renewal of a specific license shall be filed under § 228.21a (relating to notification and license requirements).

(b) If a renewal application is filed prior to 30 days before the expiration of a license, the existing license does not expire until definitive notice has been given by the Department of its action on the renewal application. This subsection also applies to new license applications incorporating other licenses.

Source

The provisions of this § 228.24a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 228.23a (relating to expiration and termination of a license).

§ 228.25. [Reserved].

Source

The provisions of this § 228.25 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (204012) to (204013).

§ 228.25a. Amendment of license at the request of the licensee.

A licensee filing an application for an amendment shall utilize the procedures in § 228.21a (relating to notification and license requirements). The application shall specify the requested amendment and the reason for the amendment.

Source

The provisions of this § 228.25a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.26. [Reserved].

Source

The provisions of this § 228.26 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.26a. Department action on applications to renew and amend.

In considering an application by a licensee to renew or amend a license, the Department will apply criteria in the act and this article.

Source

The provisions of this § 228.26a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.31. [Reserved].

Source

The provisions of this § 228.31 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.31a. Limitations.

(a) The facility shall operate within the terms and conditions of the license issued for the operation of the accelerator.

(b) A licensee may not permit an individual to act as an operator of an accelerator until the individual:

(1) Has been instructed in radiation safety and has demonstrated an understanding thereof.

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(2) Has received copies of and instruction in this chapter and Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations), pertinent license conditions and the licensee's operating and emergency procedures and demonstrated understanding thereof.

(3) Has demonstrated competence to use the accelerator, related equipment and survey instruments which will be utilized in that individual's assignment.

(c) The radiation safety officer shall have the authority to restrict or terminate operations at an accelerator facility if the action is necessary to minimize danger to health and safety, property or the environment.

Source

The provisions of this § 228.31a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249354) and (282437).

§ 228.32. [Reserved].

Source

The provisions of this § 228.32 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.32a. Shielding and safety design requirements.

(a) The licensee shall consult a qualified expert for radiation protection concerning the shielding design of an accelerator installation.

(b) An accelerator facility shall have primary and secondary protective barriers that are necessary to assure compliance with 10 CFR Part 20, Subpart D (relating to dose limits for individual members of the public).

Source

The provisions of this § 228.32a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282437).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.33. [Reserved].

Source

The provisions of this § 228.33 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.33a. Facility and shielding requirements.

In addition to the requirements in Chapter 219 (relating to standards for protection against radiation), the following are required:

(1) The control panel shall be located outside the treatment or irradiation room.

(2) For accelerators not used in the healing arts, provision shall be made to permit continuous observation of the material being irradiated and any transfer or conveyance of material within the irradiation room.

(3) For accelerators used in the healing arts, provision shall be made to permit continuous observation of and communication with the patient during irradiation.

(4) Windows, mirror systems or closed-circuit television viewing screens used for observing the patient or the material being irradiated shall be located so that the operator can maintain direct surveillance over both the control panel and the patient or the material being irradiated.

(5) If the surveillance conducted under paragraph (4) is provided solely by electronic means, and if a malfunction of this surveillance equipment occurs, irradiation activities shall cease until repair of that surveillance equipment is performed and the equipment is found to be functioning normally.

(6) Irradiation or treatment room entrances shall be provided with warning lights in a readily observable position near the outside of access doors. These will indicate when the useful beam is on.

(7) Interlocks shall be provided so that entrance or access doors are closed before irradiation or treatment can be initiated or continued.

(8) For accelerators used to irradiate materials by means of a transfer or conveyance system, a means shall be provided which either terminates the irradiation or prevents entry if an individual attempts access to the irradiation room.

Source

The provisions of this § 228.33a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.34. [Reserved].

Source

The provisions of this § 228.34 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204014).

§ 228.34a. Accelerator controls and interlock systems.

(a) Instrumentation, readouts and controls on the accelerator control console shall be clearly identified and easily discernible.

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(b) Entrances into a target room or high radiation areas shall have interlocks that meet the requirements of 10 CFR Part 20, Subpart G (relating to control of exposure from external sources in restricted areas) and 10 CFR 20.1902 (relating to posting requirements). If the radiation beam is interrupted by a door opening, it shall be possible to reinitiate the radiation exposure only by closing the door first and then by manual action at the control panel.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the interlock position, and lastly at the main control console.

(d) Safety interlocks shall be fail-safe, that is, designed so that a defect or component failure in the interlock system prevents operation of the accelerator.

(e) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. The cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

Source

The provisions of this § 228.34a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282438) and (285703).

§ 228.35. Operating procedures.

(a) Accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) An interlock may not be used to turn off the accelerator beam except in an emergency or for testing the interlock.

(c) Each safety and warning device, including interlocks, shall be checked at least every 3 months for proper functioning and shall be repaired as necessary. Results of these checks and records of repairs shall be maintained for 4 years at the accelerator facility for inspection by the Department.

(d) In the event of a malfunction of a safety or warning device, the accelerator may not be operated unless appropriate interim precautions are instituted to provide equivalent protection.

(e) If it is necessary to intentionally bypass a safety interlock system or component thereof, the action shall be the following:

(1) Authorized in writing by the radiation safety officer.

(2) Recorded in a permanent log and a notice posted at the accelerator operator's position.

(3) Terminated as soon as possible.

(f) A copy of the current operating and emergency procedures shall be maintained in the accelerator operator area.

(g) For accelerators used in the healing arts, operating procedures shall meet the following requirements:

(1) No individual other than the patient is in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system may not be used in the administration of radiation therapy unless the requirements of this chapter have been met.

(4) A medical reportable event for radiation-producing machine therapy, as defined in § 219.3 (relating to definitions), shall be reported as required under § 219.228 (relating to reports of medical reportable events for radiation-producing machine therapy).

(5) An individual who operates an accelerator system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include, but not be limited to, items included in Appendix A (relating to determination of competence). There shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

Source

The provisions of this § 228.35 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285703) to (285704).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.36. Radiation monitoring requirements.

An independent radiation monitoring system shall be provided so that the individuals entering or present in a potential very high radiation area become aware of the existence of the hazard. Independent radiation monitors shall be tested for response at least annually and after each servicing or repair.

Source

The provisions of this § 228.36 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (282440) to (282441).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.37. Production of radioactive material.

(a) A licensee who produces radioactive material incidental to the operation of an accelerator shall comply with the general license requirements of § 217.144 (relating to incidental radioactive material produced by a particle accelerator).

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(b) A licensee possessing radioactive material intentionally produced by bombarding nonradioactive material with the accelerator beam shall comply with the specific license requirements of Chapter 217 (relating to licensing of radioactive material).

Source

The provisions of this § 228.37 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282441).

§ 228.38. Radiation safety surveys.

(a) Prior to first use, a facility shall have a survey made by, or under the direction of, a qualified expert for radiation protection. A survey shall also be done after a change in the facility or equipment, including a relocation of the equipment within the irradiation or treatment room.

(b) The qualified expert shall report the survey results in writing to the individual in charge of the facility and a copy of the initial report shall be maintained by the licensee for inspection by the Department for the life of the facility. Other survey reports shall be maintained for inspection by the Department for 4 years. The facility shall be operated in compliance with limitations indicated by the survey.

(c) The report of the survey results shall include:

(1) The date of the measurements.

(2) The reason the survey is required.

(3) The manufacturer's name, model number and serial number of the therapeutic radiation machine accelerator.

(4) The instrument used to measure radiation levels.

(5) A plan of the areas surrounding the treatment room that were surveyed.

(6) The measured dose rate at several points in each area expressed in microsieverts or millirems per hour.

(7) The calculated maximum level of radiation over a period of 1 year for each restricted and unrestricted area.

(8) The signature of the individual who conducted or is responsible for conducting the survey.

(d) If the survey required by subsection (a) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 10 CFR 20.1201 (relating to occupational dose limits for adults) or 10 CFR 20.1301 (relating to dose limits for individual members of the public), the licensee shall do the following:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Chapter 219 (relating to standards for protection against radiation).

(2) Perform the survey required by subsection (a) again.

(3) Prepare and submit the report required by subsection (a). The report shall also include:

(i) The results of the initial survey.

(ii) A description of the modification made to comply with this section.

(iii) The results of the second survey.

Source

The provisions of this § 228.38 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282441) to (282442).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.39. Records.

In addition to the requirements of 10 CFR Part 20, Subpart L (relating to records), the licensee shall maintain:

(1) Records of the tests and safety and warning devices described in § 228.35 (relating to operating procedures).

(2) The surveys described in §§ 228.32a and 228.38 (relating to shielding and safety design requirements; and radiation safety survey).

(3) The radiation monitoring equipment calibrations and repairs of that equipment under § 228.36 (relating to radiation monitoring requirements).

Source

The provisions of this § 228.39 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282442).

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL AND RESEARCH ACCELERATORS

§ 228.41. [Reserved].

Source

The provisions of this § 228.41 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204014).

§ 228.41a. Warning devices.

(a) A location designated as a high radiation area and an entrance to the location shall be equipped with easily observable warning lights that operate only when radiation is being produced.

(b) A high radiation area shall meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

Source

The provisions of this § 228.41a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282443).

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§ 228.42. Circuit diagrams.

Electrical circuit diagrams of the accelerator and the associated safety, warning and interlock systems shall be kept current and maintained for inspection by the Department and shall be available to the operator at an accelerator facility.

Source

The provisions of this § 228.42 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.43. Radiation surveys.

(a) Periodic surveys shall be made to determine the amount of airborne radioactivity present in areas of airborne hazards.

(b) Periodic smear surveys shall be made to determine the amount of contamination in target and other pertinent areas.

(c) Area surveys shall be made in accordance with the written procedures established by a qualified expert for radiation protection or the radiation safety officer of the accelerator facility.

(d) Records of surveys shall be kept current and on file at an accelerator facility. Records of surveys shall be maintained as described in 10 CFR Part 20, Subpart L (relating to records).

Source

The provisions of this § 228.43 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282443).

§ 228.44. Ventilation systems.

(a) A licensee shall control the concentration of radioactive material in air to meet the requirements of 10 CFR 20.1204 (relating to determination of internal exposure).

(b) A licensee may not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which does not meet the requirements of 10 CFR 20.1301 (relating to dose limits for individual members of the public). Every reasonable effort shall be made to maintain releases of radioactive material to uncontrolled areas as far below these limits as practicable. Compliance with this section shall be demonstrated as described in 10 CFR 20.1302 (relating to compliance with dose limits for individual members of the public).

Source

The provisions of this § 228.44 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282443) to (282444).

§ 228.45. Portable or mobile accelerators.

Portable or mobile accelerators used for industrial radiography or research shall comply with Chapter 225 (relating to radiation safety requirements for industrial radiographic operations).

Source

The provisions of this § 228.45 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

§ 228.61. Leakage radiation to the patient area.

(a) New equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the dose due to leakage radiation, including X-rays, electrons and neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, may not exceed 0.1% of the maximum dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

(2) For each system, the licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records for 5 years on leakage radiation measurements for inspection by the Department.

(b) Existing equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, including neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam 1 meter from the virtual source, may not exceed 0.1% of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(2) For each system, the licensee shall have available the leakage radiation data existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records on radiation leakage for 5 years for inspection by the Department.

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Source

The provisions of this § 228.61 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282444) and (249363).

Cross References

This section cited in 25 Pa. Code § 228.62 (relating to leakage radiation outside the patient area for new equipment).

§ 228.62. Leakage radiation outside the patient area for new equipment.

(a) The absorbed dose due to leakage radiation except in the area specified in § 228.61(a)(1) (relating to leakage radiation to the patient area) when measured at any point 1 meter from the path of the charged particles, before the charged particles strike the target or window, may not exceed 0.1% for X-ray leakage nor 0.5% for neutron leakage of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in § 228.61(a)(1).

(b) The licensee shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in subsection (a) for specified operating conditions. Radiation measurements, including neutrons, shall be averaged over an area up to but not exceeding 200 square centimeters.

Source

The provisions of this § 228.62 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.63. Beam limiting devices.

Adjustable or interchangeable beam limiting devices shall be provided and the devices may transmit no more than 5% of the useful beam at the normal treatment distance. The neutron component of the useful beam may not be included to comply with this requirement.

Source

The provisions of this § 228.63 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.64. Filters.

(a) A filter which is removable from the system shall be clearly identified. Documentation shall contain a description of the filter which includes a drawing showing dimensions and noting materials of construction.

(b) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters the following apply:

(1) Irradiation may not be possible until a selection of a filter has been made at the control panel.

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(3) An interlock shall be provided to prevent irradiation if a filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the control panel.

Source

The provisions of this § 228.64 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.65. Electron beam quality.

The licensee shall determine that the following beam quality requirements are met:

(1) The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons may not exceed the values in Table I. Linear interpolation shall be used for values not stated.

Table I

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 paragraph (1) 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.

(iii) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

(3) The licensee shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose due to stray neutrons in the useful beam for specified operating conditions.

Source

The provisions of this § 228.65 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

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§ 228.66. Beam monitors.

(a) Therapy systems shall be provided with radiation detectors in the radiation head.

(b) New equipment shall be provided with at least two radiation detectors incorporated into two separate dose monitoring systems.

(c) Existing equipment shall be provided with at least one radiation detector incorporated into a primary dose monitoring system.

(d) The detector in a dose monitoring system shall be:

(1) Permanently installed and interlocked to prevent incorrect positioning.

(2) Part of a dose monitoring system that provides readings in dose monitor units which can be used to calculate the absorbed dose at a reference point in the treatment volume.

(3) Capable of independently monitoring and controlling the useful beam.

(e) For new equipment, the design of dose monitoring systems shall assure that:

(1) The malfunctioning of one system does not affect the correct functioning of the second system.

(2) The failure of an element common to both systems which could affect the correct function of both systems terminates irradiation.

(f) A dose monitoring system shall have a legible display at the control panel. For new equipment, a display shall:

(1) Maintain a reading until intentionally reset to zero.

(2) Have only one scale and no scale multiplying factors.

(3) Utilize a design so that increasing dose is displayed by increasing numbers and that the absorbed dose may be accurately determined under all conditions of use.

(4) Provide that, in the event of a power failure, the dose monitoring information required in this subsection displayed at the control panel at the time of failure shall be retrievable.

Source

The provisions of this § 228.66 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 228.74 (relating to absorbed dose rate).

§ 228.67. Beam symmetry.

(a) In new equipment inherently capable of producing useful beams with asymmetry exceeding 5%, at least four different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device.

(b) If the difference in dose rates between two of the different parts required in subsection (a) exceeds 10%, the irradiation shall be terminated.

Source

The provisions of this § 228.67 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.68. Selection and display of dose monitor units.

(a) Irradiation may not be possible until a selection of a number of dose monitor units has been made at the control panel.

(b) The preselected number of dose monitor units shall be displayed at the control panel until reset manually to zero before subsequent treatment can be initiated.

Source

The provisions of this § 228.68 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.69. Termination of irradiation by the dose monitoring system or systems.

(a) A dose monitoring system shall be capable of independently terminating irradiation.

(b) A primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(c) A secondary dose monitoring system shall terminate irradiation when either 110% of the preselected number of dose monitor units or 10 dose monitor units (whichever is greater) has been detected by the secondary dose monitoring system.

(d) For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

Source

The provisions of this § 228.69 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.70. Interruption and termination switches.

The operator shall be able to interrupt or terminate irradiation and equipment movement at any time from the control panel. Following an interruption, the operator shall be able to resume irradiation without reselection of operating conditions.

Source

The provisions of this § 228.70 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 228.73 (relating to selection of stationary beam therapy or moving beam therapy).

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§ 228.71. Timer.

(a) The control panel shall have a timer that is graduated in minutes and fractions of minutes or seconds. The timer shall have a preset time selector and an elapsed time indicator.

(b) The timer shall be cumulative and activated only during irradiation and shall retain its reading after irradiation is interrupted or terminated.

(c) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.

Source

The provisions of this § 228.71 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.72. Selection of radiation type.

Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation may not be possible until a selection of radiation type and appropriate energy has been made and displayed at the control panel.

(2) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

(3) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the control panel.

(4) An interlock system shall be provided to prevent:

(i) Irradiation with X-rays except to obtain a port film when electron applicators are fitted.

(ii) Irradiation with electrons when accessories specific for X-ray therapy are fitted.

(5) For new equipment, a system shall be provided to terminate irradiation if the energy of the electrons striking either the X-ray target or electron window deviates by more than +20% or 3 MeV, whichever is smaller, from the selected nominal energy.

Source

The provisions of this § 228.72 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.73. Selection of stationary beam therapy or moving beam therapy.

Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following additional requirements:

(1) Irradiation may not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the control panel.

(2) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

(3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment rooms do not agree with the selected operations carried out at the control panel.

(4) The mode of operation shall be displayed at the control panel.

(5) An interlock system shall be provided to terminate irradiation if one of the following occurs:

(i) Movement of the gantry during stationary beam therapy.

(ii) Movement of the gantry stops during moving beam therapy unless the stoppage is a preplanned function.

(6) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered along an arc differs by more than 10% from the selected value. Termination of irradiation shall be as required by § 228.70 (relating to interruption and termination switches).

Source

The provisions of this § 228.73 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.74. Absorbed dose rate.

New equipment shall have a system that provides information from which the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in § 228.66 (relating to beam monitors) may form part of this system. The dose monitor unit rate shall be displayed at the control panel.

Source

The provisions of this § 228.74 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.75. Calibrations.

(a) The calibration of systems subject to this subchapter shall be performed in accordance with an established calibration protocol. The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent. The calibration shall be performed as follows:

(1) Before the system is first used for irradiation of a patient and, at time intervals which do not exceed 1 year.

(2) After a change which alters the calibration, spatial distribution or other characteristics of the therapy beam.

(b) The calibration shall be performed by, or under the direct supervision of, a qualified expert for radiation therapy calibrations.

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(c) Calibration radiation measurements required by subsection (a) shall be performed using a dosimetry system meeting the following specifications:

(1) The system has an exposure calibration factor appropriate to the beam energy measured and traceable to a National standard.

(2) The system has been calibrated within the previous 2 years and after servicing that may have affected its calibration.

(3) The system has been calibrated so that an uncertainty can be stated for the radiation quantities monitored by the system.

(4) The system has had constancy checks performed on the system as specified by a qualified expert for radiation therapy calibrations.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

(e) The calibration of the therapy beam shall include, but is not limited to, the following determinations:

(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and beam limiting device (collimator) system.

(2) The absorbed dose rate at various depths (depth dose) and beam profile measured in water and the beam flatness and symmetry for the range of field sizes used, for each beam energy.

(3) The uniformity of the radiation field and a dependency upon the direction of the useful beam.

(4) Verification of depth-dose data and isodose curves applicable to the specific machine.

(5) Verification of the applicability of transmission factors of accessories such as wedges, shadow trays, compensators and their effects on electron buildup.

(6) The dose per monitor unit, end effect, linearity and dose rate dependence of the dose monitor systems.

(7) For photon beams, the congruence of the light field and the radiation field.

(8) For electron beams, the validity of commissioning data for virtual source distances or effective source-to-skin distances is to be verified at a single electron energy with a beam restriction device. When the replacement of a beam restriction device occurs, the determination will be required for each electron energy.

(f) Records of calibration measurements under subsection (a) and dosimetry system calibrations under subsection (c) shall be preserved for 5 years.

(g) A copy of the latest calibration performed under subsection (a) shall be available at the facility.

Source

The provisions of this § 228.75 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249369) to (249370).

Cross References

This section cited in 25 Pa. Code § 228.76 (relating to spot checks).

§ 228.76. Spot checks.

Spot checks shall be performed on systems subject to this subchapter during full calibrations and thereafter once in each calendar month. The spot checks shall meet the following requirements:

(1) The procedures shall be in writing and developed by a qualified expert for radiation therapy calibrations.

(2) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a qualified expert within 15 days of the completion of the spot check.

(3) 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.

(4) The spot-check procedures shall specify the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the full calibration.

(5) If a spot check indicates a change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in § 228.75 (relating to calibrations).

(6) Records of spot-check measurements performed under this section shall be maintained by the licensee for 5 years after completion of the spot-check measurements and necessary corrective actions.

(7) Spot check measurements shall be performed using a dosimetry system that has been calibrated in accordance with § 228.75(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with § 228.75(c). This alternative calibration method shall have been performed within the previous year and after a servicing that may have affected the system calibration.

Source

The provisions of this § 228.76 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249370) to (249371).

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APPENDIX A
DETERMINATION OF COMPETENCE

The licensee shall ensure training on the subjects listed in Appendix A has been conducted. The individual shall be trained and competent in the general operation of the radiation therapy equipment and its functions, and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

(1) Basic properties of radiation.
(2) Units of measurement.
(3) Sources of radiation exposure.
(4) Methods of radiation protection.
(5) Biological effects of radiation exposure.
(6) Medical accelerator operation.
(7) Treatment planning and execution.
(8) Patient positioning and protection.
(9) Operating and emergency procedures.
(10) Quality assurance.
(11) Regulations.

Source

The provisions of this Appendix A adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249371) to (249372).

Cross References

This appendix cited in 25 Pa. Code § 228.35 (relating to operating procedures).

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CHAPTER 229. [Reserved].

Source

The provisions of this Chapter 229 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4956), (119235) to (119236), (26466) to (26468), (4962) to (4968) and (119237).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 229.1. [Reserved].

Source

The provisions of this § 229.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended February 27, 1976, effective March 15, 1976, 6 Pa.B. 391; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119235) to (119236) and (26466).

§ 229.2. [Reserved].

Source

The provisions of this § 229.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.3. [Reserved].

Source

The provisions of this § 229.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.4. [Reserved].

Source

The provisions of this § 229.4 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.5. [Reserved].

Source

The provisions of this § 229.5 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.6. [Reserved].

Source

The provisions of this § 229.6 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended February 27, 1976, effective March 15, 1976, 6 Pa.B. 391; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26467).

§ 229.11. [Reserved].

Source

The provisions of this § 229.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26467).

§ 229.12. [Reserved].

Source

The provisions of this § 229.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (26467) to (26468).

§ 229.13. [Reserved].

Source

The provisions of this § 229.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26468).

§ 229.14. [Reserved].

Source

The provisions of this § 229.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26468).

§ 229.15. [Reserved].

Source

The provisions of this § 229.15 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26468).

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§ 229.16. [Reserved].

Source

The provisions of this § 229.16 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4962).

§ 229.17. [Reserved].

Source

The provisions of this § 229.17 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4962).

§ 229.21. [Reserved].

Source

The provisions of this § 229.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4962).

§ 229.22. [Reserved].

Source

The provisions of this § 229.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4963).

§ 229.23. [Reserved].

Source

The provisions of this § 229.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4963).

§ 229.24. [Reserved].

Source

The provisions of this § 229.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4964).

§ 229.25. [Reserved].

Source

The provisions of this § 229.25 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4964).

§ 229.31. [Reserved].

Source

The provisions of this § 229.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4964).

§ 229.32. [Reserved].

Source

The provisions of this § 229.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.33. [Reserved].

Source

The provisions of this § 229.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.34. [Reserved].

Source

The provisions of this § 229.34 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.41. [Reserved].

Source

The provisions of this § 229.41 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.42. [Reserved].

Source

The provisions of this § 229.42 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4965) to (4966).

§ 229.43. [Reserved].

Source

The provisions of this § 229.43 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

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§ 229.44. [Reserved].

Source

The provisions of this § 229.44 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

§ 229.45. [Reserved].

Source

The provisions of this § 229.45 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

§ 229.46. [Reserved].

Source

The provisions of this § 229.46 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

§ 229.51. [Reserved].

Source

The provisions of this § 229.51 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4967).

§ 229.52. [Reserved].

Source

The provisions of this § 229.52 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4967).

§ 229.53. [Reserved].

Source

The provisions of this § 229.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4967).

§ 229.54. [Reserved].

Source

The provisions of this § 229.54 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.55. [Reserved].

Source

The provisions of this § 229.55 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.56. [Reserved].

Source

The provisions of this § 229.56 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.57. [Reserved].

Source

The provisions of this § 229.57 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.58. [Reserved].

Source

The provisions of this § 229.58 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119237).

§ 229.59. [Reserved].

Source

The provisions of this § 229.59 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119237).

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CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subch.		Sec.
A.	SCOPE AND DEFINITIONS	230.1
B.	GENERAL	230.11
C.	[Reserved]	230.21
D.	OPERATING CONTROLS AND PROCEDURES	230.41
E.	[Reserved]	230.51

Authority

The provisions of this Chapter 230 issued under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 230 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 232.1 (relating to purpose and scope).

Subchapter A. SCOPE AND DEFINITIONS

Sec.
230.1. Purpose and scope.
230.2. [Reserved].
230.3. Incorporation by reference.
230.4. Effect of incorporation of 10 CFR Part 71.
230.5. Communications.

§ 230.1. Purpose and scope.

This chapter establishes requirements for packaging, preparation for shipment and transportation of radioactive material. This chapter applies to a person who transports radioactive material or delivers radioactive material to a carrier for transport.

§ 230.2. [Reserved].

Source

The provisions of this § 230.2 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204173) to (204176).

§ 230.3. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100 are not incorporated by reference.

Source

The provisions of this § 230.3 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282446).

§ 230.4. Effect of incorporation of 10 CFR Part 71.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), the following words and phrases shall be substituted for the language in 10 CFR Part 71 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 230.4 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 230.5. Communications.

Notwithstanding the incorporation by reference of 10 CFR 71.1 (relating to communications and records), all communications concerning the requirements of this chapter should be sent to the address listed under § 215.41 (relating to address).

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Source

The provisions of this § 230.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Subchapter B. GENERAL

Sec.
230.11 and 230.12. [Reserved].
230.13. Transportation of licensed material.
230.14. [Reserved].

§§ 230.11 and 230.12. [Reserved].

Source

The provisions of these §§ 230.11 and 230.12 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (245185).

§ 230.13. Transportation of licensed material.

In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), if 67 Pa. Code Chapters 229, 231 and 403 (relating to interstate motor carrier safety requirements; intrastate motor carrier requirements; and hazardous materials transportation) or the regulations of the United States Department of Transportation in 49 CFR Parts 171—180 and 388—397 do not apply to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

Source

The provisions of this § 230.13 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 230.14. [Reserved].

Source

The provisions of this § 230.14 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (243186).

Subchapter C. [Reserved]

§§ 230.21—230.26. [Reserved].

Source

The provisions of these §§ 230.21—230.26 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204179) to (204183).

Subchapter D. OPERATING CONTROLS AND PROCEDURES

Sec.
230.41—230.46. [Reserved].
230.47. Advance notification of transport of nuclear waste.

§§ 230.41—230.46. [Reserved].

Source

The provisions of these §§ 230.41—230.46 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204184) to (204188).

§ 230.47. Advance notification of transport of nuclear waste.

In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive materials), the licensee is responsible for the following:

(1) Prior to the transport of nuclear waste specified in 10 CFR 71.97(b) (relating to advance notification of shipment of irradiated reactor fuel and nuclear waste) outside the licensee's facility or other place of use or storage, or prior to delivery to a carrier for transport, each licensee shall provide advance notification of the transport to the Governor, or the Governor's designee, of each state through which the waste will be transported, and to the Department.

(2) The notification required by paragraph (1) shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Department. A notification delivered by mail shall be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger shall reach the office of the governor, or governor's designee, and the Department, at least 4 days before the beginning of the 7-day period during which the departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 3 years.

(3) The licensee shall notify each appropriate governor, or governor's designee, and the Department of changes to schedule information provided under paragraph (1). The notification shall be by telephone to a responsible individual in the office of each appropriate governor, or governor's designee, and the Department. The licensee shall maintain for 3 years a record of the individual contacted.

(4) Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to each appropriate governor, or governor's designee, and to the Department. A copy of the notice shall be retained by the licensee for 3 years.

(5) A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, United States Nuclear Regulatory Commission, Washington, DC 20555.

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Source

The provisions of this § 230.47 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Subchapter E. [Reserved]

§ 230.51. [Reserved].

Source

The provisions of this § 230.51 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204189) to (204190).

APPENDIX A. [Reserved]

Source

The provisions of this Appendix A reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204191) to (204202).

[Next page is 231-1.]

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CHAPTER 231. [Reserved]

Source

The provisions of this Chapter 231 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119239) to (119243).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 231.1. [Reserved].

Source

The provisions of this § 231.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119239).

§ 231.2. [Reserved].

Source

The provisions of this § 231.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.11. [Reserved].

Source

The provisions of this § 231.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.12. [Reserved].

Source

The provisions of this § 231.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.13. [Reserved].

Source

The provisions of this § 231.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.21. [Reserved].

Source

The provisions of this § 231.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.22. [Reserved].

Source

The provisions of this § 231.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119241).

§ 231.31. [Reserved].

Source

The provisions of this § 231.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119241).

§ 231.32. [Reserved].

Source

The provisions of this § 231.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119241) to (119242).

§ 231.33. [Reserved].

Source

The provisions of this § 231.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119243).

§ 231.34. [Reserved].

Source

The provisions of this § 231.34 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119243).

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CHAPTER 232. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Sec.
232.1. Purpose and scope.
232.2. Incorporation by reference.
232.3. Effect of incorporation of 10 CFR Part 36.

Authority

The provisions of this Chapter 232 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 232 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualification); and 25 Pa. Code § 217.1 (relating to purpose and scope).

§ 232.1. Purpose and scope.

(a) This chapter contains the requirements for the issuance of a license authorizing the use of radioactive materials in sealed sources to irradiate objects or materials with gamma radiation.

(b) The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements in this article, in particular, the requirements and provisions of Chapters 215, 217—220 and 230.

§ 232.2. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, §§ 36.5, 36.8, 36.91 and 36.93 are not incorporated by reference.

§ 232.3. Effect of incorporation of 10 CFR Part 36.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators), the following words and phrases shall be substituted for the language in 10 CFR Part 36 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or Agreement State.

(3) The definition of "sealed source" includes NARM.

(4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

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CHAPTER 233. [Reserved]

Source

The provisions of this Chapter 233 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119245) to (119247), (4977) to (4982) and (119249) to (119250).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 233.1. [Reserved].

Source

The provisions of this § 233.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119246) to (119247).

§ 233.2. [Reserved].

Source

The provisions of this § 233.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119247).

§ 233.11. [Reserved].

Source

The provisions of this § 233.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119247) and (4977).

§ 233.12. [Reserved].

Source

The provisions of this § 233.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4977).

§ 233.13. [Reserved].

Source

The provisions of this § 233.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4977).

§ 233.14. [Reserved].

Source

The provisions of this § 233.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4978).

§ 233.15. [Reserved].

Source

The provisions of this § 233.15 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4978) to (4979).

§ 233.21. [Reserved].

Source

The provisions of this § 233.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4979).

§ 233.22. [Reserved].

Source

The provisions of this § 233.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4979).

§ 233.23. [Reserved].

Source

The provisions of this § 233.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4979) to (4980).

§ 233.31. [Reserved].

Source

The provisions of this § 233.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4980).

§ 233.32. [Reserved].

Source

The provisions of this § 233.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4980) to (4981).

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§ 233.41. [Reserved].

Source

The provisions of this § 233.41 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4981) to (4982).

§ 233.42. [Reserved].

Source

The provisions of this § 233.42 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4982) and (119249).

§ 233.43. [Reserved].

Source

The provisions of this § 233.43 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119249).

§ 233.51. [Reserved].

Source

The provisions of this § 233.51 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119249).

§ 233.52. [Reserved].

Source

The provisions of this § 233.52 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119250).

§ 233.53. [Reserved].

Source

The provisions of this § 233.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119250).

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CHAPTER 235. [Reserved]

Source

The provisions of this Chapter 235 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119251) to (119256).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations).

§ 235.1. [Reserved].

Source

The provisions of this § 235.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119251).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.11. [Reserved].

Source

The provisions of this § 235.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119251) to (119252).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.12. [Reserved].

Source

The provisions of this § 235.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119252).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.13. [Reserved].

Source

The provisions of this § 235.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119252).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.14. [Reserved].

Source

The provisions of this § 235.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119253).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.15. [Reserved].

Source

The provisions of this § 235.15 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119253).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.21. [Reserved].

Source

The provisions of this § 235.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119253).

§ 235.22. [Reserved].

Source

The provisions of this § 235.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119253) to (119254).

§ 235.23. [Reserved].

Source

The provisions of this § 235.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119254).

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§ 235.24. [Reserved].

Source

The provisions of this § 235.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119254).

§ 235.31. [Reserved].

Source

The provisions of this § 235.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119255).

§ 235.32. [Reserved].

Source

The provisions of this § 235.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119255).

§ 235.33. [Reserved].

Source

The provisions of this § 235.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119255) to (119256).

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CHAPTER 236. LOW-LEVEL RADIOACTIVE WASTE MANAGEMENT AND DISPOSAL

Subchap.		Sec.
A.	GENERAL PROVISIONS	236.1
B.	REQUIREMENTS FOR SITING THE REGIONAL DISPOSAL FACILITY	236.101
C.	REGIONAL FACILITY LICENSE	236.201
D.	DESIGN REQUIREMENTS FOR THE REGIONAL DISPOSAL FACILITY	236.301
E.	REQUIREMENTS FOR THE CONSTRUCTION, OPERATION AND CLOSURE OF THE REGIONAL DISPOSAL FACILITY	236.401
F.	WASTE CLASSIFICATION, WASTE CHARACTERISTICS, LABELING AND MANIFESTS	236.501
G.	FINANCIAL ASSURANCES AND LIABILITY	236.601
H.	INSPECTIONS, TESTS AND RECORDS	236.701

Authority

The provisions of this Chapter 236 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); section 5 of The Clean Streams Law (35 P. S. § 691.5); section 302 of the Low-Level Radioactive Waste Disposal Act (35 P. S. § 7130.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 236 adopted October 27, 1989, effective October 28, 1989, 19 Pa.B. 4665, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); and 25 Pa. Code § 287.2 (relating to scope).

Subchapter A. GENERAL PROVISIONS

GENERAL

Sec.
236.1. Purpose and scope.
236.2. Definitions.

DISPOSAL SITE PERFORMANCE OBJECTIVES

236.11. Scope.
236.12. General requirement.
236.13. Protection of the general population and environment from releases of radioactivity.

236.14. Protection of individuals from inadvertent intrusion.
236.15. Protection of individuals during operations.
236.16. Stability of the disposal site.

Cross References

This subchapter cited in 25 Pa. Code § 236.108 (relating to site justification); 25 Pa. Code § 236.141 (relating to general requirements); 25 Pa. Code § 236.143 (relating to demography and land use); 25 Pa. Code § 236.145 (relating to meteorology and climatology); 25 Pa. Code § 236.146 (relating to seismology); 25 Pa. Code § 236.147 (relating to surface geology and hydrology); 25 Pa. Code § 236.148 (relating to subsurface geology and hydrology); 25 Pa. Code § 236.149 (relating to natural resources); 25 Pa. Code § 236.208 (relating to specific technical information); 25 Pa. Code § 236.209 (relating to technical analyses); 25 Pa. Code § 236.245 (relating to content of license application for closure); 25 Pa. Code § 236.246 (relating to application and transfer of license to the Commonwealth); 25 Pa. Code § 236.301 (relating to scope and purpose); 25 Pa. Code § 236.311 (relating to general requirements); 25 Pa. Code § 236.312 (relating to compatibility with site); 25 Pa. Code § 236.315 (relating to recoverability); 25 Pa. Code § 236.326 (relating to remedial measures); 25 Pa. Code § 236.330 (relating to performance assessment); 25 Pa. Code § 236.403 (relating to facility operation plan); and 25 Pa. Code § 236.409 (relating to monitoring plan).

GENERAL

§ 236.1. Purpose and scope.

(a) This chapter establishes procedures, criteria and terms and conditions upon which the Department issues a license for the disposal of low-level radioactive wastes received from other persons. The requirements of this chapter are in addition to other applicable requirements of this article.

(b) This chapter establishes performance objectives, and technical and procedural requirements which are applicable to any method of disposal except shallow land burial, as defined in § 236.2 (relating to definitions).

(c) This chapter does not apply to disposal of byproduct material, as defined in section 11(e)(2) of the Atomic Energy Act of 1954 (42 U.S.C.A. § 2014(e)(2)) in quantities greater than 10,000 kilograms containing more than 5 millicuries of radium-226.

§ 236.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Account—The Long Term Care Account.

Act—The Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

Active fault—A fault along which there is recurrent movement that is demonstrated by measurable periodic displacements or seismic activity.

Active institutional control period—See the definition of time periods.

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Active maintenance—Significant activity needed during the long term care period to maintain reasonable assurance that the performance objectives in this subchapter are met. The term includes major remedial actions such as replacement of disposal unit covers. The term does not include custodial activities, such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor repair of disposal unit covers and general disposal site upkeep such as mowing grass.

Affected municipality—A unit of local government other than the host municipality designated as an affected municipality under section 318 of the act (35 P. S. § 7130.318). The term may include a county, city, borough, township or school district.

Broker—An intermediate person who collects, consolidates, handles, treats, processes, stores, packages, ships or otherwise has responsibility for or possesses low-level radioactive waste.

Buffer zone—A portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

Capable fault—A fault which exhibited movement at or near the ground surface within the past 35,000 years.

Carrier—A person who transports low-level radioactive waste from or to a generator or waste management facility or to the regional disposal facility.

Chelating agent—An organic chemical that bonds with a central metal atom or ion at two or more points such as amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acids and polycarboxylic acids.

Commencement of construction—Clearing of land, excavation or other substantial action that would adversely affect the environment of the disposal facility. The term does not include disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

Commission—The Appalachian States Low-Level Radioactive Waste Commission.

Compact—The Compact entered into by the Commonwealth under the terms of the Low-Level Radioactive Waste Policy Act of 1980 (42 U.S.C.A. §§ 2021b—2021j) and as contained in the act of December 22, 1985 (P. L. 539, No. 120), known as the Appalachian State Low-Level Radioactive Waste Compact Law (35 P. S. §§ 7125.1—7125.4).

Compact states—The combined states, including the Commonwealth, which have entered into the Compact.

Container—The first enclosure which encompasses the radioactive waste.

Containment—The function of isolating radioactive waste from the biosphere by emplacement of the waste within a container, waste module or disposal unit.

Custodial agency—An agency of the government designated by the Governor to act on behalf of the government owner of the disposal site. The agency is responsible for the long term monitoring and care of the disposal site. The term does not include the Department.

Disposal—The isolation of low-level radioactive wastes from the biosphere.

Disposal facility—The buildings, equipment and other engineered features, including disposal units and temporary holding facilities, within the disposal site which are used for the disposal of low-level radioactive waste.

Disposal site—The property, including improvements thereon, which is used for disposal of low-level radioactive waste. The term consists of the disposal units and the buffer zone.

Disposal Unit—A discrete portion of the disposal site into which waste is placed for disposal.

Disqualifying criteria—Conditions which would eliminate an area from further consideration for disposal.

Engineered barrier—A manmade structure or device that is intended to improve the disposal facility's ability to meet the performance objectives in this chapter.

Engineered cover—A manmade structure constructed over the disposal facility.

Engineered structure—A manmade state-of-the-art barrier designed to:

(i) Provide additional measures for containment of radioactive waste from the environment.

(ii) Provide protection for an inadvertent intruder.

(iii) Provide stability of the disposal facility.

(iv) Prevent radioactive release.

Enhanced containment—Additional isolation of the radioactive waste from the environment as provided by engineered structures.

Explosive material—A chemical compound, mixture or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

Fund—The Low-Level Waste Fund.

Generate—To produce low-level radioactive waste requiring disposal.

Generator—A person whose activity results in the production of low-level radioactive waste requiring disposal.

Groundwater—The part of the subsurface water that is in the zone of saturation, perennial or otherwise.

Hazardous life—The time required for radioactive materials to decay to safe levels of radioactivity, as defined by the time period for the concentration of radioactive materials within a given container or package to decay to maximum

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permissible concentrations as defined by Federal law or by standards to be set by the host state, whichever is more restrictive.

Hazardous wastes—Wastes as defined in section 103 of the Solid Waste Management Act (35 P. S. § 6018.103) and regulations thereunder.

Host municipality—A city, borough, incorporated town or township, excluding a county, in which the low-level waste disposal facility will be constructed, as designated by the Department under section 318 of the act (35 P. S. § 7130.318).

Inadvertent intruder—A person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

Intruder barrier—A manmade structure or sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the requirements under § 236.320 (relating to protection from inadvertent intruders) and the performance objectives in this subchapter.

Isolation—Protection of the public and the environment from inadvertent intrusion or direct release of radioactive material from the disposal site.

Leak resistance—The material properties of the disposal facility design which retard or prevent migration of water.

Long term care period—See the definition of time periods.

Low-level radioactive waste—Radioactive waste that meets one of the following criteria:

(i) Is not high-level radioactive waste, spent nuclear fuel or by-product material as defined in section 11(e)(2) of the Atomic Energy Act of 1954 (42 U.S.C.A. § 2014(e)(2)), waste generated as a result of atomic energy defense activities of the Federal government and waste for which the Federal government is responsible under section 3(b)(1) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (42 U.S.C.A. § 2021c(b)(1)).

(ii) Is classified by the Federal government as low-level waste, consistent with the Low-Level Radioactive Waste Policy Amendments Act of 1985 or waste that contains naturally occurring or accelerator produced radioactive material which is not excluded by subparagraph (i).

Management—The reduction, collection, consolidation, storage, processing, incineration, separation, minimization, compaction, segregation, solidification, evaporation, packaging or treatment of low-level radioactive waste.

Mixed waste—Waste that is low-level radioactive waste, as defined in this subchapter, and either contains a hazardous waste or exhibits a hazardous characteristic as contained in the Solid Waste Management Act (35 P. S. §§ 6018.101—6018.1003).

Monitoring—Observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

Municipality—A county, city, borough, home rule or incorporated town or township as defined in 1 Pa.C.S. § 1991 (relating to definitions).

Passive institutional control period—See the definition of time periods.

Person—Includes the following:

(i) The definition contained in § 215.2 (relating to definitions).

(ii) An individual, corporation, partnership, association, public or private institution, cooperative enterprise, municipal authority, public utility, trust, estate, group, Federal government or agency, other than the United States Nuclear Regulatory Commission or a successor thereto, State institution and agency or other legal entity which is recognized by law as the subject of rights and duties. The term includes officers and directors of a corporation or other legal entity having officers and directors.

Postclosure observation and maintenance period—See the definition of time periods.

Potentially suitable site—An area containing approximately 500 acres, for the disposal site, that meets the screening requirements in Subchapter B (relating to requirements for siting the regional disposal facility) and would reasonably be expected to meet the performance objectives in this subchapter and site suitability requirements in Subchapter B.

Protection fund—The Regional Facility Protection Fund.

Public water system—A water system which provides water to the public for human consumption and which has at least 15 service connections or regularly services an average of at least 25 individuals daily, at least 60 days out of the year.

Pyrophoric material—aterial that ignites spontaneously. The term includes any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.5°C), or a solid, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious transportation, handling or disposal hazard. The term also includes spontaneously combustible and water reactive materials.

Shallow land burial—The disposal of low-level radioactive waste directly in subsurface trenches without additional confinement in engineered structures and in proper packaging as determined in the act.

Site closure and stabilization—Actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

Stability—Structural stability.

Surveillance—onitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion and compliance with other license, permit and regulatory requirements.

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Time periods—Specific periods of time associated with the life of the disposal facility. The term includes the following time periods presented in chronological order:

(i) *Postclosure observation and maintenance period*—The period of time following site closure during which the site operator is preparing the site for transfer to the custodial agency.

(ii) *Long term care period*—The period of time which includes both the active and passive institutional control periods.

(iii) *Active institutional control period*—The period of time following site closure and the postclosure observation and maintenance period during which active access control, surveillance, monitoring and custodial care is maintained. This period will last for a minimum of 100 years.

(iv) *Passive institutional control period*—The period of time after the active institutional control period during which monitoring and passive access control of the facility is maintained. This period will be at least as long as the hazardous life of the radioactive waste.

Waste—Low-level radioactive waste.

Waste module—A discrete assembly of waste containers within a disposal unit.

Cross References

This section cited in 25 Pa. Code § 236.1 (relating to purpose and scope); 25 Pa. Code § 236.311 (relating to general requirements); and 25 Pa. Code § 237.2 (relating to definitions).

DISPOSAL SITE PERFORMANCE OBJECTIVES

§ 236.11. Scope.

The disposal site performance objectives establish the minimum overall level of safety that the disposal facility is required to meet. Operation within these levels will provide protection of public health, safety and the environment.

§ 236.12. General requirement.

The disposal facility shall be sited, designed, operated, closed and controlled after closure so that reasonable assurance exists that exposures to individuals are within the requirements established in the performance objectives in §§ 236.13—236.16.

§ 236.13. Protection of the general population and environment from releases of radioactivity.

Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants or animals may not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid and 25 millirems to any other organ of any

member of the public. Releases of radioactivity in effluents to the general environment shall be as low as reasonably achievable and within the most restrictive Federal and Commonwealth regulations and standards which are applicable.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); 25 Pa. Code § 236.15 (relating to protection of individuals during operations); 25 Pa. Code § 236.225 (relating to requirements for issuance of a license); 25 Pa. Code § 236.314 (relating to enhanced containment); and 25 Pa. Code § 236.603 (relating to assurance for onsite cleanup during operation).

§ 236.14. Protection of individuals from inadvertent intrusion.

Design, operation and closure of the disposal facility shall ensure protection of an individual from inadvertently intruding into the disposal site and occupying the site or contacting the waste after active institutional controls over the disposal site have been removed.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); and 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.15. Protection of individuals during operations.

Operations at the disposal facility shall be conducted in compliance with the standards for radiation protection in Chapter 219 (relating to standards for protection against radiation), except for releases of radioactivity in effluents from the disposal facility, which shall be governed by § 236.13 (relating to protection of the general population and environment from releases of radioactivity). Effort shall be made to maintain radiation exposures as low as is reasonably achievable.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); and 25 Pa. Code § 236.603 (relating to assurance for onsite cleanup during operation).

§ 236.16. Stability of the disposal site.

The disposal facility shall be sited, designed, used, operated and closed to achieve long term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring or minor custodial care are required.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); and 25 Pa. Code § 236.314 (relating to enhanced containment).

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Subchapter B. REQUIREMENTS FOR SITING THE REGIONAL DISPOSAL FACILITY

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Cross References

This subchapter cited in 25 Pa. Code § 236.2 (relating to definitions); 25 Pa. Code § 236.225 (relating to requirements for issuance of a license); 25 Pa. Code § 236.301 (relating to scope and purpose); and 25 Pa. Code § 236.312 (relating to compatibility with site).

GENERAL

§ 236.101. Scope and applicability.

This subchapter contains the requirements for siting a low-level radioactive waste disposal facility in this Commonwealth. The low-level radioactive waste disposal facility shall satisfy other requirements of this chapter. The criteria for siting a low-level radioactive waste disposal facility are divided into two phases, §§ 236.121—236.128 (relating to Phase I screening requirements) and §§ 236.141—236.149 (relating to Phase II site suitability requirements). The proposed site for licensing shall meet the Phase I and Phase II requirements.

§ 236.102. Summary and purpose.

(a) The site selection process for the low-level radioactive waste disposal facility addresses a wide range of public health, safety, environmental, social and economic factors. Considerations such as public health and safety, flooding, tectonics, protection of lands in the public trust, protection and exploitation of natural resources, demographics, transportation, wildlife, air quality, ecology, topography and hydrogeology are addressed in the siting requirements. The primary goal of the siting process is to identify a site that is capable of protecting public health, safety and the environment and to identify a site that is licensable.

(b) Application of the site selection process eliminates land in this Commonwealth that is unsuitable for use as a disposal site. From the remaining land, a site is to be selected by the applicant which will be submitted in the license application for the construction of the low-level radioactive waste disposal facility. At the initiation of the site selection process, all of the land in this Commonwealth is considered suitable for siting the facility. Through application of Phase I screening requirements, the applicant shall evaluate multiple areas and determine whether the areas are qualified or unqualified until the applicant has identified and submitted three sites, of approximately 500 acres each, to the EQB as the preferred potentially suitable sites. Through application of Phase I and Phase II site suitability requirements, the preferred potentially suitable sites will be studied in detail—characterized—and compared to identify the proposed site to be submitted for licensing.

§ 236.103. Siting plan.

(a) The applicant shall submit a siting plan to the Department for approval. The siting plan shall meet the requirements of this subchapter and the act and follow the siting process discussed in the applicant's proposal. A quality assurance/quality control plan, which will be implemented throughout site screening and characterization, shall be submitted as part of the siting plan. Siting activities cannot begin until approval of the siting plan has been granted by the Department.

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(b) The Department will utilize its oversight role to ensure that the applicant is implementing the approved siting plan throughout the site screening and site characterization period.

Cross References

This section cited in 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.206 (relating to program plans).

§ 236.104. Siting process.

(a) The applicant shall screen this Commonwealth for potentially suitable sites using the criteria in §§ 236.121—236.128 (relating to Phase I screening requirements). Screening shall be conducted consistent with the applicant's siting plan under § 236.103 (relating to siting plan), proposal and contract with the Department made under section 306 of the act (35 P. S. § 7130.306). The applicant shall propose three preferred potentially suitable sites and submit those sites to the EQB for approval.

(b) The EQB will hold at least one public information meeting and one public hearing in each proposed potentially suitable area, evaluate the three proposed potentially suitable sites and determine compliance with §§ 236.121—236.128. As part of this determination, the EQB will make a determination that the screening process has identified three of the best potential locations in this Commonwealth, based on the administrative record before the EQB. The administrative record shall consist of the screening report, site justification report, the study of short and long term environmental effects on the potentially suitable sites, the conclusions and siting recommendations of the Department, the testimony presented at the EQB's public hearings and comments received during the comment period.

(c) Upon preliminary approval of the three preferred potentially suitable sites by the EQB, the applicant shall obtain access to the sites and conduct detailed characterization studies under §§ 236.141—236.149 (relating to Phase II site suitability requirements). The studies shall be conducted consistent with the applicant's site characterization plan, proposal and contract with the Department made under section 306 of the act. After concluding the characterization studies, the applicant shall select the site to be considered for licensing.

(d) Detailed site characterization at a site may be discontinued by the applicant if conditions are encountered that would prevent that site from meeting the Phase I site screening evaluation requirements or the Phase II site suitability requirements. If no disqualifying conditions are encountered, the applicant shall continue detailed site characterization.

(e) If disqualifying conditions are encountered at the three sites, the applicant shall submit three other potentially suitable sites under this section prior to reinitiation of Phase II.

Cross References

This section cited in 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.105. Preferred potentially suitable site selection procedure.

(a) The applicant shall propose three preferred potentially suitable sites for preliminary approval for further study and submit those sites to the EQB and the Department.

(b) The proposal shall be accompanied by the following:

(1) A site screening report under § 236.107 (relating to screening report).

(2) A site justification under § 236.108 (relating to site justification).

(3) An environmental impact report under § 236.109 (relating to environmental impact report).

(c) At the same time that the proposal is submitted, the applicant shall submit to the Department a social and economic impact study for each site. Each study shall propose a host municipality and affected municipalities.

(d) The Department will evaluate the proposal and submit its recommendations to the EQB.

(e) The EQB will evaluate the three potentially suitable sites in accordance with section 307(e) of the act (35 P. S. § 7130.307(e)).

§ 236.106. Selection procedure for the proposed site.

(a) Prior to initiating detailed site characterization studies, the applicant shall prepare and submit for the Department's approval a detailed plan for characterizing the three preferred potentially suitable sites.

(b) The site characterization plan shall include:

(1) Detailed plans and procedures, including quality assurance/quality control, for collecting detailed site specific information for compliance with the Phase I and Phase II siting requirements.

(2) The method for determining the proposed site for licensing.

(c) Upon approval of the three preferred potentially suitable sites by the EQB and Department approval of the site characterization plan, the applicant shall obtain access to the sites and commence detailed characterization studies.

(d) Information collected shall be compiled and included as part of the content of the license application as specified in § 236.204 (relating to content of a license application).

§ 236.107. Screening report.

(a) The applicant shall submit a site screening report to the EQB as part of its proposal for approval of three preferred potentially suitable sites. The report shall include the following:

(1) A comprehensive presentation of the information collected.

(2) The analyses conducted.

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(3) The evaluation process that was used in screening this Commonwealth to identify the preferred potentially suitable sites.

(b) The screening report shall identify the stages incorporated in the process to narrow the search from the entire Commonwealth to the level at which the three preferred potentially suitable sites are identified.

(c) The screening report shall include a description of how the Phase I screening requirements were utilized in the process and a description of how meaningful public input was solicited and incorporated in each stage of the process.

(d) The screening report shall include a detailed discussion of how requests for consideration as a potentially suitable site from interested municipalities were considered.

(e) The screening report shall include documentation and references to substantiate the validity of the information presented and the conclusions reached through every stage of analysis. The report shall describe the research and analytical techniques and identify the principal persons responsible for conducting the research and preparing the report. Presentations of information shall be clear, concise and complete to the level that allows for independent evaluation by the EQB.

Cross References

This section cited in 25 Pa. Code § 236.105 (relating to preferred potentially suitable site selection procedure).

§ 236.108. Site justification.

(a) The applicant shall submit site justifications which explain the reasons for the choice of each preferred potentially suitable site.

(b) The applicant shall use the process established in the proposal and the siting plan as approved by the Department, for applying the requirements of §§ 236.121—236.128 (relating to Phase I screening requirements) and show how the process was used to identify each preferred potentially suitable site.

(c) Site justifications shall predict the ability of each preferred site to meet the Phase II site suitability requirements and the performance objectives in Subchapter A (relating to general provisions).

(d) Site justifications shall utilize comparisons of information collected and analyzed during the screening process to defend and justify the choice of a preferred potentially suitable site.

Cross References

This section cited in 25 Pa. Code § 236.105 (relating to preferred potentially suitable site selection procedure).

§ 236.109. Environmental impact report.

An environmental impact report shall be prepared for each of the preferred potentially suitable sites and affected areas. The report shall consider the short and long term effects that a disposal facility would have on public health and safety and the environment at each preferred potentially suitable site and affected areas.

Cross References

This section cited in 25 Pa. Code § 236.105 (relating to preferred potentially suitable site selection procedure).

§ 236.110. Social and economic impact study.

(a) A social and economic impact study shall be prepared for each of the preferred potentially suitable sites. The study shall include information, analyses and discussion to clearly identify social and economic impacts. The level of information that is submitted shall be sufficient to permit the Department to conduct an independent evaluation.

(b) Each social and economic impact study shall:

(1) Propose to the Department a host municipality and affected municipalities.

(2) Evaluate the long and short term potential impacts of the facility on social and economic conditions including the following:

(i) Tax revenue.

(ii) Public and private infrastructure compatibility with regional and local economic goals.

(iii) Emergency management capabilities.

(iv) Loss of resources.

(v) Social service demands.

(c) The Department will use the social and economic impact reports in its consideration for identifying host and affected municipalities.

(d) The Department will identify the host and affected municipalities and incorporate them into the disposal facility license.

§ 236.111. Distances.

The distances from a facility to a feature or structure described in this chapter shall be measured from the boundary of the disposal site.

PHASE I SCREENING REQUIREMENTS

§ 236.121. General requirements.

(a) This section and §§ 236.122—236.128 contain both disqualifying criteria and evaluation requirements.

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(b) Disqualifying criteria denote conditions that are unacceptable for the siting of a low-level radioactive waste disposal facility. Implementation of disqualifying criteria requires that areas be evaluated to determine the existence of disqualifying conditions. Siting a low-level radioactive waste disposal facility in an area containing disqualifying conditions is prohibited. The EQB will deny a proposed site without further review if the proposed site contains disqualifying conditions. The applicant bears the burden of proving that the site contains no disqualifying conditions.

(c) Evaluation requirements denote conditions that require identification, investigation and assessment to determine acceptability. The EQB will not approve a site unless the applicant successfully demonstrates with clear and convincing evidence that the site complies with the evaluation requirements.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.108 (relating to site justification).

§ 236.122. Demography and land use.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located where nearby facilities, activities, population or development will mask monitoring of the disposal site or affect the disposal site's compliance with the performance objectives.

(b) *Evaluation requirements.* Demographic and land use characteristics that could be affected by a potentially suitable site relate to items, such as population distribution and future growth, land use, nearby facilities, safety and support services and economic conditions. Evaluations shall be made to determine the effects a proposed site location could have on existing and projected future conditions.

(1) Conditions of ownership, such as surface ownership, mineral rights, rights-of-way and liens shall be identified and evaluated with respect to site acquisition requirements of section 307 of the act (35 P. S. § 7130.307).

(2) An evaluation of compatibility with adopted county and municipal plans for land use and zoning, population distribution, projected population growth and restrictions shall be on record.

(3) The evaluations shall show potential impacts on facilities and structures, including schools, parks, hospitals, churches, retail centers, nursing homes and business establishments.

(4) An evaluation of support and safety services, including utilities, fire protection, police and medical capabilities shall be currently available upon which the disposal facility would rely. The evaluation shall include an assessment of future service needs necessary to adequately support the disposal facility.

(5) Economic conditions within the affected area of a potentially suitable site shall be described and analyzed. Potential impacts on the existing conditions shall be determined. Sufficient information and analysis shall be provided to allow for assessment of benefits and guarantees under section 318 of the act (35 P. S. § 7130.318).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.123. Evaluation requirements for transportation.

Existing and projected access roads, from potentially suitable sites to points of exit off existing interstate or limited access highways, shall be identified, described and evaluated with respect to:

(1) Their general type, conditions, upgrade or construction needs.

(2) Potential hazards for transportation.

(3) Residential dwellings per road mile.

(4) Facilities such as schools, parks or hospitals, per road mile.

(5) A total travel distance between a potentially suitable site and points of exit from existing interstate or limited access highways.

(6) Past highway safety records.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.124. Evaluation requirements for meteorology and climatology.

Averages and extremes for regional climatic and site-specific meteorology characteristics, such as temperature, precipitation, humidity, freeze-thaw characteristics and historical trends for airflow patterns, pressure systems and frontal movements, shall be described and evaluated to determine potential effects on a potentially suitable site. The potential for severe weather phenomena such as tornadoes and other storm events based on historical data shall be evaluated.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.125. Seismology.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located within 1 mile of an active fault.

(b) *Evaluation requirements.*

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(1) Potentially suitable sites shall be evaluated with respect to regional tectonic history and geologic structure, including stability, faults, folds, joints and fractures.

(2) Capable faults identified in the vicinity of a site shall be evaluated to determine correlation of the fault with recorded or suspect earthquake activity and potential impact on site stability.

(3) Potentially suitable sites shall be evaluated to determine the proximity to known or reported seismic epicenters within 200 miles. The probable seismic risk and impact associated with those epicenters that reported a Mercalli intensity of (IV) or greater shall be evaluated.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.126. Surface geology and hydrology.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located:

(1) Within the limits of the 100-year floodplain of a waterway as defined in the Flood Plain Management Act (32 P. S. §§ 679.101—679.601).

(2) Within the limits of a coastal floodplain as defined in Federal Executive Order 11988, *Flood Plain Management Guidelines* (42 U.S.C.A. § 4321, note).

(3) Within the area below a dam which may be threatened with loss of life or serious damage to property if a failure of the dam occurs.

(4) Where erosional processes or mass movement of landforms, such as mass wasting and landslides, would affect the long term stability and isolation of waste.

(5) Where there are slopes greater than 15% on areas of the disposal site where disposal units may be located, as mapped on USGS 7.5-minute quadrangles utilizing a scale of 1:24,000 with a contour interval of either 10 feet or 20 feet or on county topographic maps that utilize a scale of 1:50,000 and a contour interval of 20 feet.

(b) *Evaluation requirements.* Potentially suitable sites shall be evaluated:

(1) With respect to regional and local geomorphology. Evaluations shall discuss geomorphic features pertinent to site stability and the relationships between regional and local geomorphic features.

(2) With respect to local and site-specific surface hydrology. Characteristics to be evaluated include:

(i) Site drainage conditions.

(ii) Rates of evapotranspiration and infiltration.

(iii) Rates and directions of runoff.

(iv) Fluvial features.

(v) Historical flow conditions.

(vi) Chemical and physical properties of the waters.

(3) To determine the potential for, and the impacts from, major modifications of upstream drainage by others.

(4) With respect to local and site specific erosional processes. Characteristics such as rates, types and directions of erosion shall be described. The potential for mass movement of landforms, including landslides, slumping and mass wasting, shall also be evaluated.

(5) To determine the probable existence and extent of surface water features, including wetlands, springs and ponds that are sustained by groundwater. This evaluation shall also address the potential for future ponding and surface water discharges.

(6) To determine the magnitude, frequency and duration of storm events that would cause inundating floods and probable maximum flood conditions.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.127. Subsurface geology and hydrology.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located in areas where there is limestone or other predominantly carbonate lithologic units which exhibit one of the following characteristics:

(1) Outcrop at the surface.

(2) Occur within 50 feet of the surface and are greater than 5 feet thick.

(3) Have been identified as areas with a potential for subsidence.

(4) Currently exhibit evidence of subsidence at the surface.

(b) *Evaluation requirements.*

(1) The geology at potentially suitable sites shall be evaluated with respect to regional and local stratigraphy, lithologies and potential impact on site stability. Descriptions, illustrations and evaluations shall include characteristics such as local stratigraphic units and their accepted names, relative ages, lithologic descriptions and genetic relationships.

(2) Depths to local and regional zones of permanent saturations including seasonal fluctuations, shall be evaluated. The probability and extent of both permanent and seasonal perched water tables potentially affected by a site shall be evaluated.

(3) Local and potentially affected aquifers shall be described, evaluated and illustrated with respect to the following:

(i) Characteristics, such as lateral extent and thickness.

(ii) Rates, directions and volumes of groundwater flow.

(iii) Porosities and permeabilities.

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(iv) Recharge areas and discharge areas.

(v) Reported chemical properties.

(4) Site-specific and local soil conditions shall be evaluated with respect to physical, chemical and mineralogical properties. Characteristics to be evaluated include:

(i) Lateral extent and thickness of soil horizons.

(ii) Classification names.

(iii) Relative ages.

(iv) Genetic relationships.

(v) Porosities and permeabilities.

(vi) Rates, directions and conditions of surface and subsurface flow.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.128. Natural resources.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located:

(1) Within 1/2 mile of a well or spring which is used as a public water supply.

(2) Within 1/2 mile of either side of a stream or impoundment for a distance of 5 stream miles upstream of a surface water intake for a public water supply.

(3) Within 1/2 mile of an existing important wetland, as defined in Chapter 105 (relating to dam safety and waterway management).

(4) Within the boundaries of the following:

(i) National Park Systems.

(ii) National Forests.

(iii) Natural Landmarks designated by the National Park Service.

(iv) National Wildlife Refuges.

(v) National Fish Hatcheries.

(vi) National Wild and Scenic River Systems, including study rivers designated under section 5(a) of the Wild and Scenic River Act (15 U.S.C.A. § 1276(a)).

(vii) National System of Trails.

(viii) National Wilderness Preservation Systems.

(ix) Exceptional Value Watersheds.

(x) Historic sites listed on the National Register of Historic Places.

(xi) State, county or municipal park systems.

(xii) Land owned by the Historical and Museum Commission.

(xiii) Lands protected by the Wild and Scenic Rivers Program.

(xiv) Designated natural and wild areas.

(5) Within the boundaries of State Forest and State Game Lands unless the agency administering the lands has been given authority by statute or ordinance to allow the siting and operation of the regional disposal facility.

(6) In areas over active or inactive oil and gas wells or gas storage areas. The phrase "active or inactive oil and gas wells or storage areas" has the same meaning as used in the Oil and Gas Act (58 P. S. §§ 601.101—601.605).

(7) On agricultural land established under the Agricultural Area Security Law (3 P. S. §§ 901—915) or Class I agricultural land as defined by the United States Soil Conservation Service.

(8) In areas over active or inactive mines that are identified and substantiated by public records.

(b) *Evaluation requirements.* Potentially suitable sites shall be evaluated:

(1) With respect to water use characteristics of potentially affected water supplies. Existing private, public and community water supplies located onsite or within 3 miles shall be identified and evaluated. The ability to replace existing water supplies with alternate supplies of like quality and quantity shall be evaluated.

(2) To determine potential impact on designated high quality watersheds that may be affected.

(3) To determine the existence of, and potential impact on, endangered and threated species as defined in the Endangered Species Act of 1973 (16 U.S.C.A. §§ 460K-1, 4601-9, 668aa—668cc-6, 668dd, 715i, 715s, 1362, 1371, 1372, 1402 and 1531—1543).

(4) To determine the existence of, and potential impact on, biologic habitats identified as either endangered, threatened, rare or exemplary; and geologic features identified as outstanding on the Pennsylvania Natural Diversity Inventory.

(5) To determine to what extent previous exploration or exploitation practices have disturbed the natural geologic setting in the area. Evaluations shall identify locations, types and extent of disturbances; and estimate potential impact on site stability.

(6) To determine the types, quantities and physical locations of the natural resources contained therein and shall include an evaluation of the availability of these resources from other areas outside the site. Priority shall be given to avoid areas where natural resources that may be rare or unique to the site exist.

(c) *Wetlands.* The preferred potentially suitable sites submitted to the EQB for approval will be evaluated by the Department to determine the existence of wetlands. The results of this evaluation will be part of the Department's review that will be submitted to the EQB.

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Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

PHASE II SITE SUITABILITY REQUIREMENTS

§ 236.141. General requirements.

(a) This section and §§ 236.142—236.149 establish and identify the requirements that a site is required to meet to be considered suitable for the proposed low-level radioactive waste disposal facility. Phase II, site-specific characterization of the three preferred potentially suitable sites, begins after approval is granted by the EQB under § 236.104 (relating to siting process) and after the Department approves the site characterization plan. Site characterization will require access to the sites.

(b) Implementation of the site suitability requirements requires the collection, documentation, analysis, discussion and illustration of detailed site-specific data to supplement the data collected during Phase I screening. The Phase II effort will substantiate or disprove the validity of evaluations and projections made for the three preferred potentially suitable sites chosen in Phase I. The applicant shall clearly demonstrate that the preferred site meets the Phase I and Phase II siting requirements and contributes to compliance with the performance objectives of Subchapter A (relating to general provisions). The findings from the detailed site characterization studies shall be presented as part of the license application required in Subchapter C (relating to regional facility license).

(c) For the type of criteria in which the data collected are considered time variant by the Department, there shall be a minimum of 1 year of data acquisition to substantiate the validity of analyses and conclusions.

(d) The issuance of a license by the Secretary constitutes final approval of the site for the disposal facility.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); and 25 Pa. Code § 236.104 (relating to siting process).

§ 236.142. Characterization and modeling.

A disposal site shall be capable of being characterized, modeled, analyzed and monitored. Characterization shall be adequate to define characteristics and conditions, both onsite and offsite, through monitoring, analysis, modeling and demonstration, to substantiate that the site can satisfy site suitability requirements and meet the performance objectives.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.143. Demography and land use.

A disposal site shall be located so that projected population growth and future developments are not likely to affect the ability of the disposal site to meet the performance objectives in Subchapter A (relating to general provisions).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.144. Transportation.

A disposal site shall be located so that the roads connecting the site to an existing or limited access highway allow for safe transportation so that risks to the general population will be as low as reasonably achievable.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.145. Meteorology and climatology.

A disposal site shall be located so that adverse climatic and meteorologic conditions will not affect the ability of the disposal site to meet the performance objectives in Subchapter A (relating to general provisions).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.146. Seismology.

A disposal site shall be tectonically stable to meet the performance objectives in Subchapter A (relating to general provisions). An area shall be avoided where tectonic processes such as faulting, folding or seismic activity may occur with a frequency and to an extent which may affect the isolation of waste and the long term stability of the site.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

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§ 236.147. Surface geology and hydrology.

(a) A disposal site area shall be located where topography and surface geologic processes occur at rates, frequency and extent that they will not affect meeting the performance objectives in Subchapter A (relating to general provisions).

(b) A disposal site shall be generally well drained and free of areas of flooding or frequent ponding. The disposal facility may not be located in a wetland, as defined in Chapter 105 (relating to dam safety and waterway management).

(c) A disposal site shall be located so that upstream drainage areas are minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.148. Subsurface geology and hydrology.

(a) A disposal site may not be located where hydrologic conditions such as hydraulic conductivity or geologic features such as fractured bedrock occur at rates, frequency or extent that could adversely affect the isolation of waste or the ability to meet the performance objectives in Subchapter A (relating to general provisions).

(b) A disposal site shall be located in a hydrogeologic setting that provides sufficient separation from the groundwater, so that water intrusion into disposal units, perennial or otherwise, will not occur.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.149. Natural resources.

(a) A disposal site shall be located so that resources, such as those protected by law, those suitable for human consumption and those culturally or historically unique, can be protected during siting, design, construction, operation, closure, decommissioning and long term care.

(b) A disposal site may not be located where exploration or exploitation of natural resources, such as hydrocarbons, industrial minerals, metallic ores and mineral fuels located on the site or in adjacent areas could affect isolation of waste or, the ability to meet the performance objectives in Subchapter A (relating to general provisions).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

Subchapter C. REGIONAL FACILITY LICENSE

LICENSE APPLICATION

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Cross References

This subchapter cited in 25 Pa. Code § 236.141 (relating to general requirements).

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LICENSE APPLICATION

§ 236.201. Scope.

This subchapter addresses the requirements for licensing the regional disposal facility operator. The requirements included are as follows:

(1) Application for a license.

(2) License application review procedures and standards.

(3) Procedures for requesting changes to the disposal facility.

§ 236.202. License required.

(a) A person may not construct, alter, own or operate a low-level waste disposal facility or may receive, possess or dispose of waste received from other persons at the regional disposal facility unless authorized by a license issued by the Department under this chapter.

(b) A person shall file an application with the Department under § 236.212 (relating to filing and distribution of license application) and obtain a license as provided in this subchapter before commencement of construction of the disposal facility. Failure to comply with this requirement will be grounds for denial of a license.

§ 236.203. License application fee.

The license application fee is $800,000.

§ 236.204. Content of a license application.

In addition to the requirements in § 236.212 (relating to filing and distribution of license application), an application to receive from others, possess and dispose of wastes shall consist of:

(1) General information, program plans, a quality assurance/quality control program, specific technical information, institutional control information and financial information as set forth in §§ 236.205—236.211.

(2) An impact analysis report. The report shall address the impact of licensing the activity and include:

(i) A detailed assessment of the radiological and nonradiological impacts to the public health and the environment.

(ii) A detailed assessment of the impact on the quality and quantity of the surface and groundwater within a 5-mile radius of the site.

(iii) A discussion of the long term public health and environmental impacts, including closure, decommissioning, decontamination and reclamation of the site and facilities associated with the licensed activities and management of radioactive materials which will remain on the site after closure, decommissioning, decontamination and reclamation.

(iv) A discussion of the short and long term social and economic impacts of the regional disposal facility on the host and affected municipali-

ties. These impacts will be used to create a minimum set of items to be considered as part of the host and affected municipality benefit negotiations. At a minimum, the study shall include the impacts on local tax revenues, public and private infrastructures, emergency management capabilities and social service demands.

(v) A preoperational environmental radiation survey and a preoperational health survey of cancer and other disease rates and birth defects within 5 miles of the site.

(vi) Justification for the choice of the proposed site over the other two preferred potentially suitable sites.

Cross References

This section cited in 25 Pa. Code § 236.106 (relating to selection procedure for the proposed site).

§ 236.205. General information.

The license application shall include general information as follows:

(1) The identity of the applicant, including:

(i) The full name, address, telephone number and description of the business or occupation of the applicant.

(ii) The name and address of each partner and the principal location where the partnership does business, if the applicant is a partnership.

(iii) The following, if the applicant is a corporation or an unincorporated association:

(A) The state in which it is incorporated or organized and the principal location at which it does business.

(B) The names and addresses of its directors and principal officers.

(iv) Information required under this section with respect to the other person, if the applicant is acting as an agent or representative of another person in filing the application.

(2) Qualifications of the applicant as follows:

(i) The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority, key positions and assignments of responsibilities, whether in the form of administrative directives, contract provisions or otherwise.

(ii) The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in subparagraph (i) shall be provided.

(iii) A description of the applicant's personnel training program.

(iv) The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling and disposal operations in a safe manner.

(3) A description of:

(i) The location of the proposed disposal site.

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(ii) The general character of the proposed activities.

(iii) The types and quantities of waste to be received, possessed and disposed of.

(iv) The proposed facilities and equipment.

(4) Proposed schedules for construction, receipt of waste and first emplacement of waste at the disposal facility.

(5) A description of the applicant's compliance with State and Federal environmental protection statutes including the Radiation Protection Act and Low-Level Radioactive Waste Disposal Act, the Appalachian States Low-Level Radioactive Waste Compact Act or other state or Federal statute relating to environmental protection or to protect the public health and safety.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.226 (relating to conditions of the license).

§ 236.206. Program plans.

(a) The applicant shall submit the following detailed program plans:

(1) A siting plan under § 236.103 (relating to siting plan).

(2) A quality assurance/quality control plan under § 236.207 (relating to quality assurance/quality control program).

(3) A monitoring plan under § 236.409 (relating to monitoring plan).

(4) A security plan under § 236.403(a)(1) (relating to facility operation plan).

(5) An operations plan under § 236.403.

(6) A contingency plan under § 236.404 (relating to contingency plans).

(7) A radiation control plan under § 236.403(c).

(8) A construction plan under § 236.402 (relating to construction plan).

(9) A site closure and decommissioning plan under § 236.411 (relating to site closure and decommissioning plan).

(b) The plans set forth in subsection (a), and subsequent changes thereto, will be reviewed and approved by the Department. The requirement to implement the approved plans will be incorporated into the facility license.

(c) The plans shall demonstrate that the necessary technical information and analyses can be obtained and used to demonstrate compliance with the performance objectives.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.245 (relating to content of license application for closure).

§ 236.207. Quality assurance/quality control program.

A quality assurance/quality control plan shall be submitted to the Department for approval. The plan shall include a description of the quality assurance/quality

control program for the determination of natural disposal site characteristics and for quality assurance/quality control during the design, construction, operation and closure of the disposal facility and the receipt, handling and emplacement of waste. Audits and managerial controls shall be included.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.206 (relating to program plans).

§ 236.208. Specific technical information.

The specific technical information shall include information needed for demonstrating that the performance objectives and the applicable technical requirements of this chapter will be met. The following shall be included:

(1) A description of the natural and demographic disposal site characteristics as determined by site screening and characterization activities contained in Subchapter B (relating to requirements for siting the regional disposal facility). The description shall include demographic, meteorologic, climatologic, biotic, ecologic, hydrologic, geologic (including geochemical and geotechnical) and natural resource features of the disposal site and vicinity.

(2) A description of the design features of the disposal facility and the disposal units. The description shall include those design features related to the following:

(i) Minimization of water intrusion.

(ii) Integrity of covers for disposal units.

(iii) Structural stability.

(iv) Contact of wastes with standing water.

(v) Disposal site drainage.

(vi) Closure and stabilization.

(vii) Recoverability.

(viii) Elimination to the extent practicable of long term active maintenance.

(ix) Protection from inadvertent intrusion.

(x) Occupational exposures.

(xi) Monitoring.

(xii) Adequacy of the size of the buffer zone for monitoring and potential remedial measures.

(3) A description of the principal design features and their relationship to the performance objectives.

(4) A description of the engineered structures which the applicant has incorporated into the design and which will apply to construction of the disposal facility.

(5) A description of codes and standards which the applicant has applied to the design and which will apply to construction of the disposal facility.

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(6) A description of the construction and operation of the disposal facility. The description shall include at a minimum:

(i) Methods of constructing the disposal units.

(ii) Waste emplacement.

(iii) Procedures for and areas of waste segregation.

(iv) Types of intruder barriers.

(v) Onsite traffic and drainage systems.

(vi) Survey control program.

(vii) Methods and areas of waste storage.

(viii) Methods to control water access to the wastes.

(ix) The methods to be employed in the handling and disposal of wastes containing chelating agents or other nonradiological substances that might affect meeting the performance objectives of Subchapter A (relating to general provisions).

(7) A description of the disposal site closure and decommissioning plan under § 236.411 (relating to site closure and decommissioning plan); specifically those design features which are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance.

(8) An identification of the known natural resources at the disposal site, exploitation of which could result in inadvertent intrusion into the waste after removal of active institutional control.

(9) A description of the various low-level waste streams and the physical and chemical properties, and the volumes and different classes of waste proposed to be received, possessed and disposed of at the disposal facility. The description shall include consideration of projected variations in future waste streams and volumes and their potential affect on the disposal facility.

(10) A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in Subchapter A and occupational radiation exposure to ensure compliance with Chapter 219 (relating to standards for protection against radiation) and to control contamination of personnel, vehicles, equipment, buildings and the disposal site. Both routine operations and accidents shall be addressed. The program description shall include procedures, instrumentation, facilities and equipment. Application of as low as reasonably achievable shall be discussed.

(11) A description of the monitoring program under § 236.409 (relating to monitoring plan) to provide data to evaluate disposal facility performance, potential health and environmental impacts and the plan for taking remedial measures.

(12) A description of the administrative procedures that the applicant will apply to control activities at the disposal facility.

(13) A description of potential operational accidents and the methodology to assure that likely accident scenarios are bounded.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application).

§ 236.209. Technical analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of Subchapter A (relating to general provisions) will be met:

(1) Analyses of the pathways demonstrating protection of the general population from releases of radioactivity. Pathways analyzed shall include air, soil, groundwater, surface water, plant uptake and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate that there is assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in the performance objectives in Subchapter A.

(2) Analyses of the protection of individuals from inadvertent intrusion. The analyses shall include a demonstration that there is assurance that the waste classification and segregation requirements will be met and that barriers to inadvertent intrusion will be provided.

(3) Analyses of the protection of individuals during operations. The analyses shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage and disposal of waste. The analyses shall provide assurance that exposures will be controlled to meet the requirements of Chapter 219 (relating to standards for protection against radiation).

(4) Analyses of the long term stability of the disposal site to determine the need for ongoing active maintenance after closure. These analyses shall consider active natural processes, including erosion, mass wasting, slope failure, settlement of wastes, infiltration through disposal covers and surface drainage of the disposal site. The analyses shall provide assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application).

§ 236.210. Institutional control information.

The institutional control information submitted by the applicant shall include:

(1) A certification by the Commonwealth that the custodial agency is prepared to accept transfer of the license when § 236.246 (relating to application and transfer of license to the Commonwealth) is met and will assume responsibility for institutional control after site closure and the postclosure observation and maintenance period.

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(2) If the proposed disposal site is on land not owned by the Federal government or the Commonwealth, the applicant shall submit evidence that arrangements have been made for assumption of ownership by the Commonwealth before the Department issues a license.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.211. Financial information.

The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet the financial assurance requirements of section 316 of the act (35 P. S. § 7130.316) and Subchapter G (relating to financial assurances and liability). The applicant shall provide documented evidence of the availability of funds. If debt capital will be used, letters of commitment from the financial sources shall be provided.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application).

§ 236.212. Filing and distribution of license application.

(a) An application package to obtain a license under this chapter and the Department licenses and permits necessary to construct and operate the disposal facility shall be filed with the Secretary. The applicant shall submit one signed original and 35 copies to the Secretary.

(b) The application package shall contain a statement, signed by a responsible official of the applicant and attested by a notary public, that certifies that the information contained in the application package is true and correct to the best of the official's information and belief.

(c) The application package shall consist of the following:

(1) The application for a license.

(2) An impact analysis report.

(3) The Department license and permit applications necessary for construction and operation of the disposal facility.

Cross References

This section cited in 25 Pa. Code § 236.202 (relating to license required); 25 Pa. Code § 236.204 (relating to content of a license application); 25 Pa. Code § 236.241 (relating to amendments for closure and transfer); and 25 Pa. Code § 236.247 (relating to termination of license).

§ 236.213. Contact person.

Except as otherwise specified, communications and reports concerning this chapter and applications filed under it shall be addressed to the Secretary, Department of Environmental Resources, Post Office Box 2063, Harrisburg, Pennsylvania 17120.

LICENSE REVIEW PROCEDURES AND STANDARDS

§ 236.221. Verification of receipt of application.

The Department will notify the applicant of its receipt of the license application.

§ 236.222. Public notice.

(a) Upon receipt of the license application, the Department will notify the public of receipt of the application. The notification will include a listing of the locations in which the application can be reviewed by the public. Notification will be provided in the *Pennsylvania Bulletin*, local media, newspapers of wide general circulation and newspapers in the area the regional facility is proposed to be located.

(b) The Department will make the license application available for review in the host municipality.

Cross References

This section cited in 25 Pa. Code § 236.223 (relating to public comment and hearing); 25 Pa. Code § 236.224 (relating to revising the license application); and 25 Pa. Code § 236.241 (relating to amendments for closure and transfer).

§ 236.223. Public comment and hearing.

(a) The Department will hold one public hearing and one public information meeting on the initial license application in the area the regional facility is proposed to be located. The Department will issue a 30-day public notice in the *Pennsylvania Bulletin* and newspapers of general circulation in the area of the proposed host municipality to announce the hearing and meeting dates. There will be a minimum of 30 days time between the public hearing and the public meeting.

(b) Interested persons may submit to the Department written comments regarding the application. Comments shall be submitted within 180 days after notification has been made under § 236.222 (relating to public notice). Interested persons may submit comments at the hearing. A person wishing to examine witnesses shall submit to the Department a numbered list of contentions. The contentions shall be limited to failure of the license application and its contents to conform with the act and this chapter. The applicant shall submit two copies of its testimony 2 weeks before the date the hearing is scheduled. The applicant or

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licensee shall make its staff available to answer questions. The Department may establish the duration for oral testimony and may limit the scope of questioning during the hearing.

(c) Written comments and the transcript of the hearing will be considered in the Secretary's decision on the application and become part of the public record.

(d) The Department will provide a written response to comments or testimony at the time a final action is taken.

Cross References

This section cited in 25 Pa. Code § 236.241 (relating to amendments for closure and transfer).

§ 236.224. Revising the license application.

(a) If the license application is rejected, a revised application may be submitted and may incorporate the portions of the previous application that were not the bases of the rejection.

(b) The Department will notify the public of an application rejection. Notification will be issued under § 236.222 (relating to public notice).

§ 236.225. Requirements for issuance of a license.

A license will not be issued unless the applicant affirmatively demonstrates to the satisfaction of the Department that:

(1) The operation will not endanger public health, safety and welfare or the environment.

(2) The application is accurate and complete and the requirements of the act and this chapter have been satisfied.

(3) The applicant is qualified by reason of training and experience to carry out the disposal operations requested in a manner that protects health and minimizes danger to life or property.

(4) The applicant's proposed disposal site, disposal facility design, disposal facility operations, including equipment, facilities and procedures, disposal site closure and postclosure institutional control are adequate to protect the public health and safety by providing assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in § 236.13 (relating to protection of the general population and environment from releases of radioactivity).

(5) The applicant's proposed disposal site, disposal facility design, disposal facility operations, including equipment, facilities and procedures, disposal site closure and postclosure institutional control are adequate to protect the public health and safety by providing assurance that individual inadvertent intruders are protected in accordance with the performance objective in § 236.14 (relating to protection of individuals from inadvertent intrusion).

(6) The applicant's proposed disposal facility design and disposal facility operations, including equipment, facilities and procedures, are adequate to pro-

tect the public health and safety by providing assurance that the standards for radiation protection in Chapter 219 (relating to standards for protection against radiation) will be met.

(7) The applicant's proposed disposal site, disposal facility design, disposal facility operations, disposal site closure and postclosure institutional control are adequate to protect the public health and safety by providing assurance that long term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance following closure.

(8) The technical requirements of Subchapters B and D—F will be met.

(9) The applicant's proposal for institutional control, as required in § 236.210 (relating to institutional control information), provides assurance that the control will be provided for the long term care period.

(10) The financial or surety arrangements meet the requirements of Subchapter G (relating to financial assurances and liability).

Cross References

This section cited in 25 Pa. Code § 236.241 (relating to amendments for closure and transfer); 25 Pa. Code § 236.242 (relating to other amendments); and 25 Pa. Code § 236.246 (relating to application and transfer of license to the Commonwealth).

§ 236.226. Conditions of the license.

(a) A license issued under this chapter, or a right thereunder, may not be transferred, assigned or disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to another person, unless the Department finds, after securing full information, that the transfer is in accordance with the act and the Department gives its consent in writing in the form of a license amendment.

(b) The licensee shall submit written statements under oath upon request of the Department, before termination of the license, to enable the Department to determine whether the license should be modified, suspended or revoked.

(c) The license will be transferred to the custodial agency on the full implementation of the site closure and decommissioning plan as approved by the Department, including postclosure observation and maintenance.

(d) The licensee shall be subject to the act and to this title and orders of the Department. The terms and conditions of the license are subject to amendment, by reason of amendments to, or by reason of this title and order issued under the act.

(e) The person licensed by the Department under this chapter shall confine possession and use of materials to the locations and purposes authorized in the license.

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(f) The licensee may not dispose of waste until the Department has inspected the disposal facility and has found it to be in conformance with plans described in the application for a license and approved by the Department.

(g) The Department may incorporate in the license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession and disposal of waste as the Department deems appropriate or necessary to:

(1) Protect health or minimize danger to life or the environment.

(2) Provide for inspections or activities under the license that may be necessary or appropriate to effectuate the purposes of the act and regulations thereunder.

(3) Require tests, reports and the keeping of records.

(h) The authority to dispose of wastes expires on the date stated in the license. The Department will, on a 5-year basis, review the license and conditions of the license. An expiration date on the license applies only to operational activities and to the authority to dispose of waste. Failure to revise the license does not relieve the licensee of responsibility for implementing site closure and decommissioning, postclosure observation and transfer of the license to the Commonwealth.

(i) The license may be revoked, suspended or modified for a material false statement in the application, or because of conditions revealed by a report, record or inspection or other means which would warrant the Department to refuse to grant a license for the original application.

(j) The licensee shall allow the Department, its agents and employes, and the host municipality and host county inspectors, without advance notice or search warrant, upon presentation of appropriate credentials and without delay, to have access to areas where disposal activities are conducted and to examine the records and books relating thereto.

(k) The licensee shall update on an annual basis the general information required under § 236.205 (relating to general information) and other information the Department may require.

§ 236.227. Effective date of decision.

The initial decision to issue a license under this chapter or an amendment to the license shall become effective immediately upon signed order of the Secretary or a delegated representative.

CHANGES TO THE REGIONAL FACILITY LICENSE

§ 236.241. Amendments for closure and transfer.

An application for a license amendment for site closure or license transfer shall be filed under § 236.212 (relating to filing and distribution of license application) and shall fully describe the changes desired. The application shall be subject to

the notice, comment and hearing requirements of §§ 236.222 and 236.223 (relating to public notice; and public comment and hearing). The application for site closure or transfer will not be approved by the Department unless the applicant has demonstrated to the Department's satisfaction that the standards in § 236.225 (relating to requirements for issuance of a license) have been met.

§ 236.242. Other amendments.

Except for site closure or license transfer, if the operator wishes to amend the license, the licensee shall notify the Department and the host municipality of the proposed amendments. The Department will provide public notice of the application in the *Pennsylvania Bulletin.* The public shall have opportunity to comment on the proposed amendments during a period of 60 days after the notification has been published. The application for license amendment will not be approved by the Department unless the applicant has demonstrated to the Department's satisfaction that the standards in § 236.225 (relating to requirements for issuance of a license) have been met.

§ 236.243. Fees.

The Department will determine license amendment application fees on a case by case basis. The fees will be based on administrative costs incurred by the Department.

§ 236.244. Application for closure.

(a) An application for closure under § 236.245 (relating to content of a license application for closure) shall be filed at least 90 days prior to license expiration.

(b) An application for closure shall be filed under § 236.245. Information contained in previous applications, statements or reports filed with the Department under the license may be incorporated by reference if the references are clear and specific.

§ 236.245. Content of a license application for closure.

(a) Prior to final closure of the disposal site, or as otherwise directed by the Department, the licensee shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure and decommissioning plan submitted under § 236.206 (relating to program plans) that includes the following:

(1) Additional geologic, hydrologic or other data pertinent to the long term containment of emplaced wastes obtained during the operational period.

(2) The results of tests, experiments or other analyses relating to the long term containment of emplaced waste within the disposal facility.

(3) Proposed revision of plans for:

(i) Decontamination or dismantlement of facilities, or both.

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(ii) Stabilization of the disposal site for postclosure care.

(4) Significant new information regarding the environmental impact of closure activities and long term performance of the disposal site.

(b) Upon review and consideration of an application to amend the license for closure submitted under this section, the Department will issue an amendment authorizing closure if there is assurance that the long term performance objectives of Subchapter A (relating to general provisions) will be met.

Cross References

This section cited in 25 Pa. Code § 236.244 (relating to application for closure).

§ 236.246. Application and transfer of license to the Commonwealth.

(a) Following closure and the postclosure observation and maintenance period, the licensee may apply for an amendment to transfer the license to the Commonwealth. The license will not be transferred unless the licensee demonstrates to the Department's satisfaction that:

(1) The closure of the disposal site has been made in conformance with the licensee's site closure and decommissioning plan, as approved as part of the license.

(2) The performance objectives of Subchapter A (relating to general provisions) have been met and will continue to be satisfied.

(3) Funds collected for the Account and necessary records for care have been transferred to the Commonwealth.

(4) The monitoring program is operational for implementation by the Commonwealth.

(5) The custodial agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under § 236.225(i) (relating to requirements for issuance of a license) will be met.

(b) Upon demonstration of the requirements of subsection (a), the disposal facility license will be transferred to the Commonwealth and the operator's license will be terminated.

Cross References

This section cited in 25 Pa. Code § 236.210 (relating to institutional control information); 25 Pa. Code § 236.414 (relating to radiation dose rates at the surface); and 25 Pa. Code § 236.415 (relating to postclosure observation and maintenance).

§ 236.247. Termination of license.

(a) At any period of time during the long term care period, the custodial agency—licensee—may apply for an amendment to terminate the license.

(b) The application shall be filed under § 236.212 (relating to filing and distribution of license application) and the requirements of this section.

(c) The licensee shall demonstrate to the satisfaction of the Department that the standards of § 236.508 (relating to determination of hazardous life of the waste) are met.

Subchapter D. DESIGN REQUIREMENTS FOR THE REGIONAL DISPOSAL FACILITY

GENERAL

Sec.
236.301. Scope and purpose.

DESIGN CRITERIA

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236.326. Remedial measures.
236.327. Class C waste.
236.328. Mixed waste.
236.329. Nonradiological hazards.
236.330. Performance assessment.

Cross References

This subchapter cited in 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

GENERAL

§ 236.301. Scope and purpose.

(a) This subchapter implements section 305 of the act (35 P. S. § 7130.305). The requirements of this subchapter specify the design criteria for an above-grade low-level radioactive waste disposal facility.

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(b) The selected disposal technology shall meet the design criteria that are established in this subchapter and as a goal, be designed and constructed for zero release of radioactive material. The design requirements for addressing containment of waste and the goal of zero release are specified in § 236.314 (relating to enhanced containment). Furthermore, the site in which the disposal facility is to be located shall independently comply with Subchapter B (relating to requirements for siting the regional disposal facility). Consequently, the design criteria have been established to require the applicant to demonstrate that the disposal technology can complement and augment the site's ability to meet the performance objectives of Subchapter A (relating to general provisions).

DESIGN CRITERIA

§ 236.311. General requirements.

(a) Shallow land burial, as defined in § 236.2 (relating to definitions) is prohibited.

(b) Waste emplaced in the disposal facility shall be above the natural grade of the land which shall be known as above-grade disposal. An above-grade disposal facility shall be used unless the applicant can demonstrate that other designs provide significant improvement for recoverability, monitoring and protection of public health and the environment.

(c) The design and construction methods may not adversely affect the ability of the disposal facility to meet the performance objectives of Subchapter A (relating to general provisions).

§ 236.312. Compatibility with site.

(a) The disposal facility shall be compatible with the natural characteristics of the site, as identified in Subchapter B (relating to requirements for siting the regional disposal facility).

(b) The disposal facility shall complement and augment the natural disposal site's ability to assure that the performance objectives of Subchapter A (relating to general provisions) are met.

§ 236.313. Acceptance of diverse waste streams.

(a) The disposal facility shall be capable of accepting low-level radioactive waste generated within the Appalachian Compact region that is classified as a state responsibility under the Low-Level Radioactive Waste Policy Amendments Act of 1985 (42 U.S.C.A. §§ 2021b—2021j).

(b) The disposal facility shall have sufficient capacity to accommodate at least a 30-year useful facility life, as required by the Appalachian State Low-Level Radioactive Waste Compact. Design consideration for disposal capacity shall be based on reasonable waste projections and be capable of accommodating unanticipated changes in waste streams or volumes.

2(c) The disposal facility shall be capable of accommodating low-level waste streams with different physical and chemical properties.

§ 236.314. Enhanced containment.

(a) The disposal facility shall include engineered structures. The engineered structures shall provide additional measures for isolation of waste from the environment. For the purpose of this section, the container by itself cannot satisfy requirements for enhanced containment.

(b) At a minimum, the engineered structures shall provide:

(1) Leak resistance for a minimum of 100 years, following the postclosure observation and maintenance period.

(2) Structural stability to the disposal units. Design goals for the material integrity and stability of the engineered structure shall be commensurate with the time periods specified in subsection (d).

(c) The disposal facility shall independently comply with performance objectives in §§ 236.13 and 236.16 (relating to protection of the general population and environment from releases of radioactivity; and stability of the disposal site) without consideration of natural site features, through the active institutional control period.

(d) The design goal for the disposal facility to provide containment of the different classes of waste shall be for the following minimum time periods:

(1) Class A radioactive waste—100 years.

(2) Class B radioactive waste—300 years.

(3) Class C radioactive waste—500 years.

(4) Mixed waste—500 years.

Cross References

This section cited in 25 Pa. Code § 236.301 (relating to scope and purpose); 25 Pa. Code § 236.324 (relating to disposal unit monitoring); and 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.315. Recoverability.

(a) The disposal facility design shall allow for recovery of the waste. This section may not compromise or otherwise lessen the ability of the disposal facility to meet the performance objectives of Subchapter A (relating to general provisions) and the stability requirements of § 236.322 (relating to long term stability of disposal units).

(b) Determinations for recovery of the waste shall be based on the analysis of information collected under §§ 236.324, 236.325 and 236.410 (relating to disposal unit monitoring; material performance monitoring; and environmental monitoring).

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Cross References

This section cited in 25 Pa. Code § 236.327 (relating to class C waste); and 25 Pa. Code § 236.328 (relating to mixed waste).

§ 236.316. Passive isolation.

The disposal facility shall be designed for long term isolation and avoidance of the need for remedial action after site closure.

§ 236.317. Minimization of water intrusion during operations.

(a) The design goal for the disposal facility shall be to prevent the contact of waste and waste containers with water prior to and during disposal.

(b) The disposal facility design shall preclude the contact of waste containers with standing water during emplacement into the disposal units.

§ 236.318. Water management.

(a) The design goal for the disposal facility shall be to prevent infiltration of water and eliminate the accumulation of standing water in the disposal units following waste disposal.

(b) The disposal facility shall be designed to direct surface water drainage away from disposal units at velocities and gradients which would not result in erosion that would require ongoing active maintenance.

§ 236.319. Disposal facility cover system.

The disposal units shall include an engineered cover. The design goal for the cover shall be to prevent water infiltration. The cover shall be designed to:

(1) Provide long term stability without the need for active maintenance. The engineered cover shall perform through the long term care period.

(2) Direct surface runoff away from the disposal unit.

(3) Minimize erosion, differential settlement, ponding, piping, mass wasting and slumping.

§ 236.320. Protection from inadvertent intruders.

(a) The disposal facility shall include intruder barriers for Class B, Class C and mixed wastes. At a minimum, these disposal units shall include an intruder barrier that is an engineered structure, designed to resist inadvertent intrusion for:

(1) Class B waste—300 years.

(2) Class C waste—500 years.

(3) Mixed waste—500 years.

(b) If more than one class of waste is disposed of in the same unit, the more stringent intruder requirement shall be met.

(c) The disposal facility design shall, to the extent practicable, limit radiation exposures to the inadvertent intruder to an annual whole body dose equivalent of 25 millirems.

Cross References

This section cited in 25 Pa. Code § 236.2 (relating to definitions); and 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.321. Protection of workers.

The disposal facility design shall incorporate systems and features which shall maintain exposures to workers which are as low as reasonably achievable.

§ 236.322. Long term stability of disposal units.

(a) The disposal facility shall be designed to provide long term stability to the engineered structures of the disposal units.

(b) At a minimum, the stability requirements for the engineered structures for the different classes of waste shall be:

(1) Class A radioactive waste—100 years.

(2) Class B radioactive waste—300 years.

(3) Class C radioactive waste—500 years.

(4) Mixed waste—500 years.

(c) If more than one class of waste is disposed of in the same disposal unit, the more stringent stability requirement shall be met.

(d) Waste containers or modules shall be emplaced in the disposal unit in a manner that maintains physical integrity.

(e) Waste containers or modules shall be designed and emplaced in the disposal unit in a manner that minimizes void space.

Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); and 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.323. Disruptive external events.

The disposal facility shall be designed to maintain its structural integrity and provide waste containment capability during an external, disruptive, natural or manmade event which may occur in the area.

§ 236.324. Disposal unit monitoring.

(a) The disposal facility design shall include provisions for a continuous monitoring program. The program shall commence upon placement of the waste into the disposal units and continue through the long term care period.

(b) The disposal unit monitoring system that is used to support the continuous monitoring program shall be capable of detecting and identifying the location, within each disposal unit, of leached radioactive materials. The disposal unit monitoring system shall be designed to be compatible with design provisions for waste recovery in § 236.314 (relating to enhanced containment).

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Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); 25 Pa. Code § 236.327 (relating to class C waste); 25 Pa. Code § 236.328 (relating to mixed waste); and 25 Pa. Code § 236.409 (relating to monitoring plan).

§ 236.325. Material performance monitoring.

(a) An analysis of the materials and components of the engineered structures shall be conducted to demonstrate that the disposal facility can perform through the long term care period.

(b) The disposal facility design shall include provisions for a monitoring program which can provide ongoing verification of the performance of the engineered structure. At a minimum, the program shall provide performance verification beginning at initial operation and up to and including the active institutional control period.

Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); 25 Pa. Code § 236.327 (relating to class C waste); 25 Pa. Code § 236.328 (relating to mixed waste); and 25 Pa. Code § 236.409 (relating to monitoring plan).

§ 236.326. Remedial measures.

The disposal facility shall be designed to facilitate remedial action. This criterion may not compromise or otherwise lessen the ability of the disposal facility to meet the performance objectives of Subchapter A (relating to general provisions).

§ 236.327. Class C waste.

(a) Class C waste disposal shall be performed apart from other low-level radioactive waste disposal, and Class C waste shall be placed in individual modules.

(b) A Class C module shall be monitored under §§ 236.324 and 236.325 (relating to disposal unit monitoring; and material performance monitoring) and be recoverable under § 236.315 (relating to recoverability).

Cross References

This section cited in 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.328. Mixed waste.

(a) Mixed waste disposal shall comply with this chapter and Article VII (relating to hazardous waste management).

(b) Mixed waste shall be in a solid and stable form and shall be disposed apart from other low-level radioactive waste disposal.

(c) Mixed waste shall be placed in individual modules. A mixed waste module shall be monitored under §§ 236.324 and 236.325 (relating to disposal unit

monitoring; and material performance monitoring) and be recoverable under § 236.315 (relating to recoverability).

§ 236.329. Nonradiological hazards.

The disposal facility design and operational procedures shall reduce nonradiological hazards to individuals to levels as low as reasonably achievable.

§ 236.330. Performance assessment.

The performance of the disposal facility shall be characterized, analyzed and modeled in order to predict interactions of the disposal units with the environment and compliance with the performance objectives in Subchapter A (relating to general provisions).

Subchapter E. REQUIREMENTS FOR THE CONSTRUCTION, OPERATION AND CLOSURE OF THE REGIONAL DISPOSAL FACILITY

Sec.
236.401. Scope and purpose.
236.402. Construction plan.
236.403. Facility operation plan.
236.404. Contingency plans.
236.405. Receipt and handling of waste.
236.406. Package integrity.
236.407. Minimization of void space.
236.408. Operational activity.
236.409. Monitoring plan.
236.410. Environmental monitoring.
236.411. Site closure and decommissioning plan.
236.412. Boundary locations.
236.413. Buffer zone.
236.414. Radiation dose rates at the surface.
236.415. Postclosure observation and maintenance.
236.416. Institutional control.

Cross References

This subchapter cited in 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.401. Scope and purpose.

(a) Only Classes A, B, C and mixed waste are acceptable for disposal at the regional disposal facility. Waste disposal activities at the regional facility shall meet the construction, operation and closure requirements of this subchapter. The planning and implementation of these activities shall contribute to the goal of zero release of radioactive material.

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(b) A mixed waste is not acceptable for disposal at the regional disposal facility if either the facility operator or the Department has reason to believe that the hazardous waste, as originally generated, was not radioactive.

(c) Waste received at the regional disposal facility may not be intentionally diluted by the licensee to alter its classification as identified on the manifest received under § 236.536 (relating to disposal facility operator requirements).

§ 236.402. Construction plan.

The applicant shall submit a construction plan. The plan shall describe procedures that will be implemented to ensure quality work that will consistently conform to applicable standards and codes.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans).

§ 236.403. Facility operation plan.

(a) The applicant shall submit a facility operation plan for approval by the Department. The plan shall:

(1) Include detailed descriptions of the method of construction of the disposal units, waste emplacement, procedures for and areas of waste segregation, onsite traffic and drainage systems, site security, methods and areas of waste storage, methods to control access of water, mixed wastes or other nonradiological substances or waste that may affect meeting the performance objectives of Subchapter A (relating to general provisions).

(2) Be compatible with other plans required by this chapter.

(b) The plan shall include detailed descriptions of closure and stabilization measures that will be carried out as each disposal unit is filled.

(c) A site health and safety plan which addresses radiological health under Chapter 219 (relating to standards for protection against radiation) and occupational hazards shall be submitted. The plan shall be adequate to protect public health and safety, and the environment and provide reasonable assurance that the standards for radiation protection in Chapter 219 will be met. The plan shall identify measures that are intended to provide assurance that radiation exposures to workers are as low as reasonably achievable.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans).

§ 236.404. Contingency plans.

(a) The applicant shall submit contingency plans for unplanned occurrences, such as fire, industrial accidents, radiological contamination, severe natural events, disposal unit repairs and waste recovery which may adversely affect the health and safety of disposal facility workers or the general public.

(b) The plans shall identify the necessary training, management, procedures, equipment and human resources required to provide emergency response.

(c) The operator shall include one of the following in the license application:

(1) Signed agreements from necessary emergency response units that they will respond to requests from the operator.

(2) Provisions by the operator for adequate emergency response capability as identified in subsections (a) and (b), approved by the Department.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans).

§ 236.405. Receipt and handling of waste.

(a) The applicant shall submit a plan for the receipt, inspection and handling of waste entering the disposal facility. The plan shall include waste acceptance criteria that define specifications for waste acceptable for disposal at the facility and waste containers that are acceptable for disposal.

(b) The plan shall be designed to ensure that:

(1) Waste that arrives at the disposal site complies with Subchapter F (relating to waste classification, waste characteristics, labeling and manifests).

(2) The procedures and equipment for moving, segregating and storing the waste will be carried out in a safe manner and eliminate, to the maximum extent practicable, the contact of the waste with water.

§ 236.406. Package integrity.

Wastes shall be emplaced in a manner that maintains the container integrity and minimizes the void spaces between containers.

§ 236.407. Minimization of void space.

Void spaces between waste containers shall be minimized to reduce the potential for future subsidence.

§ 236.408. Operational activity.

Active waste disposal operations may not have an adverse effect on disposal units for which closure and stabilization measures have been completed.

§ 236.409. Monitoring plan.

(a) The applicant shall submit a monitoring plan. The monitoring plan shall discuss the function and interrelationship of the requirements of §§ 236.324, 236.325 and 236.410 (relating to disposal unit monitoring; material performance monitoring; and environmental monitoring).

(b) The licensee shall have a contingency plan for taking remedial measures including recovery of waste if the disposal unit monitoring system or environmental monitoring system detects radioactive material which would indicate that

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the performance objectives of Subchapter A (relating to general provisions) may not be met. The plan shall identify the necessary training, management procedures and equipment required for corrective action.

(c) The plan shall specifically address monitoring during the preoperational, operational, closure and long term care periods.

(d) An offsite radiation measurement that exceeds the natural background, as established during preoperational environmental monitoring, shall be reported immediately to the Department and host municipality and county. Actions shall be initiated by the licensee to identify and abate the source of the offsite radiation that exceeds the natural background.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans); 25 Pa. Code § 236.208 (relating to specific technical information); and 25 Pa. Code § 236.413 (relating to buffer zone).

§ 236.410. Environmental monitoring.

(a) At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to establish background radiation levels and to provide basic environmental data on the site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry and seismology of the site. For those characteristics that are subject to seasonal variation, data shall cover at least a 12-month period.

(b) During disposal facility construction and operation, the licensee shall maintain an onsite and offsite environmental monitoring program. Measurements and observations shall be made and recorded to provide data to evaluate the potential health and environmental impacts from all significant pathways during the construction and the operation of the facility and to enable the evaluation of long term effects and the need for mitigating measures. The monitoring system shall be capable of providing early warning of releases of waste from the disposal units.

(c) After the disposal site is closed, the custodial agency responsible for postoperational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system shall be capable of providing early warning of releases of waste from the disposal units.

Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); and 25 Pa. Code § 236.409 (relating to monitoring plan).

§ 236.411. Site closure and decommissioning plan.

(a) The applicant shall submit a plan for closure and decommissioning. The plan shall describe:

(1) Closure, stabilization and monitoring of individual disposal units and their relationship to the final site closure and decommissioning plan.

(2) Methods and procedures that will be implemented to ensure that closed disposal units are not adversely affected by final site closure and decommissioning.

(3) A compatible approach for final closure, decommissioning and stabilization of the regional disposal facility.

(b) The site closure and decommissioning plan will be incorporated into the facility license and will be reviewed every 5 years or at the request of the Department.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans); and 25 Pa. Code § 236.208 (relating to specific technical information).

§ 236.412. Boundary locations.

The boundaries and locations of each disposal unit shall be accurately located and mapped by means of a land survey. Disposal units shall be marked so that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, shall be established on the site to facilitate surveys. The USGS or NGS control stations shall provide horizontal and vertical controls as checked against USGS or NGS record files.

§ 236.413. Buffer zone.

A buffer zone of land shall be maintained between disposed waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out monitoring activities specified in § 236.409 (relating to monitoring plan) and take remedial measures if needed.

§ 236.414. Radiation dose rates at the surface.

Waste shall be emplaced in a manner that limits the radiation dose rate at the surface of the engineered cover to levels that at a minimum will permit the licensee to comply with this chapter at the time the license is transferred under § 236.246 (relating to application and transfer of license to the Commonwealth).

§ 236.415. Postclosure observation and maintenance.

The licensee shall observe and monitor the disposal site, and carry out necessary maintenance and repairs until the site closure and decommissioning is complete and the license is transferred by the Department under § 236.246 (relating to application and transfer of license to the Commonwealth). Responsibility for postclosure observation and maintenance for the disposal site shall be maintained by the licensee for at least 5 years.

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§ 236.416. Institutional control.

(a) The Commonwealth's custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control from the disposal site operator. During the active institutional control period, the program shall include active methods for access control, surveillance, monitoring, custodial care and administration of funds to cover the costs for these activities.

(b) During the passive institutional control period, the program shall include passive access control, monitoring and administration of funds to cover the costs for these activities.

Subchapter F. WASTE CLASSIFICATION, WASTE CHARACTERISTICS, LABELING AND MANIFESTS

LOW-LEVEL RADIOACTIVE WASTE CLASSIFICATION SYSTEM

Sec.
236.501. Scope and considerations.
236.502. Classes of waste.
236.503. Waste classification.
236.504. Classification by long- and short-lived radionuclides.
236.505. Classification of wastes other than § 236.503.
236.506. Sum of fractions rule.
236.507. Determination of radionuclide concentrations in waste.
236.508. Determination of hazardous life of the waste.

LOW-LEVEL RADIOACTIVE WASTE CHARACTERISTICS

236.521. Minimum requirements for classes of waste.
236.522. Stability requirements for waste form.
236.523. Stabilization of liquid waste.
236.524. Minimization of void spaces within waste packages.

LABELING AND WASTE MANIFESTS

236.531. Labeling.
236.532. Waste manifest.
236.533. Generator requirements.
236.534. Carrier requirements.
236.535. Broker requirements.
236.536. Disposal facility operator requirements.
236.537. Nonacknowledgment.

Cross References

This subchapter cited in 25 Pa. Code § 236.225 (relating to requirements for issuance of a license); and 25 Pa. Code § 236.405 (relating to receipt and handling of waste).

LOW-LEVEL RADIOACTIVE WASTE CLASSIFICATION SYSTEM

§ 236.501. Scope and considerations.

Determination of the classification of waste involves the following considerations:

(1) Consideration shall be given to the concentration of long-lived radionuclides—and their short-lived precursors—whose potential hazard will persist long after precautions such as the active institutional control period and improved waste form have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. The magnitude of the potential dose is limited by the concentration and availability of the radionuclides at the time of exposure.

(2) Consideration shall be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form and disposal methods are effective.

§ 236.502. Classes of waste.

(a) Class A waste is a waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste shall meet the minimum requirements in § 236.521 (relating to minimum requirements for classes of waste). Class A waste shall also be emplaced in a disposal facility that meets the requirements in §§ 236.314 and 236.322 (relating to enhanced containment; and long term stability of disposal units).

(b) Class B waste is waste that meets more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste shall meet both the minimum and stability requirements in §§ 236.521 and 236.522 (relating to stability requirements for waste form). Class B waste shall also be emplaced in a disposal facility that meets the requirements in §§ 236.314 and 236.322. In addition, Class B waste requires protection against inadvertent intrusion, as set forth in § 236.320 (relating to protection from inadvertent intruders).

(c) Class C waste is waste that not only meets more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility including measures to protect against inadvertent intrusion. The physical form and characteristics of Class C waste shall meet both the minimum and stability requirements in §§ 236.521 and 236.522. Class C waste shall also be emplaced in a disposal facility that meets the requirements in §§ 236.314,

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236:320 and 236.322. In addition, Class C waste shall be disposed of in accordance with § 236.327 (relating to Class C waste).

§ 236.503. Waste classification.

(a) *Classification by long-lived radionuclides.* If the waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

(1) If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.

(2) If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.

(3) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for disposal.

(4) For waste containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined under § 236.506 (relating to sum of fractions rule).

Table 1

Radionuclide	Concentration (curies/cubic meter)*
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha-emitting radionuclides with half-life greater than 5 years except Uranium	100**
Pu-241	3,500**
Cm-242	20,000**
Ra-226	100**

*To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabequerels (GBq), multiply by 37.

**Units are nanocuries per gram.

(b) *Classification by short-lived radionuclides.* If the waste does not contain any radionuclide listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. If the waste does not contain a radionuclide listed in Table 1 or Table 2, it is Class A.

(1) If the concentration does not exceed the value in Table 2, Column 1, the waste is Class A.

(2) If the concentration exceeds the value in Table 2, Column 1, but does not exceed the value in Table 2, Column 2, the waste is Class B.

(3) If the concentration exceeds the value in Table 2, Column 2, but does not exceed the value in Table 2, Column 3, the waste is Class C.

(4) If the concentration exceeds the value in Table 2, Column 3, the waste is not generally acceptable for disposal.

(5) For waste containing mixtures of the radionuclides listed in Table 2 the total concentration shall be determined under § 236.506.

Table 2

Radionuclide	*Concentration (curies/cubic meter)*		
	Col. 1	Col. 2	Col. 3
Total of all radionuclides with less than 5-year half-life	700	**	**
H-3	40	**	**
Co-60	700	**	**
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7,000
Sr-90	0.04	150	7,000
Cs-137	1	44	4,600

To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabequerels (GBq), multiply by 37.

**There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table 1 determine the waste to be Class C independent of these radionuclides.

Cross References

This section cited in 25 Pa. Code § 236.504 (relating to classification by long- and short-lived radionuclides); 25 Pa. Code § 236.505 (relating to classification of wastes other than § 236.503); and 25 Pa. Code § 236.506 (relating to sum of fractions rule).

§ 236.504. Classification by long- and short-lived radionuclides.

If the waste contains a mixture of radionuclides, some of which are listed in Table 1 of § 236.503 (relating to waste classification) and some of which are listed in Table 2 of § 236.503 classification shall be determined as follows:

(1) If the concentration of a radionuclide listed in Table 1 of § 236.503 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of radionuclides listed in Table 2 of § 236.503.

(2) If the concentration of a radionuclide listed in Table 1 of § 236.503 exceeds 0.1 times the value listed in Table 1, but does not exceed the value in

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Table 1, the waste shall be Class C, if the concentration of radionuclides listed in Table 2 of § 236.503 does not exceed the value shown in Table 2, Column 3.

§ 236.505. Classification of wastes other than § 236.503.

If the waste does not contain a radionuclide listed in either Table 1 or Table 2 of § 236.503 (relating to waste classification), it is Class A waste.

§ 236.506. Sum of fractions rule.

For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits shall be taken from the same column of the same table. The sum of the fractions for the column shall be less than, or equal to, 1 if the waste class is to be determined by that column.

Example: A waste contains Sr-90 in a concentration of 50 Ci/m (1.85 TBq/m) and Cs-137 in a concentration of 22 Ci/m (814 GBq/m). Since the concentrations both exceed the values in Table 2 of § 236.503, Column 1, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = .5; the sum of the fractions = 0.83. Since the sum is less than 1, the waste is Class B.

Cross References

This section cited in 25 Pa. Code § 236.503 (relating to waste classification).

§ 236.507. Determination of radionuclide concentrations in waste.

The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured; or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocuries per gram.

§ 236.508. Determination of hazardous life of the waste.

The hazardous life of the waste is the amount of time that it takes for the disposed low-level radioactive waste to decay to levels so that it can be demonstrated that unrestricted use of the site would result in a dose to a member of the public using the site that is no greater than the dose from natural background radioactivity, in the soil, prior to the site being used for disposal.

Cross References

This section cited in 25 Pa. Code § 236.247 (relating to termination of license).

LOW-LEVEL RADIOACTIVE WASTE CHARACTERISTICS

§ 236.521. Minimum requirements for classes of waste.

The following are minimum requirements for classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site. The requirements are as follows:

(1) Waste shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. If the conditions of the site license are more restrictive than this chapter, the site license conditions shall govern.

(2) Waste may not be packaged for disposal in cardboard, wooden or fiberboard boxes.

(3) Liquid waste shall be solidified.

(4) Waste that has been dewatered shall contain as little free-standing liquid as is reasonably achievable, but the liquid may not exceed 1% of the volume.

(5) Waste may not be capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(6) Waste may not contain, or be capable of generating, quantities of toxic gases, vapors or fumes harmful to persons transporting, handling or disposing of the waste. This restriction does not apply to radioactive gaseous waste packaged under paragraph (8).

(7) Waste may not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared and packaged to be nonflammable.

(8) The Department will review on a case-by-case basis, requests for disposal of gaseous waste. Gaseous waste disposal is required to receive Department approval prior to disposal. Waste in gaseous form shall be packaged at a gauge pressure that does not exceed 1.5 atmospheres at 20°C. Total activity may not exceed 100 curies—3.7 TBq—per container.

(9) Waste containing hazardous, biological, pathogenic or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

Cross References

This section cited in 25 Pa. Code § 236.502 (relating to classes of waste); 25 Pa. Code § 236.523 (relating to stabilization of liquid waste); and 25 Pa. Code § 271.1 (relating to definitions).

§ 236.522. Stability requirements for waste form.

(a) The requirements of this section and §§ 236.523 and 236.524 (relating to stabilization of liquid waste; and minimization of void spaces within waste packages) are minimum requirements that are intended to provide stability of the

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waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse or other failure of the disposal unit. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(b) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture and microbial activity, and internal factors, such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form or placing the waste in a disposal container or structure that provides stability after disposal.

Cross References

This section cited in 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.523. Stabilization of liquid waste.

Notwithstanding § 236.521(3) and (4) (relating to minimum requirements for classes of waste), liquid waste or waste containing liquid, shall be converted into a form that contains as little freestanding liquid as is reasonably achievable. The liquid may not exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or .5% of the volume of the waste for waste processed to a stable form.

Cross References

This section cited in 25 Pa. Code § 236.522 (relating to stability requirements for waste form).

§ 236.524. Minimization of void spaces within waste packages.

Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

Cross References

This section cited in 25 Pa. Code § 236.522 (relating to stability requirements for waste form).

LABELING AND WASTE MANIFESTS

§ 236.531. Labeling.

A container of waste shall be clearly labeled to identify whether it is Class A, Class B or Class C Waste or mixed waste, under this subchapter.

§ 236.532. Waste manifest.

(a) A shipment of waste shall be accompanied by a shipment manifest that contains the name, address, telephone number and Department permit identifica-

tion number of the generator, the carrier who is to transport the waste and the broker who will manage the waste. The manifest may also designate alternate carriers or brokers.

(b) The manifest shall contain a physical description of the waste, the waste volume, radionuclide identity and quantity, the total radioactivity, the principal chemical form and the waste classification—for example, Class A, Class B, Class C or mixed waste in accordance with this chapter. Waste containing more than .1% chelating agents by weight shall be identified and the weight percentage of the chelating agent shall be identified. The manifest shall show the total quantity of the radionuclides H-3, C-14, Tc-99 and I-129.

(c) The manifest shall have a manifest identification number, and if the shipment contains hazardous waste, an EPA hazardous waste identification number.

(d) The waste manifest shall be on a form prepared by the Department. The information provided shall be sufficient to develop a waste data base and conduct performance assessment analyses.

(e) The manifest shall include a certification by the waste generator that the transported materials are properly classified, described, packaged, marked and labeled and are in proper condition for transportation according to 49 CFR Parts 170—179, 10 CFR Part 71 (relating to packaging and transportation of radioactive material) and this title. The certification shall acknowledge that the signer is subject to penalties for violation of the law. The manifest shall be signed and dated by an authorized representative of the generator.

Cross References

This section cited in 25 Pa. Code § 236.534 (relating to carrier requirements).

§ 236.533. Generator requirements.

A generator who transfers waste to the disposal facility or a broker shall:

(1) Prepare waste so that the waste is classified and characterized under this chapter.

(2) Conduct a quality assurance/quality control program approved by the Department to assure compliance with this subchapter. The program shall include management evaluation of audits.

(3) Prepare a complete manifest. The manifest shall contain the number of copies which will provide the generator, carriers, brokers and the disposal facility with one copy for their records and copies to be returned to the generator and to be forwarded to the disposal facility and the Department.

(4) Obtain the handwritten signature of the initial carrier and date of acceptance on the manifest.

(5) Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer.

(6) Forward a copy of the manifest to the disposal facility and another copy to the Department.

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(7) Give the carrier the remaining copies of the manifest.

(8) Conduct an investigation under § 236.537 (relating to nonacknowledgment), for a shipment or part of a shipment for which acknowledgment of receipt has not been received within the time set forth in § 236.537.

Cross References

This section cited in 25 Pa. Code § 236.535 (relating to broker requirements).

§ 236.534. Carrier requirements.

(a) No carrier may accept waste from a generator or broker unless it is accompanied by and conforms with a complete and valid manifest under § 236.532 (relating to waste manifest).

(b) Before transporting waste, a carrier shall sign and date the manifest acknowledging acceptance of the waste from the generator or broker before leaving the generator's or broker's property.

(c) The carrier shall ensure that the manifest accompanies the waste, and shall deliver it to the carrier, broker or regional facility, as designated on the manifest. The carrier shall contact the generator or broker who delivered the waste to him for further instructions, and shall revise the manifest in accordance with instructions written and signed by the generator or broker. Upon making the designated delivery, the carrier shall:

(1) Obtain a date of delivery and handwritten signature of the carrier, broker or regional facility operator.

(2) Retain a copy of the manifest.

(3) Forward a copy of the manifest to the Department.

(4) Give the remaining copies of the manifest to the regional facility operator or the broker.

(5) Retain the copies of the manifest signed by the person who delivered the waste to him, by himself and by the person receiving the waste from him for a period of 3 years.

(d) The carrier shall certify that nothing has been done to the waste which would invalidate the generator's or broker's certification.

§ 236.535. Broker requirements.

(a) No broker may receive waste from a generator, carrier or broker unless that waste is accompanied by a complete and valid manifest.

(b) The broker receiving waste shall:

(1) Sign and date each copy of the manifest to certify that the waste was received.

(2) Note in the manifest discrepancies between materials listed on the manifest and materials received. The broker shall also attempt to resolve discrepancies with the generator, carrier or broker. If the broker is unable to

resolve the discrepancies within 15 days of receiving the waste, he shall notify the Department in writing, and include a copy of the manifest with the letter.

(3) Give the carrier delivering the waste a copy of the signed manifest.

(4) Notify the generator that the waste has been received.

(5) Obtain the handwritten signature of the next carrier as designated on the manifest and date of acceptance.

(6) Retain a copy of the manifest with documentation of acknowledgment of receipt as a record of transfer for a period of 3 years.

(7) Forward a copy of the manifest to the disposal facility and another copy to the Department.

(8) Give the carrier the remaining copies of the manifest.

(9) Retain the copies of the manifest signed by the person receiving the waste from him for a period of 3 years.

(10) Conduct an investigation under § 236.537 (relating to non-acknowledgment), for a shipment or part of a shipment for which acknowledgment of receipt has not been received within the time set forth in § 236.537.

(c) If the broker repackages, processes, incinerates, solidifies, treats, evaporates or performs another process which results in the generation of a new waste or waste form, the broker shall comply with the generator requirements of § 236.533 (relating to generator requirements), including preparation and implementation of a quality assurance/quality control program, waste preparation and preparation of a new manifest. If the broker consolidates prepackaged waste into one shipment but does not generate a new waste or waste form, he may prepare a new manifest under § 236.533, or he may combine the several manifests of the consolidated shipments.

§ 236.536. Disposal facility operator requirements.

(a) The disposal facility operator may not receive waste from a generator, broker or carrier unless it is accompanied by a complete and valid manifest.

(b) The disposal facility operator shall:

(1) Sign and date the manifest to certify that the waste was received.

(2) Note in the manifest discrepancies between materials listed on the manifest and materials received. The operator shall also attempt to resolve any discrepancies with the operator generator, carrier or broker. If the disposal operator is unable to find an explanation for the discrepancies within 15 days of receiving the waste, the operator shall notify the Department in writing, explaining the discrepancies and attempts to resolve them, and include a copy of the manifest with the letter.

(3) Give the carrier delivering the waste a copy of the signed manifest.

(4) Notify the generator and broker within 15 days of its receipt.

(5) Retain the copies of completed manifests until the license is transferred to the custodial agency. During license transfer, the disposal facility operator

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shall transfer the manifests to the custodial agency. The custodial agency shall maintain copies of the manifest until the license is terminated.

Cross References

This section cited in 25 Pa. Code § 236.401 (relating to scope and purpose).

§ 236.537. Nonacknowledgment.

A generator or broker who has not received acknowledgment of receipt of the waste shipment from the next broker or the regional facility operator within 15 days of delivery shall immediately investigate why the shipment has not been received by the person so designated on the manifest. If the generator or broker is unable to locate the shipment, he shall prepare a report on the investigation conducted and shall file the report with the Department within 2 weeks after completion of the investigation.

Cross References

This section cited in 25 Pa. Code § 236.533 (relating to generator requirements); and 25 Pa. Code § 236.535 (relating to broker requirements).

Subchapter G. FINANCIAL ASSURANCES AND LIABILITY

Sec.
236.601. Scope.
236.602. Applicant qualifications and assurance.
236.603. Assurance for onsite cleanup during operation.
236.604. Assurance for liability during operation.
236.605. Funding for site closure and decommissioning.
236.606. Assurance for long term care.
236.607. Assurance for liability following site closure.

Cross References

This subchapter cited in 25 Pa. Code § 236.211 (relating to financial information); and 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.601. Scope.

The applicant is required to demonstrate, prior to receipt of a license, that funds are available to cover costs for all phases of the facility life. The applicant is provided with several examples of financial or surety arrangements that are acceptable for demonstrating that the necessary funds are available.

§ 236.602. Applicant qualifications and assurance.

Prior to the issuance of a license the applicant shall show to the satisfaction of the Department that the applicant has or can reasonably expect to have necessary

funds to cover the estimated costs of conducting licensed activities over the planned operating life of the project, including costs for construction, operation, closure, postclosure monitoring and emergencies related to the disposal facility.

§ 236.603. Assurance for onsite cleanup during operation.

(a) Prior to receipt of a license, and annually thereafter, the applicant shall provide assurances to the satisfaction of the Department that sufficient funds are available to cover emergency actions necessary to prevent the unpermitted release of radioactive material to the general environment. See §§ 236.13 and 236.15 (relating to protection of the general population and environment from releases of radioactivity; and protection of individuals during operations). In determining the cost of taking emergency actions, the applicant shall provide to the Department any information requested by the Department related to the management, transportation and disposal of low-level radioactivity waste.

(b) The Department will consider factors that may affect the cost of taking emergency actions. The factors include site and waste characteristics, facility design and operating procedures. Based on consideration of the factors, the Department will determine an amount necessary for compliance with the financial assurance requirements of this section. Its determination will include consideration of costs incurred if an independent contractor were hired to perform the work.

(c) Compliance with the financial assurance requirements of this section does not affect the licensee's duty to take emergency actions or have available funds that may be necessary to enable the licensee to take required emergency actions.

(d) Subject to the approval of the Department, the applicant may use financial assurance, insurance or surety arrangements or a combination of arrangements to meet the financial assurance requirements of this section.

§ 236.604. Assurance for liability during operation.

(a) Prior to accepting waste, the licensee shall have in effect insurance or other financial assurance approved by the Department to compensate persons for bodily injury or property damage from sudden or nonsudden incidents arising from the operation of the facility.

(b) In approving the licensee's insurance or other financial assurance, the Department will consider factors that may affect the licensee's potential exposure to liability. The factors include site and waste characteristics, facility design, operating procedures, population within 3 miles of the facility and industrial, commercial or other economic activity within 3 miles of the site.

(c) In approving the licensee's insurance or other financial assurance the Department will consider the licensee's potential exposure to liability as a result of claims for bodily injury or property damage brought against the licensee; and the licensee's duty to defend and indemnify the Commonwealth, the host munici-

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pality, the host county and their agents and employes against claims, actions, demands, liabilities and losses at law and equity.

(d) Based on consideration of the factors described in subsections (b) and (c), the Department will determine an amount initially sufficient for providing liability coverage in compliance with this section. The amount determined may not be less than the capital cost of bidding for, siting, acquiring, licensing, planning, developing and constructing the facility.

(e) After commencement of operation, the licensee shall annually provide to the Department information the Department deems necessary for its consideration in determining additional amounts of liability coverage necessary to meet the requirements of the act and this chapter. In determining the additional amounts of liability coverage required, the Department will consider the factors identified in subsections (b) and (c).

(f) The determination and approval by the Department of amounts or types of financial assurance under this section does not affect the licensee's liability or the duty of the licensee to have available funds that may be necessary to satisfy the liability.

(g) Subject to the approval of the Department, the licensee may use an insurance, financial or surety arrangement or combination of arrangements to provide the assurances required by this section. The licensee may provide evidence of commercial insurance, alone or in combination with other acceptable financial or surety arrangements, to satisfy the requirements of this section.

(h) Evidence of commercial insurance shall include the insurer's policy, including endorsements thereto, evidencing the liability insurance coverage it intends to issue covering the facility for third party claims for bodily injury and property damage caused by sudden incidents or nonsudden incidents arising from the operation of the facility.

(i) A commercial insurance policy offered to comply with the requirement for compensation of third parties for bodily injury and property damage caused by sudden or nonsudden incidents arising from the operation of the facility shall contain the following provisions:

(1) Bankruptcy or insolvency of the insured does not relieve the insurer of its obligations under the policy.

(2) The insurer is liable for the payment of any amount within a deductible which may apply to the policy, with a right of reimbursement by the insured or, in the alternative, the insurer includes, within the policy, a provision to pay on behalf of the insured a deductible amount.

(3) The beginning and ending dates, including tail periods, for the policy.

(4) The insurer will give at least 90 days notice to the Department and the insured before cancellation, termination or expiration of the policy, if upon expiration, the policy will not be renewed.

(5) The policy may not be cancelled by anyone before the expiration of the 90-day notice period.

(j) The insurance policy shall be issued by a primary insurer or coinsurers licensed or authorized to do business in this Commonwealth or designated by the Insurance Commissioner as an eligible surplus lines insurer. The primary insurer may reinsure the insurance policy with secondary insurers—reinsurers—who are licensed or authorized to do business in Canada, West Germany, Switzerland, France, or a state of the United States.

(k) The primary insurer may be a commercial insurer, a captive insurer—subject to subsection (j)—or a risk retention group as defined in the Product Liability Risk Retention Act of 1981 (15 U.S.C.A. §§ 3901—3906) as amended by the Liability Risk Retention Act of 1986 (15 U.S.C.A. §§ 3901—3903).

(l) The policy shall provide that the insurer will adhere to the insurance law of the Commonwealth regarding settlement of claims and will be bound by the Unfair Insurance Practices Act (40 P. S. §§ 1171.1—1171.15).

(m) The insurance policy shall follow the comprehensive general liability policy forms approved by the Insurance Department and shall include coverage for environmental impairment liability.

§ 236.605. Funding for site closure and decommissioning.

(a) The applicant shall provide assurances prior to the receipt of a license that sufficient funds are available to carry out disposal site closure and decommissioning, including decontamination or dismantlement of structures. The applicant shall also provide assurances regarding closure and stabilization of the disposal site so that following transfer of the disposal site to this Commonwealth, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance and monitoring are required. These assurances shall be based on cost estimates submitted by the applicant and which reflect the Department approved plan for disposal site closure and decommissioning. The applicant's cost estimates shall take into account the total costs that would be incurred if an independent contractor were hired to perform the closure and decommissioning work.

(b) The licensee's financial or surety arrangement shall be submitted as part of the application, and annually thereafter, for review by the Department to assure that sufficient funds will be available for completion of the closure and decommissioning plan.

(c) The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and decommissioning. Factors affecting closure and decommissioning cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that has already been accomplished, and other conditions affecting costs. The financial or surety arrangement shall be sufficient to cover the costs of closure and decommissioning of the disposal units that are expected to be used before the next 5 year review period.

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(d) The surety arrangement shall be written for a specified period of time, shall name the Department as the obligee and shall be automatically renewable unless the surety notifies the Department, and the principal—the licensee—at least 90 days prior to the renewal date, of its intention not to renew. In this situation, the licensee shall submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Department within 30 days before the cancellation becomes effective, the failure constitutes grounds for forfeiture of the surety.

(e) Surety bonds will only be acceptable if issued by a surety authorized to do business in this Commonwealth. If the principal place of business of a surety is outside of this Commonwealth the surety bond shall be signed by an authorized Commonwealth resident agent of the surety.

(f) Proof of the licensee's failure to replace the surety is not necessary for the Department to exercise its right of default. The right of the Department to declare a default because of the licensee's failure to replace the surety shall be a condition of the obligation.

(g) Financial or surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposit, government securities rated at least BBB by Standard and Poor or Baa by Moody's Investor Services, trust accounts, irrevocable stand-by letters of credit, trust funds and combinations thereof or other types of arrangements that may be approved by the Department. Self-insurance, or an arrangement which essentially constitutes self-insurance, does not satisfy the financial or surety requirements as they apply to private-sector applicants.

(h) The licensee's financial or surety arrangement shall remain in effect until the closure and decommissioning program has been completed and approved by the Department, and the license has been transferred to the Commonwealth Custodial Agency.

§ 236.606. Assurance for long term care.

Prior to the issuance of the license, the applicant shall provide for the approval of the Department, an agreement between the applicant and the Commonwealth that binds the applicant to ensuring that funds will be collected by the applicant and transferred to the Commonwealth for the purpose of covering the costs of monitoring and required remedial action during the long term care period. The Department will review on an annual basis, funds collected by the operator and paid to the Commonwealth to ensure sufficient funds will be available to provide for long term care.

§ 236.607. Assurance for liability following site closure.

(a) Upon receipt of a license the operator shall collect and transfer to the Commonwealth, at least monthly, funds for paying liability claims against the site operator, Commonwealth, host municipality and host county.

(b) The Department will assure that surcharges levied for deposit into the Protection Fund are adequate to establish a fund of at least $100 million indexed to increase with cost of living adjustments, upon the date of termination of the operator's license.

(c) The Protection Fund shall be used to pay liability claims, including personal injury or property damage, as follows:

(1) Against the Commonwealth, host municipality and host county arising from their responsibilities under the act.

(2) Against the regional facility licensee after the termination of the license and which arose from the operation of the regional facility during the term of the license.

(d) The Department will review the Protection Fund annually to ensure sufficient funds will be available to meet the requirements of subsection (a).

Subchapter H. INSPECTIONS, TESTS AND RECORDS

Sec.
236.701. Inspection of the regional disposal facility.
236.702. Inspection of records.
236.703. Penalties.
236.704. Enforcement and abatement.
236.705. Tests of the regional disposal facility.
236.706. Maintenance of records.
236.707. Recording receipt of waste shipments.
236.708. Submittal of reports to the Department.
236.709. Transfer of records.
236.710. Submittal of reports by generators and brokers.

§ 236.701. Inspection of the regional disposal facility.

The licensee shall provide the Department, its agents and employes, and the host municipality and host county inspectors, with immediate access to inspect the following for the purpose of determining compliance with the license conditions and applicable regulations and laws:

(1) Waste not yet disposed.

(2) Premises, equipment, operations and facilities in which wastes are received, possessed, handled, treated, stored or disposed.

§ 236.702. Inspection of records.

The licensee shall make available for inspection to the Department, its agents and employes, and the host municipality and host county inspectors records kept by it under this chapter. Authorized representatives of the Department, the host municipality or host county inspectors may copy and use any record required to be kept under this chapter.

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§ 236.703. Penalties.

(a) A person who violates the act, this chapter or an order promulgated or issued under the act commits a summary offense and will, upon conviction, be sentenced to pay a fine of at least $100 but not more than $1,000 for each offense. Default of the fine payment will result in a prison term of a maximum of 90 days.

(b) A person who violates the act, this chapter, a license condition or an order promulgated or issued under the act, within 2 years of having been convicted of a summary offense under the act, commits a misdemeanor of the third degree and will, upon conviction, be sentenced to pay a fine of at least $1,000 but not more than $25,000 for each offense or a maximum prison term of 1 year, or both.

(c) A person who intentionally violates the act or this chapter, an order, permit condition or license condition of the Department under the act and whose action causes the possibility of a public nuisance or bodily harm to a person commits a felony of the second degree and shall, upon conviction, be sentenced to pay a fine of at least $2,500 but not more than $100,000 for each offense per day for each violation or be subject to a prison term of at least 1 year but not more than 10 years, or both.

(d) Each day of continued violation of the act or this chapter, an order, permit condition or license condition of the Department issued under the act shall constitute a separate offense.

(e) In addition to subsections (a)—(d) or in equity for a violation of the act or this chapter, an order, permit condition or license condition of the Department issued under the act, the Department may assess a civil penalty. The civil penalty will not exceed $25,000 for each violation.

(f) Civil payments shall be paid under section 504(e) of the act (35 P. S. § 7130.504(e)).

§ 236.704. Enforcement and abatement.

(a) A violation of section 505 of the act (35 P. S. § 7130.505) or this chapter, an order, permit condition or license condition of the Department issued under the act constitutes a public nuisance. A person committing the violation shall be liable for the costs of abatement of the nuisance. The Environmental Hearing Board has jurisdiction over actions to recover costs of the abatement and civil penalties.

(b) The Department may issue orders, injunctions, declarations of emergency or take other actions as specified in section 505 of the act to abate a public nuisance or protect public health and safety and the environment.

§ 236.705. Tests of the regional disposal facility.

The licensee shall perform or permit the Department, its agents and employes, and the host municipality and host county inspectors to perform tests it deems appropriate or necessary for the administration of this chapter, including, but not limited to, tests of:

(1) Waste.

(2) Facilities used for the receipt, storage, treatment, handling or disposal of waste.

(3) Radiation detection and monitoring instruments.

(4) Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage or disposal of waste.

§ 236.706. Maintenance of records.

(a) The licensee shall maintain records and make reports in connection with the licensed activities as may be required by the conditions of the license or by this chapter and orders of the Department.

(b) Records which are required by this chapter or by license conditions shall be maintained for a period specified by this chapter or by license condition. If a retention period is not otherwise specified, the records shall be maintained and transferred to the officials specified in § 236.709 (relating to transfer of records) as a condition of license transfer unless the Department otherwise authorizes their disposition.

(c) Records which shall be maintained under this subchapter may be the original or a reproduced copy of microfilm if the reproduced copy of microfilm is capable of producing a copy that is clear and legible at the end of the required retention period.

Cross References

This section cited in 25 Pa. Code § 236.709 (relating to transfer of records).

§ 236.707. Recording receipt of waste shipments.

Following receipt and acceptance of a shipment of waste, the licensee shall record the date of disposal of the waste, the location in the disposal unit, the condition of the waste packages as received, discrepancies between materials listed on the manifest and those received and evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified by United States Department of Transportation and this title. The licensee shall briefly describe repackaging operations of the waste packages included in the shipment, plus other information required by the Department as a license condition.

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§ 236.708. Submittal of reports to the Department.

(a) *Annual reports.* The licensed disposal facility operator shall file a copy of its financial report or a certified financial statement annually with the Department in order to update the information base for determining financial qualifications.

(b) *Quarterly reports.*

(1) The licensed disposal facility operator shall submit its quarterly report to the Department, host municipality, host county, Low-Level Waste Advisory Committee and the public. The report shall include:

(i) Specification of the quantity of principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding quarter.

(ii) The results of the monitoring program.

(iii) A summary of licensee disposal unit survey and maintenance activities.

(iv) A summary, by waste class, of activities and quantities of radionuclides disposed of.

(v) Instances in which observed site characteristics were significantly different from those described in the application for a license.

(vi) Other information the Department may require.

(2) If the quantities of waste released during the reporting period, monitoring results or maintenance performed are significantly different from those predicted, the report shall cover this specifically.

§ 236.709. Transfer of records.

Notwithstanding § 236.706 (relating to maintenance of records), copies of records of the location and the quantity of wastes contained at the disposal site shall be provided, upon license transfer to the Commonwealth Custodial Agency, to:

(1) The chief executive of the host municipality.

(2) The chief executive of the host county.

(3) The host county zoning board or land development and planning agency.

(4) The Governor.

(5) Other State, local and Federal government agencies as designated by the Department at the time of license transfer.

Cross References

This section cited in 25 Pa. Code § 236.706 (relating to maintenance of records).

§ 236.710. Submittal of reports by generators and brokers.

Generators and brokers shall submit, on a quarterly basis, reports to the Department. The reports shall include a listing of the quantities, types and classes of low-level radioactive waste generated during the previous quarter.

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CHAPTER 237. REBUTTABLE PRESUMPTION OF LIABILITY OF THE OPERATOR OF THE REGIONAL LOW-LEVEL WASTE FACILITY

Subch.		Sec.
A.	GENERAL PROVISIONS	237.1
B.	LIABILITY OF THE OPERATOR	237.101

Authority

The provisions of this Chapter 237 issued under the Low-Level Radioactive Waste Disposal Regional Facility Act (35 P. S. §§ 7130.101—7130.703); the Radiation Protection Act (35 P. S. §§ 7110.101—7110.504); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 237 adopted October 15, 1993, effective October 16, 1993, 23 Pa.B. 4885, unless otherwise noted.

Subchapter A. GENERAL PROVISIONS

Sec.
237.1. Scope.
237.2. Definitions.

GENERAL

§ 237.1. Scope.

(a) This chapter addresses the rebuttable presumption of liability of the operator of a regional low-level radioactive waste disposal facility for all damages and radioactive contamination within 3 miles of the regional facility boundary. This chapter establishes terms, conditions and criteria for the implementation of section 319 of the act (35 P. S. § 7130.319).

(b) The presumption of liability of the regional facility operator applies only to civil and administrative proceedings initiated under the act to the extent the actions provide for recovery for damages, the abatement of radioactive contamination or the replacement of a contaminated water supply. The presumption of liability may be invoked by the Department, county and municipal officials and by private citizens instituting the legal actions under the act.

(c) The regional facility operator may not engage in an activity, operation or process prohibited by the act.

§ 237.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Act—The Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

Contributes to the damage—A causal connection between the damage to a person or property and regional facility operations.

Damages—A pecuniary compensation or indemnity which may be recovered under the act in a court of competent jurisdiction by a person who has actually sustained a loss, detriment or injury, whether to one's person or property, real or personal, associated with exposure to radioactive material.

Operator—A person who operates a regional facility.

Person—An individual, corporation, partnership, association, public or private institution, cooperative enterprise, municipal authority, public utility, trust, estate, group, Federal Government or agency, State institution or agency or another legal entity which is recognized by law as the subject of rights and duties. The term also includes officers and directors of a corporation or another legal entity having officers and directors.

Preoperational survey—The results of sampling, monitoring and data analysis to assess the presence of radioactive material in air, soil, surface water, groundwater, drinking water supply, buildings or other structures, performed by the operator-licensee designate prior to the acceptance of waste at the regional facility. The term also includes other appropriate measures performed by the operator of the regional facility to assess environmental radiation, birth defects, cancer and other disease rates within 5 miles of the regional facility prior to the acceptance of waste.

Radioactive contamination—The deposition of radioactive material into the air, soil, surface water, groundwater, drinking water supply, equipment, buildings or other structures, or on a person in concentrations or mixtures, or both, that exceed background radiation measurements established during preoperational environmental or health surveys.

Radioactive material—A material which spontaneously emits alpha, beta or gamma radiation, X-rays, neutrons, protons, high energy electrons or other atomic particles.

Rebuttable presumption—A presumption that can be overcome upon an affirmative showing of clear and convincing evidence.

Regional facility—A facility which has been approved by the Appalachian States Low-Level Radioactive Waste Commission and licensed under the act. The term includes "disposal facility" and "facility site" as defined in § 236.2 (relating to definitions).

Regional facility boundary—The outer limits of the licensed disposal site established by land survey.

Regional facility operations—Activities, operations or processes conducted within the regional facility boundary which are attributable to the receipt, handling, management, storage or disposal of low-level radioactive waste.

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Subchapter B. LIABILITY OF THE OPERATOR

Sec.
237.101. Presumption of liability.
237.102. Defenses to overcome the presumption.

§ 237.101. Presumption of liability.

It is a rebuttable presumption of law that the regional facility operator is liable and responsible for all damages and radioactive contamination within 3 miles of the regional facility boundary without proof of fault, negligence or causation.

§ 237.102. Defenses to overcome the presumption.

(a) *Damages.* To rebut the presumption of liability for damages, the regional facility operator shall affirmatively prove, by clear and convincing evidence, that the operator did not contribute to the damage.

(b) *Radioactive contamination.* To rebut the presumption of liability for radioactive contamination within 3 miles of the boundary of the regional facility, the regional facility operator shall prove, by clear and convincing evidence, one of the following three defenses:

(1) The radioactive contamination existed prior to disposal operations on the site of the regional facility as determined by a preoperational survey.

(2) The landowner has refused to allow the regional facility operator access to the landowner's property to conduct a preoperational survey.

(3) The radioactive contamination occurred as a result of some cause other than regional facility operations.

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CHAPTER 240. RADON CERTIFICATION

Subchap.		Sec.
A.	GENERAL PROVISIONS	240.1
B.	CERTIFICATION	240.101
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D.	OPERATION REQUIREMENTS	240.301
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Authority

The provisions of this Chapter 240 issued under sections 12 and 13 of the Radon Certification Act (63 P. S. §§ 2012 and 2013); section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 240 adopted January 18, 1991, effective January 19, 1991, 21 Pa.B. 317, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications).

Subchapter A. GENERAL PROVISIONS

GENERAL

Sec.
240.1. Description of regulatory structure.
240.2. Scope.
240.3. Definitions.

GENERAL

§ 240.1. Description of regulatory structure.

(a) The act directs the Department to establish a Radon Certification Program. This chapter specifies the requirements to certify a person to test for and mitigate radon contamination of occupied buildings and to analyze radon samples. Persons exempt from certification are specified in § 240.2 (relating to scope).

(b) Subchapter B (relating to certification) specifies the requirement that a person shall be certified to conduct radon testing, and the requirements for obtaining certification. Subchapter B also contains the requirements for certification in mitigation and laboratory analysis.

(c) Subchapter C (relating to certification review procedures and standards) provides the standards and procedures for review of applications, renewal and modification of certification.

(d) Subchapter D (relating to operation requirements) contains operation requirements for certified persons who conduct radon-related activities. Subchap-

ter D includes the requirements concerning advertising, notice to clients and disclosure of radon information to the Department. These operation requirements are in addition to specific requirements contained in a certification.

(e) Subchapter E (relating to enforcement and decertification) contains the enforcement provisions, including inspection, decertification and assessment of civil penalties. Other enforcement actions are available under sections 308 and 309 of the Radiation Protection Act (35 P. S. §§ 7110.308 and 7110.309) and section 14 of the act (63 P. S. § 2014).

(f) Subchapter F (relating to interim certification) specifies the requirements for persons certified under the Department's Interim Certification Program.

(g) This section is for descriptive purposes only. This section does not limit the authority of the Department under the acts or this chapter.

§ 240.2. Scope.

(a) This chapter applies to all persons except a person:

(1) Testing for or mitigating against radon contamination in a building that the person owns or occupies.

(2) Using measures designed to prevent radon contamination in newly constructed buildings. This exemption does not apply to radon testing or installation of radon mitigating devices in these buildings following occupancy.

(3) Performing testing or mitigation in the course of the person's normal duties as an employee or contractor of the Department or the Federal government.

(4) Performing scientific research if the person discloses the information obtained to the Department under § 240.303 (relating to reporting of information) and the person informs the owner or occupant of the affected building of the following:

(i) That the person is not certified by the Department to test for or mitigate against radon contamination.

(ii) That the test results are not certified.

(iii) That the mitigation methods are for experimental purposes and may be unsuccessful.

(5) Purveying, but not placing, or retrieving passive radon testing devices, such as charcoal canisters or track etch monitors supplied by a certified laboratory, if radon concentrations determined by the laboratory are reported directly to the owner or occupier of the building tested.

(b) This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

Authority

The provisions of this § 240.2 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

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Source

The provisions of this § 240.2 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (204016).

Cross References

This section cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.3. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

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Act—The Radon Certification Act (63 P. S. §§ 2001—2014).

Acts—The Radon Certification Act and the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703).

Firm—A person, other than an individual.

Laboratory analysis—The act of determining radon concentrations in air, water, soil or passive radon testing devices.

Mitigate—To repair or alter a building or building design for the purpose in whole or in part of reducing the concentration of radon in the indoor atmosphere.

Person—An individual, corporation, partnership, association, trust, estate, public or private institution, group, agency or political subdivision of this Commonwealth, another state or political subdivision or agency thereof, and a legal successor, representative, agency or agency of the entities listed in this definition.

Picocurie per liter—2.2 disintegrations per minute of radioactive material per liter of air.

Radon—The radioactive noble gas Radon-222 and the short-lived radionuclides which are products of Radon-222 decay, including polonium-218, lead-214, bismuth-214 and polonium-214.

Test—The act of examining a building, soil, air or water for the presence of radon, including taking air, soil or water samples, or the act of diagnosing the cause of radon contamination in a building.

WL—working level—One working level is that amount of potential alpha-particle energy dissipated in air by the short-lived daughters in equilibrium with 100 pCi/l of Radon-222. One WL is equal to 130,000 Mev of alpha-particle energy deposited per liter of air.

Subchapter B. CERTIFICATION

CERTIFICATION FOR RADON TESTING

Sec.
240.101. Requirement for radon testing certification.
240.102. Prerequisites for radon testing certification.
240.103. Radon testing application contents.
240.104. Application filing deadline.

CERTIFICATION FOR RADON MITIGATION

240.111. Requirement for radon mitigation certification.
240.112. Prerequisites for radon mitigation certification.
240.113. Radon mitigation application contents.

240.114. Application filing deadline.

CERTIFICATION FOR RADON LABORATORY

240.121. Requirement for radon laboratory certification.
240.122. Prerequisites for radon laboratory certification.
240.123. Radon laboratory application contents.
240.124. Application filing deadline.

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

240.131. States with reciprocal agreements with the Commonwealth.
240.132. Limited radon practice in this Commonwealth.
240.133. Certification application contents.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

CERTIFICATION FOR RADON TESTING

§ 240.101. Requirement for radon testing certification.

A person may not test for radon or represent or advertise that he may so test in a building or building lot in this Commonwealth, unless the person has first applied for and obtained certification to test. For a firm to perform radon testing it shall employ at least one person certified to test, and the firm shall submit an application for certification. Not everyone within the firm is required to be certified to test. An individual performing testing and not working for a certified radon testing firm shall obtain radon testing certification prior to performing testing. A person using passive radon monitors, such as charcoal canisters, from a certified radon laboratory does not also have to become certified in radon laboratory analysis.

§ 240.102. Prerequisites for radon testing certification.

(a) *Individual certification for radon testing.* An individual will not be certified to test unless the individual has done the following:

(1) Taken a Department-approved course on radon.

(2) Taken and passed a Department-approved written exam on radon testing. The applicant shall forward an official copy of exam results to the Department.

(3) Had 1 year of professional experience in performing radon measurements.

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(4) Submitted a complete and accurate application to the Department, including applicable fees.

(b) *Firm certification for radon testing.* If the applicant for testing certification is a firm, it shall employ at least one individual who is certified to test and who is in responsible charge of the firm's testing activities. If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.

(c) *Additional requirements.* If the applicant for testing certification is a firm, or an individual performing testing and not working for a certified radon testing firm, the applicant shall also have a quality assurance program, a health and safety program and a continuing education program as required in §§ 240.304—240.307. In addition, the applicant shall be successfully enrolled in the EPA radon measurement proficiency program or equivalent, as required in §§ 240.304—240.307.

Cross References

This section cited in 25 Pa. Code § 240.103 (relating to radon testing application contents).

§ 240.103. Radon testing application contents.

An application for radon testing certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and shall contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.102 (relating to prerequisites for radon testing certification), including the services offered and experience in each. If the applicant is a firm, the application shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of $200 for individuals, $500 for firms.

(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Copies of reporting forms, information distributed to potential clients and recent advertisements.

(6) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon testing.

(7) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief, attested by a notary public or district justice.

§ 240.104. Application filing deadline.

A person who expects to conduct radon testing shall file a complete application for certification a minimum of 30 days prior to the anticipated starting date of testing activity.

CERTIFICATION FOR RADON MITIGATION

§ 240.111. Requirement for radon mitigation certification.

A person may not mitigate radon contamination in a building or represent or advertise that he may so mitigate in a building or building lot in this Commonwealth, unless the person has first applied for and obtained certification to mitigate. For a firm to perform radon mitigation it shall employ at least one person certified to mitigate, and the firm shall submit an application for certification. Not everyone within the firm is required to be certified to mitigate. An individual performing mitigation and not working for a certified radon mitigation firm shall obtain radon mitigation certification prior to performing mitigation of radon contamination.

§ 240.112. Prerequisites for radon mitigation certification.

(a) *Individual certification for radon mitigation.* An individual will not be certified to mitigate unless he has done the following:

(1) Taken a Department-approved course on radon mitigation.

(2) Taken and passed a Department-approved written exam on radon mitigation. The applicant shall forward an official copy of exam results to the Department.

(3) Had 1 year professional experience or supervised experience in radon mitigation system installation or 3 years experience in architecture, engineering, electrical contracting, plumbing, carpentry, masonry or related trades.

(4) Submitted a complete and accurate application to the Department including applicable fees.

(b) *Firm certification for radon mitigation.* If the applicant for mitigation certification is a firm, it shall employ at least one individual who is certified to mitigate and who is in responsible charge of the firm's mitigation activities. If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.

(c) *Additional requirements.* If the applicant for mitigation certification is a firm, or an individual performing mitigation and not working for a certified miti-

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gation firm, he shall also have a health and safety program, and a continuing education program, as required in §§ 240.305 and 240.306 (relating to health and safety program; and continuing education program).

Cross References

This section cited in 25 Pa. Code § 240.113 (relating to radon mitigation application contents).

§ 240.113. Radon mitigation application contents.

An application for mitigation certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and shall contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.112 (relating to prerequisites for radon mitigation certification), including the services offered and experience in each. If the applicant is a firm, the applicant shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of $200 for individuals, $500 for firms.

(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon mitigation.

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief, attested by a notary public or district justice.

§ 240.114. Application filing deadline.

A person who anticipates conducting radon mitigation services shall file a complete application for certification a minimum of 30 days prior to the anticipated starting date of mitigation activities.

CERTIFICATION FOR RADON LABORATORY

§ 240.121. Requirement for radon laboratory certification.

A person may not perform laboratory analysis or represent or advertise that he may perform laboratory analysis of radon testing devices supplied to the public

or of samples or devices received from the public or from other certified persons, unless that person has obtained radon laboratory analysis certification from the Department.

§ 240.122. Prerequisites for radon laboratory certification.

(a) *Individual certification for laboratory analysis.* A person will not be certified to perform radon laboratory analysis unless the person has done the following:

(1) Taken a Department-approved course on radon.

(2) Had 1 year professional experience in performing laboratory analysis of radon measurement devices or samples or is certified in Health Physics by the American Board of Health Physics.

(3) Received a bachelors degree in the physical sciences or engineering or related fields as approved by the Department, or the education or professional work experience equivalent to a degree, as determined by the Department.

(4) Submitted a complete and accurate application to the Department, including applicable fees.

(b) *Firm certification for laboratory analysis.* If the applicant for radon laboratory certification is a firm, it shall employ at least one individual who is certified to perform radon laboratory analysis and who is in responsible charge of the laboratory radon analytical activities. If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.

(c) *Additional requirements.* If the applicant for radon laboratory certification is a firm, or an individual performing laboratory analysis and not working for a certified laboratory, the applicant shall also have a quality assurance program and a continuing education program as required in §§ 240.304—240.307. In addition, the applicant shall be successfully enrolled in the EPA radon measurement proficiency program or equivalent, as required in §§ 240.304—240.307.

Cross References

This section cited in 25 Pa. Code § 240.123 (relating to radon laboratory application contents).

§ 240.123. Radon laboratory application contents.

An application for radon laboratory certification shall be submitted to the Department in writing on forms provided by the Department and shall contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.122 (relating to prerequisites for radon laboratory certification), including the services offered and experience in each. If the applicant is a firm, the applicant shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of $250 for individuals, $500 for firms.

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(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to laboratory analysis of radon samples.

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief, attested by a notary public or district justice.

§ 240.124. Application filing deadline.

A person who anticipates performing laboratory analysis of samples to determine radon concentrations shall file a complete application for laboratory analysis certification a minimum of 30 days prior to the anticipated starting date of laboratory analysis.

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

§ 240.131. States with reciprocal agreements with the Commonwealth.

The Department may enter into a reciprocal agreement with another state recognizing each state's radon certification program. The Department will not recognize another state's program unless the program's certification is compatible with the one established under the act and this chapter. The Department will publish a notice in the *Pennsylvania Bulletin* listing the state programs it has recognized.

§ 240.132. Limited radon practice in this Commonwealth.

A person may test, mitigate or perform laboratory analysis without first obtaining certification from the Department if the person does the following:

(1) The person has obtained certification to do so from a state with which the Department has entered into a reciprocal agreement.

(2) The person conducts that activity in this Commonwealth less than 90 days each calendar year.

§ 240.133. Certification application contents.

A person who has a certification from a state with which the Department has entered into a reciprocal agreement, and who intends to conduct the radon-related activity in this Commonwealth for at least 90 days a year, shall obtain certification from the Department. The application shall be in writing and contain:

(1) A copy of the certification from the foreign state.

(2) A nonrefundable fee of $200.

(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholders, parent corporations and certified persons within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications, or technical or administrative information related to radon testing, mitigation of radon contamination or laboratory analysis of radon samples.

(6) A verification by a responsible official of the applicant that the information contained in the application is true and correct to the best of the official's information and belief, attested by a notary public or district justice.

Subchapter C. CERTIFICATION REVIEW PROCEDURES AND STANDARDS

Sec.
240.201. Criteria for certification issuance or denial.
240.202. Terms of certification.
240.203. Conditions of certification.
240.204. Certification renewal.
240.205. Certification modification.
240.206. Notice of certification.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.201. Criteria for certification issuance or denial.

(a) A certification application will not be approved unless the applicant affirmatively demonstrates to the Department's satisfaction that the following conditions are met:

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(1) Neither the applicant nor a person identified in the application is in violation of the act or this chapter or has been decertified under § 240.403 (relating to decertification).

(2) The application is accurate and complete and the applicant is in compliance with the requirements of the act and this chapter.

(3) The applicant has the qualifications required in this chapter and is capable of performing the activities for which he is seeking certification as required by the act and this chapter.

(b) The Department may deny certification to a person who has shown a lack of ability or intention to comply with the acts or this chapter, as indicated by past or continuous conduct. A certification lapse under § 240.203(b) (relating to conditions of certification) may be considered evidence of a lack of ability or intention to comply with the acts or this chapter.

Cross References

This section cited in 25 Pa. Code § 240.204 (relating to certification renewal).

§ 240.202. Terms of certification.

(a) A certification will be valid for 2 years following issuance.

(b) Testing, mitigating or other radon-related activity may not be conducted after the expiration of the term of certification.

§ 240.203. Conditions of certification.

(a) Persons certified under this chapter shall, at a minimum, comply with the following conditions:

(1) The certified person shall conduct his activities as described in the approved application.

(2) The certified person shall allow the Department, its agents and employes, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to the person's facilities, offices and files for inspection and examination of records. The certified person shall also allow the Department, its agents and employes to accompany him while performing radon-related activities for the purpose of inspection of those activities.

(3) The certified person shall remain in compliance with the acts and this chapter.

(4) For certification of a firm, the certified person shall continue to direct the radon-related activities. The certified person shall have his duties listed in the firm's certification application.

(b) The Department may suspend certification if a condition of certification is violated. The Department will publish notice of the suspension in the *Pennsylvania Bulletin.*

Cross References

This section cited in 25 Pa. Code § 240.201 (relating to criteria for certification issuance or denial).

§ 240.204. Certification renewal.

An application for certification renewal shall contain the contents required in an initial certification application, except that the Department may permit an applicant to rely on information previously submitted if the information remains the same. A certification renewal application shall be issued or denied according to the criteria in § 240.201 (relating to criteria for certification issuance or denial).

§ 240.205. Certification modification.

The terms and conditions of a certification are subject to amendment, revision or modification for a violation of the acts, this chapter or a term or condition of the certification, or for a false statement made to the Department by the certified party, or for a change of condition which would warrant the issuance or denial of a certification on the basis of an original application.

§ 240.206. Notice of certification.

The Department will publish as a notice in the *Pennsylvania Bulletin* the name and address of each person certified under this chapter.

Subchapter D. OPERATION REQUIREMENTS

Sec.
240.301. Advertising.
240.302. Notice to clients.
240.303. Reporting of information.
240.304. Quality assurance program.
240.305. Health and safety program.
240.306. Continuing education program.
240.307. EPA Radon Measurement Proficiency Program.
240.308. Testing and mitigation protocols.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.301. Advertising.

A person may not advertise a radon-related service or product with false or misleading statements regarding the offered service or product, or the risks to health or property value. A person required to obtain certification may not advertise a service or product, unless the person has previously obtained a valid certification from the Department to perform that service or provide that product.

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§ 240.302. Notice to clients.

(a) A person may not test, mitigate against radon or provide a radon-related service or product without first offering the potential client a price list of services offered, and providing evidence of certification and a notice that only persons certified under the act and this chapter may provide the services or products. For a person who mitigates against radon, a written estimate for services shall constitute a price list. The notice shall read substantially as follows:

NOTICE

The Radon Certification Act requires that anyone who provides any radon-related service or product to the general public must be certified by the Pennsylvania Department of Environmental Protection. You are entitled to evidence of certification from any person who provides such services or products. You are also entitled to a price list for services or products offered. All radon measurement data will be sent to the Department as required in the Act and will be kept confidential. If you have any questions, comments or complaints concerning persons who provide radon-related services, please contact the Department at the Bureau of Radiation Protection, Department of Environmental Protection, P. O. Box 8469, Harrisburg, Pa. 17105-8469, (717) 783-3594.

(b) For a person performing mitigation, warranty information and information on the proper method of checking and servicing of mitigation equipment to maintain its function shall be provided in writing to the client.

§ 240.303. Reporting of information.

(a) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing the service shall submit to the Department in a format approved by the Department the results of testing, including screening measurements, follow-up measurements, premitigation measurements, postmitigation measurements and the method used to mitigate against radon contamination. At a minimum, these results will be retained for 2 years. The information shall include:

(1) The name of the person providing the service.

(2) The name and address of the owner or occupant of the building involved.

(3) The address and location of the building involved, including street and number, post office, full zip code and county.

(4) The date each measurement was taken, or the mitigation performed.

(5) The type of house or building, the types of measurements, location within the building of specific measurements, and the results in picocuries per liter or in working levels.

(6) The type and price of mitigation system installed.

(b) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing radon-related services shall report in writing to the owner or occupier of the building the results in picocuries per liter and when appropriate in working levels of radon measurements taken in the building. If a person provides the service through a certified intermediary, it is the responsibility of the intermediary to report the results.

(c) For a person performing mitigation, each building shall be tested for radon levels before and after the mitigation is performed. Each test shall be at least 24 hours in duration and follow EPA- or DEP-approved protocols. The postmitigation test shall be conducted no sooner than 48 hours after completion of the mitigation. The results of radon testing shall be reported in accordance with this section.

Cross References

This section cited in 25 Pa. Code § 240.2 (relating to scope).

§ 240.304. Quality assurance program.

A person conducting radon testing or radon laboratory analysis activities shall have a quality assurance program to assure that measurements are accurate and errors are controlled. The program shall insure that testing devices are routinely and properly calibrated. The program shall provide the information related to the following activities:

(1) Organization and responsibilities.
(2) Sampling procedures.
(3) Detector custody.
(4) Analytical procedures.
(5) Data reduction, validation and reporting.
(6) Corrective action.
(7) Quality assurance reports to management.

Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.305. Health and safety program.

A person conducting radon-related activities shall have a radon health and safety program to protect himself and employes from exposure to radon during the course of their employment. The program shall include records of each individual's exposure to radon. Persons conducting radon-related activities shall maintain exposure to radon as low as reasonably achievable.

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Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.112 (relating to prerequisites for radon mitigation certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.306. Continuing education program.

A person conducting radon-related activities shall have a radon education program to assure that the applicant and all employes have a minimum of 4 hours initial training, and the certified person shall participate in a continuing education program consisting of a minimum of 8 hours of Department-approved courses or seminars on radon testing or mitigation each year.

Source

The provisions of this § 240.306 amended March 30, 2001, effective March 31, 2001, 31 Pa.B. 1742. Immediately preceding text appears at serial page (204029).

Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.112 (relating to prerequisites for radon mitigation certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.307. EPA Radon Measurement Proficiency Program.

A person conducting radon testing or radon laboratory activities shall provide written evidence of successful participation in the most recent EPA Radon/Radon Progeny Measurement Proficiency Program or an alternative program approved by the Department for each radon measurement utilized.

Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.308. Testing and mitigation protocols.

A person conducting radon testing or mitigation for radon contamination shall conduct the testing and mitigation in accordance with EPA- or DEP-approved protocols and shall comply with applicable statutes, regulations, ordinances and building codes. The following protocols, "Interim Protocols for Screening and Follow-up Radon and Radon Decay Product Measurements," "Indoor Radon and Radon Decay Product Measurement Protocols" and "Guidelines for Radon Mitigation of Residential Dwellings" are available upon request from the following sources:

Environmental Protection Agency
Office of Radiation Programs
Washington, D.C. 20460

Department of Environmental Protection
Bureau of Radiation Protection
Rachel Carson State Office Building, 13th Floor
400 Market Street
Post Office Box 8469
Harrisburg, Pennsylvania 17105-8469

Subchapter E. ENFORCEMENT AND DECERTIFICATION

Sec.
240.401. Inspection.
240.402. Civil penalties.
240.403. Decertification.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.401. Inspection.

(a) The Department and its agents and employes will:

(1) At all reasonable times, have access to, and require the production of, books and papers, documents and physical evidence pertinent to a matter under investigation related to radon testing, mitigation of radon contamination or radon laboratory analysis.

(2) At all reasonable times, enter a building, property, premises or place of a person who conducts radon-related activities for the purpose of making an investigation or inspection necessary to ascertain the compliance or noncompliance with the act and this chapter.

(b) The Department, its agents and employes may conduct inspections of a building, property, premises or place of business of a person who conducts radon-related activities if a person presents information to the Department or the Department has access to information which gives it reason to believe that one of the following exists:

(1) A person may have violated the act or this chapter.

(2) A person is not in compliance with the terms or conditions of the person's certification.

(3) A condition or practice exists which may pose a threat to public health, safety, welfare or the environment.

(c) An agent or employe of the Department may not enter a private residence for the purpose of conducting an inspection under this section without a search warrant or without the consent of the occupant.

(d) Inspections made under this section are subject to Chapter 220 (relating to notices, instructions and reports to workers; inspections and investigations).

§ 240.402. Civil penalties.

(a) The Department may assess a civil penalty for a violation of the acts or this chapter.

(b) A civil penalty may be assessed or increased, based upon:

(1) The seriousness of the violation.

(2) The monetary loss of an owner or occupier, including the cost to the owner or occupier to remedy the violation.

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(3) The risks to health and safety.

(4) The cost to the Commonwealth in administration, inspection and enforcement, to remedy the violation.

(5) The costs avoided by the violator by the violation.

(6) The culpability of the violator.

(7) The frequency of the violation.

(c) Each day of a continuing violation is considered a separate violation for purposes of this chapter.

§ 240.403. Decertification.

(a) The Department may decertify a person who has violated the acts, this chapter or a term or condition of certification.

(b) The Department may hold a public hearing or informal conference prior to decertifying a person.

(c) The Department will publish in the *Pennsylvania Bulletin* a notice of decertification.

Cross References

This section cited in 25 Pa. Code § 240.201 (relating to criteria for certification issuance or denial).

Subchapter F. INTERIM CERTIFICATION

Sec.
240.501. Scope.
240.502. Reapplication when this chapter is adopted as final.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.501. Scope.

This subchapter applies to persons certified in accordance with the Department's interim certification program as required under section 11 of the act (63 P. S. § 2011).

§ 240.502. Reapplication when this chapter is adopted as final.

A person granted interim certification by the Department shall reapply for certification under this chapter. If a person fails to apply for certification within 60 days of Departmental notification, the interim certification automatically lapses and is void.

[Next page is 241-1.]

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ARTICLE V. RADIOLOGICAL HEALTH

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Authority

The provisions of this Article V issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed), unless otherwise noted.

Source

The provisions of this Article V adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This article cited in 28 Pa. Code § 211.14 (relating to diagnostic services); and 55 Pa. Code § 1230.41 (relating to participation requirements).

CHAPTER 215. GENERAL PROVISIONS

GENERAL PROVISIONS

Sec.
215.1. Purpose and scope.
215.2. Definitions.
215.3. Units of exposure.
215.4. [Reserved].
215.5. Effect of incorporation of CFR.

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

215.11. Records.
215.12. Inspections and investigations.
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PROHIBITIONS AND RESTRICTIONS

215.21. Sale or installation of radiation sources.
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215.28. Improper use of a monitoring device.

EXEMPTIONS

215.31. Granting exemptions.
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COMMUNICATIONS

215.41. Address.

Authority

The provisions of this Chapter 215 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 215 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

The provisions of this chapter cited in 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 220.2 (relating to posting of notices to workers); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 232.1 (relating to purpose and scope).

GENERAL PROVISIONS

§ 215.1. Purpose and scope.

(a) This article establishes requirements for the protection of public health and safety as related to radiation sources and implements the requirements of the act.

(b) This article, except as otherwise specifically provided in the act, applies to persons who use, manufacture, produce, transport, transfer, receive, acquire, possess, own or dispose of a radiation source.

(c) A person who, when required, fails to register or obtain a license for radiation sources in the possession or control of the person, shall comply with the act or with this article.

(d) This article does not apply to the extent the person is subject to regulation by the NRC.

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and §§ 150.1, 150.2, 150.3, 150.11 and 150.20 of the CFR are incorporated by reference with the exceptions set forth in paragraphs (1)—(13). Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

(1) Sections 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated.

(2) Sections 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated.

(3) Sections 30.5, 30.6, 30.8, 30.21(c), 30.34(d) and (e)(1) and (3), 30.41(a)(6), 30.55, 30.63 and 30.64 are not incorporated.

(4) Sections 31.4 and 31.14 are not incorporated.

(5) Sections 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29 and 32.40 are not incorporated.

(6) Sections 33.8, 33.21 and 33.23 are not incorporated.

(7) Sections 34.5, 34.8, 34.121 and 34.123 are not incorporated.

(8) Sections 35.8, 35.4001 and 35.4002 are not incorporated.

(9) Sections 36.5, 36.8, 36.91 and 36.93 are not incorporated.

(10) Sections 39.5, 39.8, 39.101 and 39.103 are not incorporated.

(11) Sections 40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated.

(12) Sections 70.1(c), (d) and (e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1), (c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b), 70.23a, 70.24, 70.25(a), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7), 70.32(b)(1), (3) and (4), (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55(c)(1), (2) and (3), 70.56(c) and (d), 70.57, 70.58, 70.59, 70.62, 70.71 and 70.72 are not incorporated.

(13) Sections 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100 are not incorporated.

(f) If a provision of the CFR incorporated by reference in this article includes a section which is inconsistent with this title, this title controls to the extent Federal law does not preempt Commonwealth law. If a provision of the CFR incorporated by reference in this article is beyond the scope of authority granted the Department under statute, or is in excess of the statutory authority, the provisions shall be and remain effective only to the extent authorized by the Pennsylvania law.

(g) Appropriate parts of 10 CFR (relating to energy) may be obtained from the following:

(1) The United States Government Printing Office, Book Store, Room 118, Federal Building, 1000 Liberty Avenue, Pittsburgh, Pennsylvania 15222, (412) 664-2721.

(2) The United States Government Printing Office, Book Store, 100 North 17th Street, Robert Morris Building, Philadelphia, Pennsylvania 19103, (215) 597-0677.

(3) The United States Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

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(h) To reconcile differences between this chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 215.1 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282327) to (282329).

§ 215.2. Definitions.

The definitions in 10 CFR Chapter 1, Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and 150 are incorporated by reference in this article unless indicated otherwise. In addition, the following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

AEC—United States Atomic Energy Commission.

Accelerator-produced material—Material made radioactive by a particle accelerator.

Act—The Radiation Protection Act (35 P. S. §§ 7110.101—7110.703).

Bioassay—The determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this article, "radiobioassay" is an equivalent term.

Brachytherapy—A method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary or interstitial application.

Entrance or access point—An opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radiation sources. The term includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

FDA—The Federal Food and Drug Administration.

Human use—The internal or external administration of radiation or radioactive material to human beings.

Inspection—An official examination or observation including, but not limited to, tests, surveys and monitoring to determine compliance with this article, rules, orders, requirements and conditions of the Department.

Ionizing radiation—Radiation consisting of directly ionizing charged particles—such as electrons, protons, alpha particles and the like—having sufficient kinetic energy to produce ionization by collision, or consisting of either indirectly ionizing uncharged particles—such as neutrons—or photons which can liberate directly ionizing particles or can initiate a nuclear transformation.

License—Permission issued by the Department in accordance with this article to possess and use radiation sources. Types of licenses are as follows:

(i) *General license*—Permission to possess and use radioactive material without the formal review and issuance of documents by the Department.

(ii) *Specific license*—Written permission to possess and use radioactive material issued by the Department after the Department reviews and approves an application for the possession and use of the radiation sources.

Licensed practitioner of the healing arts—An individual licensed by the Commonwealth to practice the healing arts, which for the purposes of this article shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

Licensee—A person who is licensed by the Department under this article and the act.

Licensing state—A state that has regulations equivalent to the Suggested State Regulations for Control of Radiation (United States Department of Health and Human Services) relating to, and has an effective program for, the regulatory control of NARM and which has been granted final designation as a licensing state by the Conference of Radiation Control Program Directors, Inc.

Major X-ray system component—A tube housing assembly, X-ray control, X-ray high voltage generator, X-ray table, cradle, film changer, fixed cassette holder, beam limiting device, fluoroscopic or digital radiographic imaging assembly, spot film device, image intensifier or cephalometric device.

NARM—A naturally occurring or accelerator-produced radioactive material. The term does not include by-product, source or special nuclear material.

NORM—Naturally occurring radioactive material—A nuclide which is radioactive in its natural physical state—that is, not man-made—but does not include source or special nuclear material.

NRC—United States Nuclear Regulatory Commission or its authorized representatives.

Person—An individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency or political subdivision of this Commonwealth; another state or political subdivision or agency thereof; and a legal successor, representative, agent or agency of the entities listed in this paragraph. The term does not include Federal government agencies.

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Pharmacist—An individual licensed by the Commonwealth to compound and dispense drugs, prescriptions and poisons.

Physician—An individual licensed by the Commonwealth to practice medicine or osteopathy in this Commonwealth.

Prescribed dose for therapy using radiation-producing machines—For X-ray, electron or other particle beam therapy, the total dose and dose per fraction as documented in the written directive.

Qualified expert—

(i) For radiation protection, an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs; for example: individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics or those having equivalent qualifications.

(ii) For radiation therapy calibrations, an individual having, in addition to the qualifications in subparagraph (i), training and experience in the clinical applications of radiation physics to radiation therapy.

(iii) For diagnostic X-ray performance evaluations, an individual having, in addition to the qualifications of subparagraph (i), training and experience in the physics of diagnostic radiology.

Radiation—Ionizing radiation.

Radiation producing machine—A device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

Radiation safety officer—An individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

Radiation source—An apparatus or material, other than a nuclear power reactor and nuclear fuel located on a plant site, emitting or capable of emitting ionizing radiation.

Radioactive material—A material—solid, liquid or gas—which emits radiation spontaneously.

Radioactivity—The transformation of unstable atomic nuclei accompanied by the emission of radiation.

Registrant—A person who is legally obligated to register with the Department under this article and the act.

Registration—The act of registering with the Department under this article.

Roentgen (R)—The special unit of exposure to external X-ray and gamma radiation. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air. See § 215.3 (relating to units of exposure).

Traceable to a National standard—A system which has been calibrated by the National Institute of Science and Technology or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine.

Waste handling licensees—Persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

Written directive for therapy using radiation-producing machines—An order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiation therapy treatment:

(i) For X-ray therapy at potentials less than 1 MeV: the total dose, dose per fraction, treatment site, field sizes, tube potential and filtration, and overall treatment period.

(ii) For X-ray, electron or other particle beam therapy at energies of 1 MeV and above: the total dose, dose per fraction, treatment site, field size, beam type and energy, applicator, use of beam blocking or shaping devices, treatment geometry and overall treatment period.

Source

The provisions of this § 215.2 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282329) to (282332).

Cross References

This section cited in 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 236.2 (relating to definitions).

§ 215.3. Units of exposure.

As used in this article, the unit of exposure to external X-ray and gamma radiation expressed in standard international (SI) units is the coulomb per kilogram (C/kg) of air. This represents the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The "roentgen" is a special unit of exposure. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air. One milliroentgen (mR) is equal to 1/1000 roentgen.

Source

The provisions of this § 215.3 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249207) to (249208) and (203799).

Cross References

This section cited in 25 Pa. Code § 215.2 (relating to definitions).

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§ 215.4. [Reserved].

Source

The provisionis of this § 215.4 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203799).

§ 215.5. Effect of Incorporation of the CFR.

(a) *Title and name changes.* To reconcile differences between this chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means "Department, NRC or agreement state."

(b) *Forms and documents.* References to forms in the Federal regulations incorporated by reference will be replaced by the appropriate forms prescribed by the Department.

(c) *Notifications, reports and correspondence.* Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 215.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.11. Records.

(a) Registrants shall maintain records showing the receipt, transfer and disposal of radiation producing machines.

(b) Licensees shall maintain records showing the receipt, transfer and disposal of radioactive material as described in 10 CFR 30.51 (relating to records).

Source

The provisions of this § 215.11 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203799).

§ 215.12. Inspections and investigations.

(a) *Maintenance of records.* Licensees and registrants shall maintain records under this article and have these records available for inspection by the Department at permanent sites or facilities of use identified in a license or registration issued under this article.

(b) *Rights of the Department.* The Department and its agents and employees will:

(1) Have access to, and require the production of, books, papers, documents and other records and physical evidence pertinent to a matter under investigation.

(2) Require a registrant or licensee to make reports and furnish information as the Department may prescribe.

(3) Enter the premises of a licensee or registrant for the purpose of making an investigation or inspection of radiation sources and the premises and facilities where radiation sources are used or stored, necessary to ascertain the compliance or noncompliance with the act and this chapter and to protect health, safety and the environment.

(c) *Inspections and investigations by the Department.* The Department, its employees and agents may conduct inspections and investigations of the facilities and regulated activities of registrants of radiation-producing machines and licensees of radioactive material necessary to demonstrate compliance with the act or this article.

(d) *Additional inspections and investigations.* The Department, its employees and agents may conduct additional follow-up inspections and investigations if violations of the act or regulations promulgated thereunder were noted at the time of the original inspection, or if a person presents information, or circumstances arise which give the Department reason to believe that the health and safety of a person is threatened or that the act or this article are being violated.

Source

The provisions of this § 215.12 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282334).

§ 215.13. Tests.

Licensees and registrants, upon instruction from the Department, shall perform, or permit the Department to perform, reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

(1) Radiation sources.

(2) Facilities in which radiation sources are used or stored.

(3) Radiation detection and monitoring instruments.

(4) Other equipment and devices in connection with utilization or storage of licensed or registered radiation sources.

§ 215.14. Availability of records for public inspection.

The following Department records are not available for public inspection, unless the Department determines that disclosure is in the public interest and is necessary for the Department to carry out its duties under the act:

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(1) Trade secrets or secret industrial processes customarily held in confidence.

(2) A report of investigation, not pertaining to safety and health in industrial plants, which would disclose the institution, progress or results of an investigation undertaken by the Department.

(3) Personnel, medical and similar files, the disclosure of which would operate to the prejudice or impairment of a person's reputation or personal safety.

Source

The provisions of this § 215.14 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282335).

§ 215.15. Additional requirements

The Department may impose upon a person requirements additional to those established in this article which it may deem reasonable and necessary to protect the public health and safety. As an example, when necessary or desirable to determine the extent of an individual's exposure to concentrations of radioactive material, the Department may require a licensee to provide to the individual appropriate bioassay services, medical services and the services of a qualified expert and to furnish a copy of the reports of these services to the Department.

Source

The provisions of this § 215.15 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203801).

PROHIBITIONS AND RESTRICTIONS

§ 215.21. Sale or installation of radiation sources.

No person may sell or install within this Commonwealth a radiation source which does not meet the requirements of this article.

§ 215.22. Prohibited uses.

(a) No person may operate or maintain within this Commonwealth fitting devices or machines which use fluoroscopic, X-ray or radiation principles for the purpose of selling footwear through commercial outlets.

(b) Hand-held fluoroscopic screens may not be used.

§ 215.23. Penalties.

A person who violates this article is subject to the civil and criminal penalties in the act.

§ 215.24. Human use.

(a) No human use of radiation sources may be permitted except under this article, and the following:

(1) Medical Practice Act of 1985 (63 P. S. §§ 422.1—422.45).

(2) The Osteopathic Medical Practice Act (63 P. S. §§ 271.1—271.18).

(3) The Chiropractic Registration Act of 1951 (63 P. S. §§ 601—624).

(4) The Dental Law (63 P. S. §§ 120—130g).

(5) The Podiatry Practice Act (63 P. S. §§ 42.1—42.21c).

(b) Auxiliary personnel employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices may use radiation sources in the healing arts provided those individuals comply with the applicable requirements of 49 Pa. Code Part I, Subpart A (relating to professional and occupational affairs), located in the following chapters:

(1) Chapter 5 (relating to the State Board of Chiropractic).

(2) Chapter 16 (relating to the State Board of Medicine—general provisions).

(3) Chapter 17 (relating to the State Board of Medicine—medical doctors).

(4) Chapter 18 (relating to the State Board of Medicine—practitioners other than medical doctors).

(5) Chapter 25 (relating to the State Board of Osteopathic Medicine).

(6) Chapter 29 (relating to the State Board of Podiatry).

(7) Chapter 33 (relating to the State Board of Dentistry).

(c) Auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government may only use radiation sources in the healing arts in accordance with written job descriptions and employee qualifications.

(d) Subsections (b) and (c) notwithstanding, human use of radiation sources is permitted by individuals enrolled in clinical training programs that satisfy the related accreditation requirements of the boards in subsection (b) and who are under the supervision of a licensed practitioner of the healing arts or of auxiliary personnel authorized under subsections (b) and (c) to use radiation sources in the healing arts.

Source

The provisions of this § 215.24 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282336).

§ 215.25. Deliberate misconduct.

The requirements under 10 CFR 30.10 (relating to deliberate misconduct) are incorporated by reference. This requirement also applies to registrants.

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Source

The provisions of this § 215.25 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 215.26. Employee protection.

The requirements under 10 CFR 30.7 (relating to employee protection) are incorporated by reference. This requirement also applies to registrants.

Source

The provisions of this § 215.26 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 215.27. Vacating premises.

In addition to the decommissioning requirements of 10 CFR 30.36 (relating to expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas) that are incorporated by reference under Chapter 217 (relating to licensing of radioactive material), a licensee shall notify the Department in writing of intent to vacate at least 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's activities. When deemed necessary by the Department, the licensee shall decontaminate the premises as the Department may specify.

Source

The provisions of this § 215.27 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 215.28. Improper use of a monitoring device.

The deliberate exposure of, failure to use, or improper use of, an individual monitoring device or area monitoring device by an individual is prohibited.

Source

The provisions of this § 215.28 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282337).

EXEMPTIONS

§ 215.31. Granting exemptions.

The Department may, upon application therefor or upon its own initiative, grant exemptions from this article when the Department determines that they do not result in significant risk to the health and safety of the public and safeguards that provide equivalent levels of protection in this article are implemented.

§ 215.32. Exemption qualifications.

The following sources, uses and types of users are exempt from Chapters 216—221, 223—228, 230, 232 and 240:

(1) A United States Department of Energy contractor or subcontractor and an NRC contractor or subcontractor of the following categories operating within this Commonwealth to the extent that the contractor or subcontractor under contract receives, possesses, uses, transfers, owns or acquires radiation sources:

(i) Prime contractors performing work for the United States Department of Energy at United States Government-owned or controlled sites, including the transportation of radiation sources to or from the sites and the performance of contract services during temporary interruptions of the transportation.

(ii) Prime contractors of the United States Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, nuclear weapons or components thereof.

(iii) Prime contractors of the United States Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government owned vehicle or vessel.

(iv) Other prime contractors or subcontractors of the United States Department of Energy or of the NRC if the Commonwealth and the NRC jointly determine that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and that the exemption of the contractor or subcontractor is otherwise appropriate.

(2) Federal government agencies.

(3) Electrical equipment that produces radiation incidental to its operation for other purposes if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed .5 mrem (.005 mSv) per hour at 5 centimeters from an accessible surface. The equipment is not exempt when operated without adequate shielding during testing and servicing if radiation levels exceed those specified. Electron beam welders and electron microscopes are not exempt.

(4) Radiation-producing machines in transit or in storage incident thereto.

(5) A material, product or use specifically exempted from licensing requirements by the NRC, the Department or an agreement state or authorized for distribution to persons exempt from license requirements.

Source

The provisions of this § 215.32 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282337) to (282338).

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COMMUNICATIONS

§ 215.41. Address.

Communications and reports concerning this article and applications filed under it shall be addressed to the Bureau of Radiation Protection, Department of Environmental Protection, Post Office Box 8469, Harrisburg, Pennsylvania 17105-8469.

Source

The provisionis of this § 215.41 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial page (123511).

Cross References

This section cited in 25 Pa. Code § 230.5 (relating to communications).

[Next page is 216-1.]

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CHAPTER 216. REGISTRATION OF RADIATION-PRODUCING MACHINES AND RADIATION-PRODUCING MACHINE SERVICE PROVIDERS

Sec.
216.1. Purpose and scope.
216.2. Registration of radiation-producing machines.
216.2a. Registration of radiation-producing machine service providers.
216.2b. Reporting and recordkeeping requirements for registered radiation-producing machine service providers.
216.3. Exemptions.
216.4. Renewal of certificate of registration.
216.4a. Expiration and termination of certificates of registration.
216.5. Approval not implied.
216.6. Transfer and disposal obligations.
216.7. Out-of-State radiation-producing machines.

Authority

The provisions of this Chapter 216 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 216 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 218.1 (relating to purpose and scope); and 25 Pa. Code § 220.1 (relating to purpose and scope).

§ 216.1. Purpose and scope.

(a) This chapter establishes requirements for the registration of radiation-producing machines and radiation-producing machine service providers. A person who possesses a radiation-producing machine or provides services described in this chapter shall comply with this chapter.

(b) A person possessing an accelerator as defined in § 228.2 (relating to definitions) is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines). Accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators) and license fees are specified in § 218.11(d) (relating to registration, renewal of registration and license fees).

Authority

The provisions of this § 216.1 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S.§ 510-20).

Source

The provisions of this § 216.1 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282339).

§ 216.2. Registration of radiation-producing machines.

(a) A person possessing a radiation-producing machine shall:

(1) Register with the Department within 30 days after acquisition. Registration shall be completed on forms furnished by the Department and shall contain information required on the form and accompanying instructions.

(2) Designate on the registration form an individual to be responsible for radiation protection.

(3) Notify the Department in writing within 30 days of a change of address, owner or radiation safety officer or number of machines.

(b) The registration becomes valid upon receipt of the properly completed registration form and the fee required under Chapter 218 (relating to fees).

(c) A certificate of registration will be issued by the Department to a person whose registration becomes valid under subsection (b).

(d) A registrant shall have the currently valid certificate of registration available for inspection by the Department.

(e) A certificate of registration issued under this chapter may not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, to any person without submitting a written request by the registrant to the Department.

Authority

The provisions of this § 216.2 amended under sections 301, 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.301, 7110.302 and 7110.401); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.2 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended January 1, 1988, effective January 2, 1988, 18 Pa.B. 11; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282339) to (282340).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration); 25 Pa. Code § 216.7 (relating to out-of-State radiation-producing machines); and 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees).

§ 216.2a. Registration of radiation-producing machine service providers.

After July 17, 2004, a person who engages in the business of assembling or installing radiation-producing machines or who offers to assemble or install

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radiation-producing machines or who is in the business of furnishing or offering to furnish radiation-producing machine servicing or services or who is in the business of selling, leasing or lending radiation-producing machines in this Commonwealth shall apply for registration of the activities with the Department prior to furnishing or offering to furnish those services.

(1) Registration is for 12 months and is renewable.

(2) An application for registration or renewal will not be accepted unless accompanied by the appropriate fee specified in § 218.11(h) (relating to registration, renewal of registration and license fees). Fees are not refundable after issuance of a registration.

(3) An application for registration shall be submitted on forms provided by the Department. The Department will issue a certificate of registration for radiation-producing machine services to the applicant when the application is complete, contains all the information required by the Department and when the appropriate fee specified in § 218.11(h) has been paid.

(4) A person who, on July 17, 2004, is currently in the business of providing radiation-producing machine services shall apply for registration by September 15, 2004.

Authority

The provisions of this § 216.2a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.2a adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

Cross References

This section cited in 25 Pa. Code § 216.3 (relating to exemptions); and 25 Pa. Code 216.4a (relating to expiration and termination of certificates of registration).

§ 216.2b. Reporting and recordkeeping requirements for registered radiation-producing machine service providers.

(a) A radiation-producing machine service provider who installs, services, sells, leases or otherwise transfers a radiation producing-machine or major X-ray system component in this Commonwealth shall submit information to the Department and maintain records as described in this section.

(1) The following information shall be submitted in writing to the Department within 15 days of the action:

(i) The date of installation, service or transfer.

(ii) The name, address, telephone number and registration number, if registered, of the client facility.

(iii) The type of radiation-producing machine, the manufacturer's name, model number and control panel serial number of each radiation-producing machine, or major X-ray system components involved in the transaction.

(iv) A contact name of the individual for the service action.

(2) A copy of the assembler's report on United States Food and Drug Administration (FDA) Form 2579, prepared in compliance with the Federal diagnostic X-ray standard (21 CFR 1020.30(d)(1) (relating to diagnostic x-ray systems and their major components)), when completed in full and submitted to the Department within 15 days following the service, satisfies the requirements of paragraph (1) and subsection (d) for services provided under the assembler's report.

(b) Services performed under preventative maintenance that do not involve replacement or refurbishing of major X-ray system components are exempt from the reporting requirements specified in this section except subsection (d).

(c) A radiation-producing machine service provider shall maintain a log or other record of radiation-producing machines installed or serviced in this Commonwealth. The record shall be maintained for 5 years for inspection by the Department and shall list the following information:

(1) The date the machine was installed or service provided.

(2) The name of the customer, address, telephone number and customer's State registration number.

(3) The type of radiation-producing machine, the manufacturer's name, model number and control panel serial number of each radiation-producing machine or major X-ray system component involved.

(4) The name of the individual performing the service.

(d) A radiation-producing machine service provider who services a radiation-producing machine in a radiation installation in this Commonwealth that is not registered shall report the service to the Department. The report shall be submitted in writing within 15 days after the services and contain the following information:

(1) The date service was provided.

(2) The name, address and telephone number of the client.

(3) The type of radiation-producing machine, the manufacturer's name, model number and control panel serial number of each radiation-producing machine or major X-ray system component.

(4) The name of the individual performing the service.

Authority

The provisions of this § 216.2b issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.2b adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

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Cross References

This section cited in 25 Pa. Code § 216.6 (relating to transfer and disposal obligations).

§ 216.3. Exemptions.

The following radiation-producing machines or equipment are exempt from registration:

(1) Electrical equipment that produces radiation incidental to its operation for other purposes, if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed .5 mrem (.005 mSv) per hour at 5 centimeter from an accessible surface. The production, testing or factory servicing of the equipment are not exempt. Electron beam welders and electron microscopes are not exempt.

(2) Radiation-producing machines while in transit in the possession of a transport carrier.

(3) Radiation-producing machines in the possession of vendors, installers or persons engaged in the service or repair of the machines, if applicable persons who have these machines register their activities with the Department under § 216.6 (relating to transfer and disposal obligations).

(4) Accelerators are exempt from registration. Accelerators shall be licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Accelerator service providers are not exempt from registration of services under § 216.2a (relating to registration of radiation-producing machine service providers).

Authority

The provisions of this § 216.3 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.3 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282340).

§ 216.4. Renewal of certificate of registration.

(a) The Department will send an application for renewal of the certificate of registration to the registrant at least 2 months prior to the expiration date on the certificate of registration. The application for renewal will include references to the fee due under § 218.11 (relating to registration, renewal of registration and license fees).

(b) An applicant for renewal of a registration shall submit a signed application and the fee required under § 218.11 prior to the expiration date of the certificate of registration.

(c) The renewal becomes valid upon receipt of the properly completed application and the fee required under Chapter 218 (relating to fees).

Authority

The provisions of this § 216.4 amended under sections 301, 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.301, 7110.302 and 7110.401); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.4 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203806).

Cross References

This section cited in 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration); and 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees).

§ 216.4a. Expiration and termination of certificates of registration.

(a) A certificate of registration expires on the date specified on the certificate of registration. Expiration of the certificate of registration does not relieve the registrant from the requirements of this article.

(b) When a registrant decides to terminate all activities involving radiation-producing machines under the certificate of registration, the registrant shall notify the Department immediately, in writing, and request termination of the certificate of registration. This notification and request for termination of the certificate of registration shall be in accordance with subsection (c).

(c) If a registrant does not submit a renewal for a certificate of registration under § 216.4 (relating to renewal of certificate of registration), the registrant shall, on or before the expiration date specified in the certificate of registration, do the following:

(1) Terminate use of all radiation-producing machines subject to registration under § 216.2 (relating to registration of radiation-producing machines) or cease all radiation-producing machine services subject to registration under § 216.2a (relating to registration of radiation-producing machine service providers).

(2) Transfer or dispose of all radiation-producing machines subject to registration under § 216.2 in accordance with § 216.6 (relating to transfer and disposal obligations).

(3) Remit any outstanding registration or renewal of registration fees owed to the Department under § 218.11 (relating to registration, renewal of registration and license fees).

(4) Request termination of the certificate of registration in writing to the Department.

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Authority

The provisions of this § 216.4a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.4a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249211) to (249212).

§ 216.5. Approval not implied.

No person, in an advertisement, may refer to the fact that radiation-producing machines are registered by the Department nor state that an activity under the registration has been approved by the Department.

Source

The provisions of this § 216.5 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§ 216.6. Transfer and disposal obligations.

(a) A person, distributor, retailer or other agent who, by selling, leasing, lending or gifting, transfers possession of radiation-producing machines or major X-ray system components in this Commonwealth that are not otherwise reported under § 216.2b (relating to reporting and recordkeeping requirements for registered radiation-producing machine service providers), shall notify the Department within 30 days of the following information:

(1) The name and address of persons who have received the machines or components.

(2) The manufacturer, model and serial number of a machine or component transferred.

(3) The date of transfer of a radiation-producing machine or major X-ray system component.

(b) A person who disposes of a radiation-producing machine shall notify the Department within 15 days of the method of disposal used.

Authority

The provisions of this § 216.6 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.6 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249212) and (282341).

Cross References

This section cited in 25 Pa. Code § 216.3 (relating to exemptions); and 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration).

§ 216.7. Out-of-State radiation-producing machines.

(a) If a radiation-producing machine is brought into this Commonwealth for temporary use, the person proposing to do so or an authorized agent shall give written notice to the Department at least 2 working days before the machine enters this Commonwealth. The notice shall include the type of machine, the nature, duration and scope of use and the exact location where the machine is to be used. In addition, the person shall:

(1) Comply with this title.

(2) Supply the Department with other information as the Department may reasonably request.

(3) Not operate within this Commonwealth on a temporary basis in excess of 60 calendar days per year.

(b) If for a specific case, the 2-working-day period would impose an undue hardship, the person, upon application to the Department, may receive a waiver of this requirement.

(c) When a radiation-producing machine is brought into this Commonwealth for temporary use exceeding 60 days per year, a person possessing the machine shall register with the Department under § 216.2 (relating to registration of radiation-producing machines) within 15 days after the 60th day.

Authority

The provisions of this § 216.7 amended under sections 301, 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.301, 7110.302 and 7110.401); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 216.7 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282341).

Cross References

This section cited in 25 Pa. Code § 225.5a (relating to reciprocity).

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CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

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A.	GENERAL	217.1
B.	GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL	217.11
C.	GENERAL LICENSES FOR RADIOACTIVE MATERIAL	217.141
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I.	TRANSFER OF RADIOACTIVE MATERIAL	217.191
J.	RECIPROCITY	217.201

Authority

The provisions of this Chapter 217 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 217 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.27 (relating to vacating premises); 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 218.1 (relating to purpose and scope); 25 Pa. Code § 220.1 (relating to purpose and scope); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); 25 Pa. Code § 228.37 (relating to production of radioactive material); and 25 Pa. Code § 232.1 (relating to purpose and scope).

Subchapter A. GENERAL

Sec.
217.1. Purpose and scope.
217.2. Address for communications.

§ 217.1. Purpose and scope.

(a) This chapter establishes requirements for the licensing of radioactive material. Persons who use radioactive material shall comply with this chapter. A person may not receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued under this chapter or otherwise provided in this chapter.

(b) A licensee is subject to Chapters 215, 218—220 and 230. A licensee engaged in industrial uses and radiographic operations is subject to Chapter 225 (relating to radiation safety requirements for industrial radiographic operations). A licensee using radioactive material for human use is subject to Chapter 224 (relating to medical use of radioactive material). A licensee using sealed sources in well logging is subject to Chapter 226 (relating to licenses and radiation safety requirements for well logging). A licensee using sealed sources in irradiators is subject to Chapter 232 (relating to licenses and radiation safety requirements for irradiators). A licensee for the disposal of low-level radioactive wastes received from other persons is subject to Chapter 236 (relating to low-level radioactive waste management and disposal).

(c) The use of radioactive material in this Commonwealth under a license issued by the NRC is exempt from the licensing requirements of this chapter until the Commonwealth becomes an agreement state on the date published in the *Federal Register.*

Source

The provisions of this § 217.1 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203809) to (203810).

§ 217.2. Address for communications.

An application for a license, license renewal and license amendments and other communications under this chapter shall be addressed to the Bureau of Radiation Protection, Department of Environmental Protection, Post Office Box 8469, Harrisburg, Pennsylvania 17105-8469.

Source

The provisions of this § 217.2 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203810).

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

Sec.
217.11—217.18. [Reserved].
217.21—217.24. [Reserved].
217.31 and 217.32. [Reserved].
217.41—217.44. [Reserved].
217.45. [Reserved].
217.46—217.48. [Reserved].
217.49. [Reserved].
217.51. [Reserved].
217.52. [Reserved].

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217.53—217.56.	[Reserved].
217.57.	[Reserved].
217.61—217.64.	[Reserved].
217.65.	[Reserved].
217.71—217.73.	[Reserved].
217.74.	[Reserved].
217.81—217.83.	[Reserved].
217.84.	[Reserved].
217.85—217.87.	[Reserved].
217.88.	[Reserved].
217.89.	[Reserved].
217.90—217.92.	[Reserved].
217.93.	[Reserved].
217.101.	[Reserved].
217.111—217.114.	[Reserved].
217.121.	[Reserved].
217.122.	[Reserved].
217.131.	Incorporation by reference.
217.132.	Effect of incorporation of 10 CFR Part 30.
217.133.	Persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register*.
217.134.	Filing application for specific licenses.
217.135.	Renewal of licenses.
217.136.	Exempt concentrations.
217.137.	Exempt quantities.

Cross References

This subchapter cited in 25 Pa. Code § 217.153 (relating to licensing the incorporation of NARM into gas and aerosol detectors); and 25 Pa. Code § 217.203 (relating to reciprocity of licenses of naturally occurring and accelerator-produced radioactive material).

§§ 217.11—217.18. [Reserved].

Source

The provisions of these §§ 217.11—217.18 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203810) to (203817).

§§ 217.21—217.24. [Reserved].

Source

The provisions of these §§ 217.21—217.24 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203819) to (203821).

§§ 217.31 and 217.32. [Reserved].

Source

The provisions of these §§ 217.31 and 217.32 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203821) to (203823).

§§ 217.41—217.44. [Reserved].

Source

The provisions of these §§ 217.41—217.44 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203823) to (203828).

§ 217.45. [Reserved].

Source

The provisions of this § 217.45 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203829) to (203830).

§§ 217.46—217.48. [Reserved].

Source

The provisions of these § 217.46—217.48 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203830) to (203832) and (249215) to (249216).

§ 217.49. [Reserved].

Source

The provisions of this § 217.49 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249216).

§ 217.51. [Reserved].

Source

The provisions of this § 217.51 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249217).

§ 217.52. [Reserved].

Source

The provisions of this § 217.52 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249217) to (249218).

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§§ 217.53—217.56. [Reserved].

Source

The provisions of these §§ 217.53—217.56 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249218) to (249221).

§ 217.57. [Reserved].

Source

The provisions of this § 217.57 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249221).

§§ 217.61—217.64. [Reserved].

Source

The provisions of these § 217.61—217.64 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial pages (123549) to (123556).

§ 217.65. [Reserved].

Source

The provisions of this § 217.65 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249222) to (249233).

§§ 217.71—217.73. [Reserved].

Source

The provisions of these § 217.71—217.73 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249223) to (249226).

§ 217.74. [Reserved].

Source

The provisions of this § 217.74 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249226).

§§ 217.81—217.83. [Reserved].

Source

The provisions of these §§ 217.81—217.83 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249226) to (249230).

§ 217.84. [Reserved].

Source

The provisions of this § 217.84 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249230) to (249234).

§§ 217.85—217.87. [Reserved].

Source

The provisions of these §§ 217.85—217.87 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249234) to (249235).

§ 217.88. [Reserved].

Source

The provisions of this § 217.88 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249235) to (249237).

§ 217.89. [Reserved].

Source

The provisions of this § 217.89 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249237) to (249238).

§§ 217.90—217.92. [Reserved].

Source

The provisions of these §§ 217.90—217.92 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249238) to (249242).

§ 217.93. [Reserved].

Source

The provisions of this § 217.93 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249242) to (249244).

§ 217.101. [Reserved].

Source

The provisions of this § 217.101 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203863) to (203864).

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§§ 217.111—217.114. [Reserved].

Source

The provisions of these §§ 271.111—217.114 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206. Immediately preceding text appears at serial pages (170357) to (170360).

§ 217.121. [Reserved].

Source

The provisions of this § 217.121 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203864) to (203866).

§ 217.122. [Reserved].

Source

The provisions of this § 217.122 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203866) to (203867).

§ 217.131. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 30.5, 30.6, 30.8, 30.21(c), 30.34(d), (e)(1) and (3), 30.41(a)(6), 30.55, 30.63 and 30.64 are not incorporated by reference.

Source

The provisions of this § 217.131 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 217.132. Effect of incorporation of 10 CFR Part 30.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 30, the following words and phrases shall be substituted for the language in 10 CFR Part 30 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 217.132 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 217.133. Persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register.*

On the date the Commonwealth becomes an agreement state as published in the *Federal Register*, a person who possesses a general or specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass, is deemed to possess a like license issued under this chapter and the act. The license shall expire either 90 days after receipt from the Department of a notice of expiration of the license, or on the date of expiration specified in the NRC license, whichever is earlier.

Source

The provisions of this § 217.133 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Cross References

This section cited in 25 Pa. Code § 217.203 (relating to reciprocity of licenses for byproduct, source, naturally occuring and accelerator-produced radioactive material and special nuclear material in quantities not sufficient to form a critical mass).

§ 217.134. Filing application for specific licenses.

In addition to incorporation by reference, an application for a specific license shall be accompanied by the fee required under Chapter 218 (relating to fees).

Source

The provisions of this § 217.134 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Cross References

This section cited in 25 Pa. Code § 217.135 (relating to renewal of licenses).

§ 217.135. Renewal of licenses.

(a) An application for renewal of a specific license shall be filed under § 217.134 (relating to filing application for specific licenses).

(b) If a renewal application is filed prior to 30 days before the expiration of a license, the existing license does not expire until definitive notice has been given by the Department of its action on the renewal application. This subsection also applies to new license applications incorporating other licenses.

Source

The provisions of this § 217.135 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

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§ 217.136. Exempt concentrations.

In addition to the parts of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) incorporated by reference, the following requirements apply:

(1) Except as provided in paragraph (2), a person may receive, possess, use, transfer, own or acquire products or materials containing radioactive material introduced in concentrations less than those listed in Table 1 without possession of a license under this chapter.

(2) Except under a specific license issued under Subchapter D (relating to specific licenses to manufacture or transfer certain items containing radioactive material), or the general license under Subchapter F (relating to specific domestic licenses of broad scope for radioactive material), a person may not introduce radioactive material into a product or material for distribution to persons exempt under paragraph (1) or equivalent regulations of the NRC, an agreement state or licensing state.

TABLE 1
EXEMPT CONCENTRATIONS

Note: Some of the values in Table A-1 are presented in the computer "E" notation. In this notation, a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600 and 6E+0 represents 6×10^{0} or 6.

Element (atomic number)	*Isotope*	*Column I Gas concentration µCi/ml*	*Column II Liquid and solid concentration µCi/ml*
Actinium (89)	Ac-228		9E-04
Cesium (55)	Cs-129		3E-03
Europium (63)	Eu-154		2E-04
Gallium (31)	Ga-67		2E-03
Germanium (32)	Ge-68		9E-03
Gold (79)	Au-195		1E-02
Indium (49)	In-111		1E-03
Iodine (53)	I-123		3E-04
	I-124		4E-06
	I-125		2E-06
Lead (82)	Pb-212		2E-04
Phosphorus (15)	P-33		3E-04
Potassium (19)	K-43		2E-04
Protactinium (91)	Pa-230		2E-03
Radium (88)	Ra-223		7E-06
	Ra-224		2E-05
	Ra-228		3E-07

Element (atomic number)	*Isotope*	*Column I Gas concentration μCi/ml*	*Column II Liquid and solid concentration μCi/ml*
Radon (86)	Rn-220	1E-07	
	Rn-222	3E-08	
Sodium (11)	Na-22		4E-04
Technetium (43)	Tc-97m		4E-03
Xenon (54)	Xe-127	4E-06	
Yttrium (39)	Y-88		8E-04

Source

The provisions of this § 217.136 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282351) to (282352).

§ 217.137. Exempt quantities.

In addition to the parts of 10 CFR 30 incorporated by reference, the following requirements apply:

(1) A person may receive, possess, use, transfer, own or acquire radioactive material in individual quantities each of which is less than those listed in Table 2 if the person does not produce, package or repackage radioactive material for purposes of commercial distribution or incorporate radioactive material into products intended for commercial distribution.

(2) Except under a specific license issued by the Department or the NRC under 10 CFR 32.18 (relating to manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license), a person may not, for purposes of commercial distribution, transfer radioactive material for distribution to persons exempt under paragraph (1) or equivalent regulations of the NRC, an agreement state or licensing state.

TABLE 2

EXEMPT QUANTITIES

Radioactive Material	*Microcuries*
Actinium-228 (Ac 228)	1
Beryllium-7 (Be 7)	10
Bismuth-207 (Bi 207)	10
Cesium-129 (Cs 129)	100
Cobalt-57 (Co 57)	100
Gallium-67 (Ga 67)	100
Germanium-68	10
Gold-195 (Au 195)	10

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Radioactive Material	*Microcuries*
Gold-196 (Au 196)	1
Indium-111 (In 111)	100
Iodine-123 (I 123)	100
Iodine-124 (I 124)	1
Iridium-190 (Ir 190)	100
Lead-203 (Pb 203)	100
Lead-210 (Pb 210)	0.1
Lead-212 (Pb 212)	10
Phosphorus-33 (P 33)	10
Potassium-43 (K 43)	10
Protactinium-230 (Pa 230)	10
Protactinium-231 (Pa 231)	0.1
Radium-223 (Ra 223)	1
Radium-224 (Ra 224)	1
Radium-226 (Ra 226)	0.1
Radium-228 (Ra 228)	0.1
Radon-220 (Rn 220)	1
Radon-222 (Rn 222)	1
Rhenium-183 (Re 183)	100
Rhenium-187 (Re 187)	100
Rubidium-81 (Rb 81)	10
Scandium-46 (Sc 46)	10
Sodium-22 (Na 22)	10
Technetium-96m (Tc 96m)	100
Xenon-127 (Xe 127)	1,000
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10

Source

The provisions of this § 217.137 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

Sec.
217.141. Incorporation by reference.
217.142. Effect of incorporation of 10 CFR Part 31.
217.143. Certain measuring, gauging or controlling devices.
217.144. Incidental radioactive material produced by a particle accelerator.

Source

The provisions of this Subchapter C adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.203 (relating to reciprocity of licenses of naturally occurring and accelerator-produced radioactive material).

§ 217.141. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 31 (relating to general domestic licenses for byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 31.4 and 31.14 (relating to information collection requirements: OMB approval; and criminal penalties) are not incorporated by reference.

Source

The provisions of this § 217.141 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282354).

§ 217.142. Effect of incorporation of 10 CFR Part 31.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 31 (relating to general domestic licenses for byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 31 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

§ 217.143. Certain measuring, gauging or controlling devices.

In addition to the parts of 10 CFR 31.5 (relating to certain detecting measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere) incorporated by reference, general licensees subject to registration under 10 CFR 31.5(c)(13)(i) or possessing general licensed devices containing 37 MBq (1 mCi) or more of accelerator-produced material, as determined on the date of manufacture, or 3.7 MBq (0.1 mCi) or more of radium-226 shall also comply with the following:

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(1) Conduct a physical inventory every 6 months to account for all sources or devices, or both, received and possessed under this section and do the following:

(i) Maintain the physical inventory records for 3 years from the date of each inventory.

(ii) Furnish a report to the Department annually showing to the extent practicable, the make, model, serial number, isotope, source activity and location of each device. The report shall list an individual to contact regarding questions about this report.

(2) For portable devices, also comply with the following:

(i) A person who initiates acquisition, transfer or disposal of a portable device shall notify the Department within 15 days of the action. Sending a portable device for calibration, maintenance or source replacement does not constitute transfer.

(ii) Portable devices may only be used by or under the direct supervision of individuals who have been instructed in the operating and emergency procedures necessary to ensure safe use.

(iii) For each individual that the licensee permits to use a portable device, the licensee shall maintain a record showing the type of device use permitted and the basis, such as training certificates, for that authorization. An individual's record shall be kept for at least 3 years after the individual terminates association with the licensee.

(iv) Portable devices shall be secured from access by unauthorized personnel whenever the device is not under the direct surveillance of an individual authorized to use the device.

(v) The licensee shall maintain a current sign out log at the permanent storage location of the portable device. Log entries shall be available for inspection by the Department for 3 years from the date of entry. The following information shall be recorded for each portable device:

(A) The model and serial number of the device.

(B) The name of the assigned user.

(C) The locations and dates of use.

(vi) Emergency instructions shall accompany each portable device taken off the premises of the licensee.

Source

The provisions of this § 217.143 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282354) to (282355).

Cross References

This section cited in 25 Pa. Code Chapter 218, Appendix A (relating to fees for radioactive material licenses).

§ 217.144. Incidental radioactive material produced by a particle accelerator.

A general license is issued to possess radioactive material produced incidentally to the operation of a particle accelerator. The general license is also subject to the applicable provisions of this chapter and Chapters 215, 219 and 220 (relating to general provisions; standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations). A licensee may transfer this radioactive material only under Subchapter I and Chapter 230 (relating to transfer of radioactive material; and packaging and transportation of radioactive material). A licensee may dispose of this radioactive material only with Department approval.

Cross References

This section cited in 25 Pa. Code § 228.37 (relating to production of radioactive materials).

Subchapter D. SPECIFIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING RADIOACTIVE MATERIAL

Sec.
217.151. Incorporation by reference.
217.152. Effect of incorporation of 10 CFR Part 32.
217.153. Licensing the incorporation of NARM into gas and aerosol detectors.
217.154. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226.
217.155. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

Source

The provisions of this Subchapter D adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.136 (relating to exempt concentrations).

§ 217.151. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29 and 32.40 are not incorporated by reference.

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§ 217.152. Effect of incorporation of 10 CFR Part 32.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 32 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to byproduct material includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

§ 217.153. Licensing the incorporation of NARM into gas and aerosol detectors.

An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subchapter B (relating to general provisions for radioactive material) will be approved if the application satisfies requirements equivalent to those in 10 CFR 32.26—32.29. The maximum quantity of radium-226 may not exceed 0.1 microcuries (3.7 kBq).

§ 217.154. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226.

In addition to the incorporation by reference of requirements in 10 CFR 32.57 (relating to calibration sources containing americium-241), applicants using plutonium and radium-226 in the manufacture of calibration or reference sources shall comply with 10 CFR 32.57.

§ 217.155. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

(a) In addition to the incorporation by reference of requirements in 10 CFR 32.71 (relating to manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license), applicants using cobalt-57 shall prepare for distribution the cobalt-57 in prepackaged units that do not exceed 10 microcuries (370 kBq) of cobalt-57.

(b) A prepackaged unit shall bear a durable, clearly visible label identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) cobalt-57.

Subchapter F. SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR RADIOACTIVE MATERIAL

Sec.
217.161. Incorporation by reference.
217.162. Effect of incorporation of 10 CFR Part 33.
217.163. Types of specific licenses of broad scope.

Source

The provisions of this Subchapter F adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.136 (relating to exempt concentrations).

§ 217.161. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 33 (relating to specific domestic licenses of broad scope for byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 33.8, 33.21 and 33.23 (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

§ 217.162. Effect of incorporation of 10 CFR Part 33.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 33, the following words and phrases shall be substituted for the language in 10 CFR Part 33 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to byproduct material includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

§ 217.163. Types of specific licenses of broad scope.

In addition to the incorporation by reference of 10 CFR 33.11 (relating to types of specific licenses of broad scope), the following requirements for licensees using NARM also apply:

(1) A Type A specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the act.

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The quantities specified exceed those specified in Column I, Table 3 and are usually in the multicurie range.

(2) A Type B specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in Table 3, for an authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I, Table 3. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column I, Table 3, for that radionuclide; the sum of the ratios for radionuclides possessed under the license may not exceed unity.

(3) A Type C specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in Table 3, for an authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column II, Table 3. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Column II, Table 3, for that radionuclide; the sum of the ratios for radionuclides possessed under the license may not exceed unity.

TABLE 3

LIMITS FOR BROAD LICENSES

Radioactive Material	*Col. I curies*	*Col. II curies*
Beryllium-7	10	0.1
Cobalt-57	10	0.1
Radium-226	0.01	0.0001
Scandium-46	1	0.01
Sodium-22	0.1	0.001

Subchapter G. LICENSING OF SOURCE MATERIAL

Sec.
217.171. Incorporation by reference.
217.172. Effect of incorporation of 10 CFR Part 40.

Source

The provisions of this Subchapter G adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

§ 217.171. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 40 (relating to domestic licensing of source material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated by reference.

Source

The provisions of this § 217.171 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282359).

§ 217.172. Effect of incorporation of 10 CFR Part 40.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 40 (relating to domestic licensing of source material), the following words and phrases shall be substituted for the language in 10 CFR Part 40 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Subchapter H. LICENSING OF SPECIAL NUCLEAR MATERIAL

Sec.
217.181. Incorporation by reference.
217.182. Effect of incorporation of 10 CFR Part 70.

Source

The provisions of this Subchapter H adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

§ 217.181. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 70 (relating to domestic licensing of special nuclear material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 70.1(c), (d) and (e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1),

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(c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b), 70.23a, 70.24, 70.25(a), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7) and (b)(1), (3) and (4) and (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55(c)(1), (2) and (3), 70.56(c) and (d), 70.57, 70.58, 70.59, 70.62, 70.71 and 70.72 are not incorporated by reference.

§ 217.182. Effect of incorporation of 10 CFR Part 70.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 70 (relating to domestic licensing of special nuclear material), the following words and phrases shall be substituted for the language in 10 CFR Part 70 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Subchapter I. TRANSFER OF RADIOACTIVE MATERIAL

Sec.
217.191. Transfer of material.

Source

The provisions of this Subchapter I adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator).

§ 217.191. Transfer of material.

The requirements of 10 CFR 30.41 (relating to transfer of byproduct material) also apply to NARM.

Subchapter J. RECIPROCITY

Sec.
217.201. Incorporation by reference.
217.202. Effect of incorporation of 10 CFR Part 150.
217.203. Reciprocity of licenses for byproduct source, naturally occurring and accelerator-produced radioactive material and special nuclear material in quantities not sufficient to form a critical mass.

Source

The provisions of this Subchapter J adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

§ 217.201. Incorporation by reference.

Except as provided in this subchapter, the requirements of 10 CFR 150.1, 150.2, 150.3, 150.11 and 150.20 are incorporated by reference.

Source

The provisions of this § 217.201 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282361).

§ 217.202. Effect of incorporation of 10 CFR Part 150.

To reconcile differences between this subchapter and the incorporated sections of 10 CFR Part 150 (relating to exemptions and continued regulatory authority in agreement states and in offshore waters under section 274), the following words and phrases shall be substituted for the language in 10 CFR Part 150:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 217.202 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282362).

§ 217.203. Reciprocity of licenses for byproduct, source, naturally occurring and accelerator-produced radioactive material and special nuclear material in quantities not sufficient to form a critical mass.

(a) Subject to this article, a person who holds a specific license from the NRC or a state where the licensee maintains an office, issued by the agency hav-

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ing jurisdiction to direct the licensed activity and to maintain radiation safety records, is granted a general license to conduct the activities authorized in the licensing document within this Commonwealth, except for areas of exclusive Federal jurisdiction, for a period not in excess of 180 days in a calendar year if:

(1) The licensing document does not limit the activity authorized by the document to specified installation or locations.

(2) The out-of-State licensee notifies the Department in writing at least 3 days prior to engaging in the activity. The notification shall indicate the location, period and type of proposed possession and use within this Commonwealth, and shall be accompanied by a copy of the pertinent licensing document. If for a specific case the 3-day period would impose an undue hardship on the out-of-State licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection.

(3) The out-of-State licensee complies with this title and with the terms and conditions of the licensee's document, except terms and conditions which may be inconsistent with this title.

(4) The out-of-State licensee supplies other information as the Department may request.

(5) The out-of-State licensee does not transfer or dispose of radioactive material possessed or used under the general license provided in this subsection except by transfer to a person who is one of the following:

(i) Specifically licensed by the Department, the NRC or by another state to receive the material.

(ii) Exempt from the requirements for a license for the material under Subchapter B (relating to general provisions for radioactive material).

(b) Notwithstanding the provisions of subsection (a), a person who holds a specific license issued by the NRC or a state authorizing the holder to manufacture, transfer, install or service a device described in Subchapter C (relating to general licenses for radioactive material) within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate or service the device in this Commonwealth subject to the following conditions:

(1) The person files a report with the Department within 30 days after the end of a calendar quarter in which a device is transferred to or installed in this Commonwealth. The report shall identify the general licensee to whom the device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device.

(2) The device has been manufactured, labeled, installed and serviced in accordance with the specific license issued to the person by the NRC or a state.

(3) The person assures that labels required to be affixed to the device, under regulations of the authority which licensed manufacture of the device, bear a statement that "Removal of this label is prohibited."

(4) The holder of the specific license or his intermediary shall provide a copy of the conditions of general license contained in Subchapter C to the general licensee upon transfer of the radioactive material or installation of a device containing the radioactive material.

(c) The Department may withdraw, limit or qualify its acceptance of a specific license or equivalent licensing document issued by another agency, or product distributed under the licensing document, upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

(d) When a person is granted a general license under subsection (a) and subsequently exceeds the prescribed 180-day period, the person shall file a license application with the Department under Subchapter B within 30 days after the end of the 180-day period.

(e) Implementation of the requirements of this section regarding byproduct, source and special nuclear material is subject to § 217.133 (relating to persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register*).

Source

The provisions of this § 217.203 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282362) to (282363).

APPENDIX A. [Reserved]

Source

The provisions of this Appendix A reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203868) to (203873).

APPENDIX B. [Reserved]

Source

The provisions of this Appendix B reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203874) to (203879).

APPENDIX C. [Reserved]

Source

The provisions of this Appendix C adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135. Immediately preceding text appears at serial pages (123598) to (123600).

APPENDIX D. [Reserved]

Source

The provisions of this Appendix D reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203879) to (203884).

[Next page is 218-1.]

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CHAPTER 218. FEES

GENERAL

Sec.
218.1. Purpose and scope.

PAYMENT OF FEES

218.11. Registration, renewal of registration and license fees.
218.12. Failure by registrant or licensee to pay required fee.

Authority

The provisions of this Chapter 218 issued under sections 302 and 401 of the Radiation Protection Act (35 P. S. §§ 7110.302 and 7110.401), unless otherwise noted.

Source

The provisions of this Chapter 218 adopted December 31, 1987, effective January 2, 1988, 18 Pa.B. 11, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 216.2 (relating to registration); 25 Pa. Code § 216.4 (relating to renewal of certificate of registration); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.134 (relating to filing applications for specific licenses); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 232.1 (relating to purpose and scope).

GENERAL

§ 218.1. Purpose and scope.

(a) This chapter establishes fees for registration and licensing and provides for their payment. For the purpose of this chapter, radiation-producing machines under the same administrative control in a single building are registered or licensed as a single facility. Radiation-producing machines under the same administrative control at the same address or in a contiguous group of buildings may be registered or licensed as a single facility if the Department determines that it is appropriate.

(b) Except as otherwise specifically provided, this chapter applies to a person who:

(1) Is required to register or renew registration for radiation-producing machines or radiation-producing machine service providers under Chapter 216 (relating to registration of radiation-producing machines and radiation-producing machine service providers).

(2) Is an applicant for or holder of a radioactive material license issued under Chapter 217 (relating to licensing of radioactive material).

(3) Is an applicant for or holder of an accelerator license issued under Chapter 228 (relating to radiation safety requirements for particle accelerators).

Authority

The provisions of this § 218.1 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 218.1 amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285659) to (285660).

PAYMENT OF FEES

§ 218.11. Registration, renewal of registration and license fees.

(a) Annual registration fees for radiation-producing machines, other than accelerators, are the sum of an annual administrative fee and an annual fee for each X-ray tube or radiation generating device as follows:

Type Facility	*Annual Administrative Fee*	*Annual Fee per X-ray Tube or Radiation Generating Device*
Dentists, podiatrists, veterinarians	$ 70	$35
Hospitals	$520	$35
Other Facilities	$250	$35

(b) A registrant filing an initial registration under § 216.2 (relating to registration of radiation-producing machines) or an application for renewal of a certificate of registration under § 216.4 (relating to renewal of certificate of registration) shall remit the appropriate fee calculated by using the information on the registration or application form and the fee schedule in subsection (a). Fees for any initial registration under § 216.2 are payable upon the filing of the registration. Fees for the renewal of a certificate of registration are payable upon the submission of an application for a renewal of a certificate of registration. If the number of tubes increases after an initial registration or after an application for renewal has been filed with the Department, no additional fee is required until the time of the next registration. Likewise, if the number of tubes decreases during the year, no refund will be made for that year.

(c) Annual license fees for radioactive material are set forth in Appendix A (relating to fees for radioactive material licenses).

(1) No refund will be made for termination of a license.

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(2) If, by amendment or otherwise, a license changes to another fee category, the fee for the new category will take effect on the anniversary date of the license.

(d) Particle accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Annual fees are as follows:

(i) Accelerators, below 50 MeV, other than for ion implantation—$1,500 for the first accelerator at the facility plus $500 for each additional unit at that facility.

(ii) Accelerators used for ion implantation—$500 plus $50 for each additional unit at the same facility.

(iii) Accelerators above 50 MeV—full cost of staff time to review license applications and conduct inspections as needed. (Hourly rate is $50 per hour). For the purpose of anticipating costs and compliance with subsections (e) and (f), a minimum annual fee of $1,500 for the first accelerator at the facility plus $500 for each additional unit is established. Additional invoices will be issued by the Department at regular intervals at least quarterly when net costs are incurred above the minimum annual fee.

(e) An initial application for a license or reciprocity shall be accompanied by a check payable to the Department in accordance with the fee schedules in subsections (c) and (d). Thereafter, the Department will issue an annual fee invoice in accordance with the appropriate fee schedule at least 2 months prior to the license expiration. Fees are payable by the last day of the license expiration month as shown on the license fee invoice. This provision is not applicable to full cost recovery licenses specified in Appendix A.

(f) The Department will not accept an initial application for a license prior to payment of the fees required by subsections (c) and (d).

(g) If the registration involves more than one of the facilities in subsection (a), or if a license involves more than one of the categories in subsection (c), the highest applicable fee applies.

(h) A radiation-producing machine service provider shall pay an annual registration fee of $100.

Authority

The provisions of this § 218.11 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 218.11 adopted December 31, 1987, effective January 2, 1988, 18 Pa.B. 11; amended May 3, 1991, effective May 4, 1991, 21 Pa.B. 2005; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285660) to (285661).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.2a (relating to registration of radiation-producing machine service providers); 25 Pa. Code § 216.4 (relating to renewal of certificate of registration); 25 Pa. Code § 216.4a (relating to expiration and termination of certificates of registration); and 25 Pa. Code § 228.21a (relating to notification and license requirements).

§ 218.12. Failure by registrant or licensee to pay required fee.

(a) A registrant or licensee who fails to pay an annual fee required under this chapter shall be subject to the civil and criminal penalties provided under the act.

(b) Nonpayment of fees required by this chapter shall be cause for revocation of licenses or registrations issued by the Department under the act.

Authority

The provisions of this § 218.12 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 218.12 amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280. Immediately preceding text appears at serial page (249247).

APPENDIX A

Fees for Radioactive Material Licenses

Fee Category[5,6]	*Description*	*Annual Fee ($)*[1,2,3,4,7]
1C	Special Nuclear Material Sealed Source Gauges (X-Ray Fluorescence)	875
1D	Special Nuclear Material—Other	2,475
2B	Source Material as Shielding	450
2C	Source Material—Other (not 11e2)	8,650
3A1	Manufacturing & Distribution Commercial Broad Scope—10 CFR 30, 33	19,875
3A2	Manufacturing & Distribution Commercial Broad Scope—NARM Only	4,000
3B1	Manufacturing & Distribution Commercial Specific License—10 CFR 30	4,650
3B2	Manufacturing & Distribution Commercial Specific License—NARM Only	2,000
3C1	Manufacturing & Distribution Pharmaceuticals—10 CFR 32.72—32.74	11,650

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Fee Category[5,6]	*Description*	*Annual Fee ($)*[1,2,3,4,7]
3C2	Manufacturing & Distribution Pharmaceuticals—NARM Only	4,000
3D1	Pharmaceuticals—Distribution Only—10 CFR 32.7x	2,825
3D2	Pharmaceuticals—Distribution Only—NARM Only	2,000
3E	Irradiator—Shielded Source	2,575
3F	Irradiator—Unshielded < 10kCi	4,300
3G	Irradiator—Unshielded >= 10kCi	10,750
3I	Distribution As Exempt—No Review of Device	3,525
3J	Distribution—SSD Devices to Part 31 GLs	1,550
3K	Distribution—No Review-Exempt Sealed Source	1,300
3L1	Research & Development Broad Scope	8,300
3L2	Research & Development Broad Scope—NARM Only	2,000
3M1	Research & Development	3,650
3M2	Research & Development—NARM Only	750
3N	Services other than Leak Testing, Waste Disposal or Calibration	3,875
3O	Radiography	10,850
3P1	Other Byproduct Material	1,900
3P2	NARM Licenses not covered elsewhere	750
3Q	Generally licensed devices under § 217.143 (relating to certain measuring, gauging or controlling devices)	315
4A	Waste Storage, Processing or Disposal	Full Cost *
4B	Waste Packaging or Repackaging	8,175
4C	Waste Receipt of Prepackaged for Disposal	6,125
5A	Well Logging & Non Field Flood Tracers	7,500
5B	Well Logging Field Flood Tracer Studies	Full Cost *
6A	Nuclear Laundry	14,250

Fee Category[5,6]	*Description*	*Annual Fee ($)*[1,2,3,4,7]
7A	Human Use—Teletherapy	11,275
7B1	Human Use—Broad Scope (except Teletherapy)	19,975
7B2	Human Use—Broad Scope (except Teletherapy)—NARM Only	2,000
7C1	Human Use—Specific License (except Teletherapy)	4,300
7C2	Human Use—Specific License (except Teletherapy)—NARM Only	750
8A1	Specifically licensed sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	875
8A2	Specifically licensed NARM sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	200
14	Decontamination, Decommissioning, Reclamation or Site Restoration	Full Cost *
16A	Reciprocity (180 days/year)	900
16B	Reciprocity—NARM (180 days/year)	300
$SB1_5$	Small Business—Category 1	2,100
$SB2_6$	Small Business—Category 2	400

[1] A license may include as many as four noncontiguous sites at the base fee. Sites that are within 5 miles of the main Radiation Safety Office where the license records are kept will be considered contiguous. An additional fee of 25% of the base fee will be added for each noncontiguous site above four.

[2] All fees for NARM licenses will be effective upon publication of the final rules in the *Pennsylvania Bulletin*. The fees for NRC licenses that are transferred to the Commonwealth will be effective on the next license anniversary date. NARM licenses will be changed to the corresponding category of byproduct material license on the next license anniversary date after achievement of Agreement State status and fees adjusted at that time. The NARM license categories will cease to exist one year after Agreement State status is achieved.

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[3] Annual fees for categories of NRC licenses that are not included in this table will be calculated as follows: PA Fee = 0.7 (NRC Annual Fee + 0.10 NRC Application or Renewal fee).

[4] Annual fees charged to holders of transferred NRC licenses with multiple sites will not exceed the fees charged by the NRC for the same licenses in the year of transfer, provided the number of noncontiguous sites remains constant.

[5] Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of more than $350,000 and less than $5 million; Manufacturing Entities that have an average of 35—500 employees with Gross Annual Receipts of more than $350,000 and less than $5 million; Small Government Jurisdictions (including publicly supported, nonmedical educational institutions) with a population between 20,000 and 50,000; and nonmedical Educational Institutions that are not state or publicly supported and have 35—500 employees.

[6] Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of less than $350,000; Manufacturing Entities that have an average of less than 35 employees and less than $350,000 in Gross Annual Receipts; Small Government Jurisdictions (including publicly supported nonmedical educational institutions) with a population less than 20,000; and nonmedical Educational Institutions that are not state or publicly supported and have less than 35 employees.

[7] Full cost recovery licensees and licensees required to provide financial assurance for decommissioning are not eligible for reduced fees under category SB1 or SB2.

* Full cost recovery consists of a professional fee, to cover the activities and support of Department personnel, and any other additional incidental charges incurred, such as related contracted services or laboratory costs. The professional fee component (Hourly Rate) is $50 per hour. Other costs are recovered at 100% of actual cost. Invoices shall be issued by the Department at regular intervals but at least quarterly when net costs are incurred.

Authority

The provisions of this Appendix A issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administration Code of 1929 (71 P. S. 510-20).

Source

The provisions of this Appendix A adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6280; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285662) to (285664).

Cross References

This appendix cited in 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees).

[Next page is 219-1.]

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CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subch.		Sec.
A.	GENERAL PROVISIONS	219.1
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C.	[Reserved]	219.31
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J.	PRECAUTIONARY PROCEDURES	219.151
K.	[Reserved]	219.181
L.	[Reserved]	219.201
M.	REPORTS	219.221
N.	[Reserved]	219.241

Authority

The provisions of this Chapter 219 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 219 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 220.2 (relating to posting of notices to workers); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 225.74 (relating to training and testing); 25 Pa. Code § 225.84 (relating to operating and emergency procedures); 25 Pa. Code § 225.91 (relating to radiation survey meter requirements); 25 Pa. Code § 226.1 (relating to purpose and scope); 25 Pa. Code § 228.31a (relating to limitations); 25 Pa. Code § 228.33a (relating to facility and shielding requirements); 25 Pa. Code § 228.38 (relating to radiation safety surveys); 25 Pa. Code § 232.1 (relating to purpose and scope); 25 Pa. Code § 236.15 (relating to protection of individuals during operations); 25 Pa. Code § 236.208 (relating to specific technical information); 25 Pa. Code § 236.209 (relating to technical analyses); 25 Pa. Code § 236.225 (relating to requirements for issuance of license); and 25 Pa. Code § 236.403 (relating to facility operation plan).

Subchapter A. GENERAL PROVISIONS

Sec.
219.1. Purpose.
219.2. Scope.
219.3. Definitions.
219.4. [Reserved].
219.5. Incorporation by reference.
219.6. Effect of incorporation of 10 CFR Part 20.
219.7. Effect of incorporation of 10 CFR 20.1403 "Criteria for license termination under restricted conditions."
219.8. Requirement for a Radiation Safety Committee.
219.11—219.15. [Reserved].

GENERAL PROVISIONS

§ 219.1. Purpose.

(a) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted under licenses or registrations issued by the Department. Licensees and registrants shall comply with this chapter.

(b) The requirements of this chapter are designed to control the receipt, possession, use, transfer and disposal of sources of radiation by a licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter. This chapter does not limit actions that may be necessary to protect health and safety.

Source

The provisions of this § 219.1 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial page (170385).

§ 219.2. Scope.

Except as specifically provided in other chapters of this article, this chapter applies to persons licensed or registered by the Department to receive, possess, use, transfer or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy or to voluntary participation in medical research programs.

Source

The provisions of this § 219.2 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170385) to (170386).

§ 219.3. Definitions.

The following term, when used in this subchapter, has the following meaning, unless the context clearly indicates otherwise:

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Medical reportable event for radiation-producing machine therapy—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a therapeutic radiation dose to the wrong individual.

(ii) An administration of a dose for therapy when the result is an increase in the total expected doses inside or outside of the intended treatment volume for organs, tissue or skin that exceeds 20% of the total prescribed dose for the intended target volume.

(iii) A total dose delivered to the treatment site identified in a written directive for therapy that is outside the prescribed dose range or differs from the total prescribed dose by more than 20%, or for a fractionated dose, when the weekly administered dose differs from the weekly prescribed dose by more than 30%.

Source

The provisions of this § 219.3 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282368) to (282369).

Cross References

This section cited in 25 Pa. Code § 228.35 (relating to operating procedures).

§ 219.4. [Reserved].

Source

The provisions of this § 219.4 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204037).

§ 219.5. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 20 (relating to standards for protection against radiation) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated by reference.

Source

The provisions of this § 219.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 219.6. Effect of incorporation of 10 CFR Part 20.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 20 (relating to standards for protection against radiation), the following words and phrases shall be substituted for the language in 10 CFR Part 20 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) A reference to "licensee" includes registrant.

(4) A reference to "license" includes registration.

(5) A reference to "licensed" includes registered.

(6) A reference to "Department" in 10 CFR means the United States Department of Energy.

(7) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

(8) 10 CFR Part 20, notwithstanding, exposures involving the use of X-rays may be weighted, in a manner specified by the Department, so that, with Department approval, the effective dose equivalent may be substituted for the deep dose equivalent in determining compliance with occupational exposure limits for specified groups of individuals.

Source

The provisions of this § 219.6 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282369) to (282370).

§ 219.7. Effect of incorporation of 10 CFR 20.1403 "Criteria for license termination under restricted conditions."

The Department will not terminate a license under the conditions of restricted release as provided for in 10 CFR 20.1403 (relating to criteria for license termination under restricted conditions) until a license termination plan (LTP), approved by the Department, has been in effect for a period of time sufficient to demonstrate to the Department that continued implementation of the plan will be effective in maintaining compliance with the required conditions of the plan. The Department may choose to implement the license termination process in one or more of the following steps:

(1) The license is amended to authorize activities necessary to begin decommissioning under the LTP.

(2) After decommissioning activities are complete and the provisions of 10 CFR 20.1403 are in effect under the LTP, the license may be amended to end authorization of licensed activities. The license shall remain in effect for up to 5 years being limited to ownership/possession of the decommissioned material.

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(3) At the end of the period prescribed in paragraph (2), the Department will make a determination of the effectiveness of the LTP as enacted. If the LTP has demonstrated the ability to maintain compliance with 10 CFR 20.1403, the license will be terminated subject to the revisitation provision of 10 CFR 20.1401(c) (relating to general provision and scope) regarding new evidence of a significant threat to health and safety. Otherwise, the licensee will be directed by the Department to take corrective actions as necessary to conform to 10 CFR 20.1403 and the process shall revert back to paragraph (2).

Source

The provisions of this § 219.7 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 219.8. Requirement for a Radiation Safety Committee.

The requirements of 10 CFR 35.24 (relating to authority and responsibilities for the radiation protection program) apply to registrants as well as licensees. For the purpose of this requirement, facilities that utilize two or more modalities in which patients are likely to receive, or will receive a dose to an organ in excess of 200 rads (2.0 gray), shall have a radiation safety committee.

Source

The provisions of this § 219.8 adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

§§ 219.11—219.15. [Reserved].

Source

The provisions of these §§ 219.11—219.15 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170386) to (170393).

Subchapter B. [Reserved]

§ 219.21. [Reserved].

Source

The provisions of this § 219.21 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204038) and (249251).

§ 219.22. [Reserved].

Source

The provisions of this § 219.22 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170394) to (170396).

Subchapter C. [Reserved]

§§ 219.31—219.33. [Reserved].

Source

The provisions of these §§ 219.31—219.33 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249251) to (249252) and (204041) to (204042).

§§ 219.34—219.38. [Reserved].

Source

The provisions of these §§ 219.34—219.38 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204042), (249253) to (249254) and (204045) to (204048).

§§ 219.41—219.49. [Reserved].

Source

The provisions of these §§ 219.41—219.49 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170398) to (170404).

Subchapter D. RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

Sec.
219.51. Dose limits for individual members of the public.
219.52. [Reserved].

§ 219.51. Dose limits for individual members of the public.

In addition to incorporation by reference of 10 CFR Part 20 Subpart D (relating to dose limits for individual members of the public), registrants who met the previous limit (5 mSv or 0.5 REM in 1 year) for locations having existing radiation-producing machines or equipment or other registered radiation sources will not be required to retrofit installations existing before November 18, 1995. The Department does not require the retrofitting of shielding for the replacement of equipment in the facility as long as the equipment is being replaced with similar equipment.

Source

The provisions of this § 219.51 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204048) and (249255).

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Cross References

This section cited in 25 Pa. Code § 223.7 (relating to structural shielding).

§ 219.52. [Reserved].

Source

The provisions of this § 219.52 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249256).

Subchapter E. TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

Sec.
219.61. Testing for leakage or contamination of sealed sources.
219.62—219.66. [Reserved].

§ 219.61. Testing for leakage or contamination of sealed sources.

(a) In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), a licensee possessing a sealed source shall assure that:

(1) Except as specified in subsection (b), each sealed source is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee.

(2) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals specified in the Sealed Source and Device Registry approved by the Department, a state or the NRC.

(3) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals specified in the Sealed Source and Device Registry approved by the Department, a state or the NRC.

(4) For each sealed source that is required to be tested for leakage or contamination, the sealed source is tested for leakage or contamination before further use at any time there is reason to suspect that the sealed source might have been damaged or might be leaking.

(5) Except for brachytherapy sources manufactured to contain radium, tests for leakage for sealed sources shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination

to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

(6) The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of radon-222 in a 24-hour period when the collection efficiency for radon-222 and its progeny has been determined with respect to collection method, volume and time.

(7) Tests for contamination from radium progeny shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μCi) of any radium progeny which has a half-life greater than 4 days.

(b) A licensee need not perform tests for leakage or contamination on the following sealed sources:

(1) Sealed sources containing only radioactive material with a half-life of less than 30 days.

(2) Sealed sources containing only radioactive material as a gas.

(3) Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material.

(4) Sealed sources containing only hydrogen-3.

(5) Seeds of iridium-192 encased in nylon ribbon.

(6) Sealed sources, which are stored, are not being used, and are identified as in storage. The licensee shall test each of these sealed sources for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

(c) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Department, an agreement state, a licensing state or the NRC to perform these services.

(d) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Department.

(e) The following shall be considered evidence that a sealed source is leaking:

(1) The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample.

(2) Leakage of 37 Bq (0.001 μCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

(3) The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

(f) The licensee shall immediately withdraw a leaking sealed source from use and take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this article.

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(g) Reports of test results for leaking or contaminated sealed sources shall be made under § 219.227 (relating to reports of leaking or contaminated sealed sources).

Source

The provisions of this § 219.61 adopted June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceding text appears at serial pages (282373) to (282374).

Cross References

This section cited in 25 Pa. Code § 219.227 (relating to reports of leaking or contaminated sealed sources).

§§ 219.62—219.66. [Reserved].

Source

The provisions of these §§ 219.62—219.66 adopted June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170407) to (170410).

Subchapter F. [Reserved]

§ 219.71. [Reserved].

Source

The provisions of this § 219.71 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 3135; amended June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204053).

§ 219.72. [Reserved].

Source

The provisions of this § 219.72 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204054).

§ 219.73. [Reserved]

Source

The provisions of this § 219.73 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204054) and (249257).

§§ 219.74—219.76. [Reserved].

Source

The provisions of these §§ 219.74—219.76 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170414) to (170415).

§ 219.81. [Reserved].

Source

The provisions of this § 219.81 reserved November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085. Immediately preceding text appears at serial pages (170415) to (170417).

Subchapter G. [Reserved]

§§ 219.91—219.93. [Reserved].

Source

The provisions of these §§ 219.91—219.93 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249257) to (249258) and (204057) to (204059).

Subchapter H. [Reserved]

§§ 219.111—219.113. [Reserved].

Source

The provisions of these §§ 219.111—219.113 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204060) to (204062).

Subchapter I. STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

Sec.
219.131. Security of stored sources of radiation.
219.132. Control of sources of radiation not in storage.

Source

The provisions of this Subchapter I adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted. Immediately preceding text appears at serial page (204062).

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§ 219.131. Security of stored sources of radiation.

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), the licensee or registrant shall secure from unauthorized removal or access radiation sources that are in storage.

§ 219.132. Control of sources of radiation not in storage.

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), the licensee or registrant shall maintain control of radiation producing machines that are not in storage.

Subchapter J. PRECAUTIONARY PROCEDURES

Sec.
219.151—219.158. [Reserved].
219.159. Posting of radiation-producing machines.
219.160. Exceptions to posting requirements.
219.161. Exemptions from labeling requirements.
219.162. Procedures for receiving and opening packages.

Source

The provisions of this Subchapter J adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085, unless otherwise noted.

§§ 219.151—219.158. [Reserved].

Source

The provisions of these §§ 219.151—219.158 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249259) to (249260) and (204065).

§ 219.159. Posting of radiation-producing machines.

The registrant or licensee shall ensure that each radiation producing machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized. For example:

**"CAUTION—RADIATION
THIS EQUIPMENT PRODUCES RADIATION
WHEN ENERGIZED."**

Source

The provisions of this § 219.159 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (204065).

§ 219.160. Exceptions to posting requirements.

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), a room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

Source

The provisions of this § 219.160 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204065) to (204066).

§§ 219.161 and 219.162. [Reserved].

Source

The provisions of these §§ 219.161 and 219.162 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204066) to (204068).

Subchapter K. [Reserved]

§§ 219.181—219.186. [Reserved].

Source

The provisions of these §§ 219.181—219.186 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204068) to (204070) and (249261).

Subchapter L. [Reserved]

§§ 219.201—219.211. [Reserved].

Source

The provisions of these §§ 219.201—219.211 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249261) to (249266).

Subchapter M. REPORTS

Sec.
219.221. Reports of stolen, lost or missing licensed or registered sources of radiation.
219.222. Notification of incidents and reportable events.
219.223—219.226. [Reserved].
219.227. Reports of leaking or contaminated sealed sources.

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219.228. Reports of medical reportable events for radiation-producing machine therapy.
219.229. Other medical reports.

Source

The provisions of this Subchapter M adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085, unless otherwise noted.

§ 219.221. Reports of stolen, lost or missing licensed or registered sources of radiation.

In addition to incorporation by reference of the requirements in 10 CFR Part 20 (relating to standards for protection against radiation) covering the reporting requirements associated with reports of theft or loss of licensed material, the following reporting requirements apply to radiation-producing machines:

(1) *Telephone reports.* Each licensee or registrant shall report to the Department by telephone immediately, after its occurrence becomes known, a stolen, lost or missing radiation producing machine.

(2) *Written reports.* Each licensee or registrant required to make a report under paragraph (1) shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

(i) A description of the licensed or registered source of radiation involved, including, for radiation producing machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted.

(ii) A description of the circumstances under which the loss or theft occurred.

(iii) A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved.

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred and the possible total effective dose equivalent to persons in unrestricted areas.

(v) Actions that have been taken, or will be taken, to recover the source of radiation.

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(3) *Additional information.* Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of the information.

(4) *Detachable reports.* The licensee or registrant shall prepare a report filed with the Department under this section so that the names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

Source

The provisions of this § 219.221 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249266) to (249267) and (204077).

Cross References

This section cited in 25 Pa. Code § 225.76 (relating to reporting requirements).

§ 219.222. Notification of incidents and reportable events.

In addition to incorporation by reference of the requirements in 10 CFR 20.2202 and 20.2203 (relating to notification of incidents; and reports of exposures, radiation levels and concentrations of radioactive material exceeding the constraints or limits), those notification requirements, as well as written 30-day reports under 10 CFR 20.2203(a), also apply to radiation-producing machines and NARM.

Source

The provisions of this 219.222 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204077) to (204078).

Cross References

This section cited in 25 Pa. Code § 225.76 (relating to reporting requirements).

§§ 219.223—219.226. [Reserved].

Source

The provisions of these §§ 219.223—219.226 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204078) to (204080) and (249269).

§ 219.227. Reports of leaking or contaminated sealed sources.

If the test for leakage or contamination, required under § 219.61 (relating to testing for leakage or contamination of sealed sources), indicates a sealed source is leaking or contaminated, a report of the test shall be filed within 5 days with the Department describing the equipment involved, the test results and the corrective action taken.

Cross References

This section cited in 25 Pa. Code § 219.61 (relating to testing for leakage or contamination of sealed sources).

§ 219.228. Reports of medical reportable events for radiation-producing machine therapy.

(a) For a medical reportable event for radiation-producing machine therapy, the licensee or registrant shall do the following:

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(1) Notify the Department by telephone within 24 hours after discovery of the event.

(2) Submit a written report to the Department within 15 days after discovery of the event. The written report shall include the licensee's or registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee or registrant notified the patient, or the patient's responsible relative or guardian (for notification purposes under this section, this person will be included in subsequent references to "the patient"), and if not, why not; and if the patient was notified, what information was provided to the patient. The report may not include the patient's name or other information that could lead to identification of the patient.

(3) Notify the referring physician and also notify the patient of the event within 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee or registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee or registrant shall notify the patient as soon as possible thereafter. The licensee or registrant may not delay appropriate medical care for the patient, including necessary remedial care, because of delay in notification.

(4) If the patient was notified, the licensee or registrant shall also furnish, within 15 days after discovery of the event, a written report to the patient by sending one of the following:

(i) A copy of the report that was submitted to the Department.

(ii) A brief description of both the event and the consequences, as they may affect the patient, if a statement is included that the report submitted to the Department can be obtained from the licensee or registrant.

(b) The licensee or registrant shall retain a record of each medical reportable event for radiation-producing machine therapy for 5 years. The record shall contain the names of the individuals involved (including the prescribing physician, allied health personnel, the patient and the patient's referring physician), the patient's Social Security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, this section does not affect rights or duties of licensees or registrants and physicians in relation to each other, patients or the patient's responsible relatives or guardians.

Source

The provisions of this § 219.228 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceding text appears at serial pages (282380) to (282381).

Cross References

This section cited in 25 Pa. Code § 219.229 (relating to other medical reports); and 25 Pa. Code § 228.35 (relating to operating procedures).

§ 219.229. Other medical reports.

Within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological system of a patient exposed to therapeutic or diagnostic radiation from a radiation-producing machine, the registrant or licensee shall document the finding and provide a report to the Department and provide a clinical summary to the prescribing physician and the patient. The report shall be retained for at least 5 years. Exempt from this reporting requirement are any events already reported under § 219.228 (relating to reports of medical reportable events for radiation-producing machine therapy) and any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed.

Source

The provisions of this § 219.229 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceeding text appears at serial pages (282381) to (282382).

Subchapter N. [Reserved]

§ 219.241. [Reserved].

Source

The provisions of this § 219.241 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (249270).

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APPENDIX A. [Reserved]

Source

The provisions of this Appendix A amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204084) to (204087).

APPENDIX B. [Reserved]

Source

The provisions of this Appendix B amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204088) to (204161).

APPENDIX C. [Reserved]

Source

The provisions of this Appendix C adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1987, effective June 20, 1992, 22 Pa.B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204162) to (204169).

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CHAPTER 220. NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS AND INVESTIGATIONS

Sec.
220.1. Purpose and scope.
220.2. Posting of notices to workers.
220.3—220.5. [Reserved].
220.6—220.8. [Reserved].
220.9. Incorporation by reference.
220.10. Effect of incorporation of 10 CFR Part 19.

Authority

The provisions of this Chapter 220 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 220 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 225.74 (relating to training and testing); 25 Pa. Code § 226.1 (relating to purpose and scope); 25 Pa. Code § 228.31a (relating to limitations); 25 Pa. Code § 232.1 (relating to purpose and scope); and 25 Pa. Code § 240.401 (relating to inspection).

§ 220.1. Purpose and scope.

This chapter establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration. This chapter also establishes options available to the individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the act and regulations, orders and licenses issued thereunder regarding radiological working conditions. This chapter applies to persons who receive, possess, use, own or transfer radiation sources licensed by or registered with the Department under Chapters 216 and 217 (relating to registration of radiation-producing machines and radiation-producing machine service providers; and licensing of radioactive material).

§ 220.2. Posting of notices to workers.

(a) A licensee or registrant shall post current copies of the following documents:

(1) This chapter and Chapter 219 (relating to standards for protection against radiation).

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto.

(3) The operating procedures applicable to activities under the license or registration.

(4) A notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued under Chapter 215 (relating to general provisions) and response from the licensee or registrant.

(b) If posting of a document specified in subsection (a)(1), (2) or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Department Form 2900-FM-RP0003, "Notice to Employees," shall be posted by a licensee or registrant as required by this article.

(d) Department documents posted under subsection (a)(4) shall be posted within 2 working days after receipt of the documents from the Department; the licensee's or registrant's response shall be posted within 2 working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

(e) Documents, notices or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from the particular work location to which the document applies. The documents, notices or forms shall be conspicuous and shall be replaced if defaced or altered.

Source

The provisions of this § 220.2 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283. Immediately preceding text appears at serial pages (282385) to (282386).

§§ 220.3—220.5. [Reserved].

Source

The provisions of these §§ 220.3—220.5 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (249272) and (203895).

§§ 220.6—220.8. [Reserved].

Source

The provisions of these §§ 220.6—220.8 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203895) to (203897).

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§ 220.9. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 19 (relating to notices, instructions and reports to workers; inspections and investigations) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated by reference.

Source

The provisions of this § 220.9 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 220.10. Effect of incorporation of 10 CFR Part 19.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 19 (relating to notices, instructions and reports to workers; inspections and investigations), the following words and phrases shall be substituted for the language in 10 CFR Part 19 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) A reference to "license," "licenses," "licensed" and "licensed radioactive material" also include "registration," "registrant" "registered," and "registered source of radiation," respectively.

(4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 220.10 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

[Next page is 221-1.]

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CHAPTER 221. X-RAYS IN THE HEALING ARTS

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221.3. Sale and installation.

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221.14. [Reserved].
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221.39. [Reserved].
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221.40. [Reserved].
221.40a. Indication of tube voltage and current.
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221.41a. Fluoroscopic timer.
221.42. [Reserved].
221.42a. Control of scattered radiation.
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221.44—221.49. [Reserved].

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THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

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Authority

The provisions of this Chapter 221 issued under section 301 of the The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed), unless otherwise noted.

Source

The provisions of this Chapter 221 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL

§ 221.1. Purpose and scope.

This chapter establishes requirements for the use of X-ray equipment by or under the supervision of a licensed practitioner of the healing arts. A registrant who uses X-rays in the healing arts shall comply with this chapter. This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

Authority

The provisions of this § 221.1 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (117772), (42615) and (4877) to (4880).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

AAPM—American Association of Physicists in Medicine.

ACR—American College of Radiology.

Aluminum equivalent—The thickness of type 1100 aluminum alloy—the nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, .12% copper—affording the same attenuation, under specified conditions, as the material in question.

Automatic exposure control—A device which automatically controls one or more technique factors in order to obtain at preselected locations a desired quantity of radiation.

Beam axis—A line from the source through the centers of the X-ray fields.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

Cephalometric device—A device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components—Components of X-ray systems which are subject to regulations promulgated under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C.A. §§ 263b—263n).

Certified system—An X-ray system which has one or more certified components.

Changeable filter—A filter, exclusive of inherent filtration, which can be added to or removed from the useful beam through an electronic, mechanical or physical process.

Coefficient of variation (C)—The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}} \left[{}_{i=1}^{n} \frac{(X_i - \overline{X})^2}{n-1} \right]^{1/2}$$

where

s = Estimated standard deviation of the population.

$\overline{X}$ = Mean value of observations in sample.

X_i = i^{th} observation in sample.

n = Number of observations in sample; n>1.

Contact therapy system—An X-ray system used for therapy with the X-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

Control panel—The part of the X-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

Dead-man switch—A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Dental panoramic system—A device intended to produce a radiographic image of both dental arches on one film.

Diagnostic source assembly—The tube housing assembly with a beam-limiting device attached.

Diagnostic X-ray system—An X-ray system designed for irradiation of a part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation—The scattered radiation coming directly from material irradiated by the useful beam and not scattered by other material.

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Entrance exposure rate—The exposure in air per unit time at the point where the center of the useful beam enters the patient.

Field emission equipment—Equipment using an X-ray tube in which electrons are emitted from the cathode solely by the force between an electric field and the electrons.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and preferentially absorb selected radiation.

Filtration—The amount of material placed in the useful beam to modify the radiation's characteristics, typically expressed in terms of millimeters of aluminum or copper equivalent.

Fluoroscopic imaging assembly—A subsystem in which X-ray photons produce a fluoroscopic image. The term includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic system—See fluoroscopic imaging assembly.

Focal spot—The area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

Half-value layer (HVL)—

(i) The thickness of specified material which attenuates the exposure rate by 1/2 when introduced into the path of a given beam of radiation. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(ii) The term is used to describe the penetrating ability of the radiation.

Healing arts screening—The testing of human beings using X-ray machines for the detection or evaluation of health indications when the tests are not specifically and individually ordered for the purpose of diagnosis or treatment by a licensed practitioner of the healing arts legally authorized to prescribe the X-ray tests.

Image intensifier—A device, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

Image receptor—A device, such as a fluorescent screen or radiographic film, which 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.

Intensifying screen—A fluorescent screen which transforms incident X-ray photons into a visible image.

Intraoral dental radiography—A modality of dental radiography in which the image receptor is placed inside a patient's oral cavity.

kV—Kilovolts

kVp—Peak tube potential (see kilovolts peak).

Kilovolts peak (kVp)—The maximum value of the potential difference across the X-ray tube during an exposure.

Lead equivalent—The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation—Radiation emanating from the diagnostic or therapeutic source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors—The technique factors associated with the tube housing assembly which are used in measuring leakage radiation defined as follows:

(i) For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the charge per exposure being 10 millicoulombs—10 milliampere seconds—or the minimum charge obtainable from the unit, whichever is larger.

(ii) For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of X-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(iii) For other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Licensed practitioner of the healing arts—An individual licensed by the Commonwealth to practice the healing arts, which for the purposes of this article shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

Light field—The area defined by the intersection of the light beam with a plane parallel with the plane of the image receptor. The edge of the field is defined by the points at which the light intensity is 25% of the maximum light intensity in the plane.

Line-voltage regulation—The difference between the no-load and the load line potentials expressed as a percent of the load line potential calculated using the following equation:

Percent line-voltage regulation = $100\ (V_n - V_l)/V_l$

where

V_n = No-load line potential and

V_l = Load line potential.

mA—Milliampere.

mAs—Milliampere second.

mR—Milliroentgen.

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Maximum line current—The root-mean-square current in the supply line of an X-ray machine operating at its maximum rating.

Mobile X-ray system—see X-ray equipment.

Patient—An individual subjected to healing arts examination, diagnosis or treatment.

Peak tube potential—The maximum value of the potential difference across the X-ray tube during an exposure.

Phototimer—A method for controlling the radiation exposures to an image receptor by measuring the radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated.

Portable radiation system—See X-ray equipment.

Position indicating device (PID)—A device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance.

Positive beam limitation—The automatic or semiautomatic adjustment of an X-ray beam to the size of the selected image receptor, whereby an X-ray exposure cannot be made without an adjustment.

Protective apron—An apron incorporating radiation absorbing materials.

Protective barrier—A barrier of radiation absorbing material used to reduce radiation exposure. The term includes the following types:

(i) *Primary protective barrier*—Material used to reduce radiation exposure from the useful beam.

(ii) *Secondary protective barrier*—Material used to reduce exposure from stray, leakage or scattered radiation.

Protective glove—A glove incorporating radiation absorbing materials.

Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Radiation therapy simulation system—A radiographic or fluoroscopic 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.

Radiograph—An image receptor on which an image is created directly or indirectly by an X-ray pattern and results in a permanent record.

Radiographic imaging system—A system whereby an image is produced on an image receptor by the action of ionizing radiation.

Rating—The operating limits specified by the component manufacturer.

Registrant—A person who is legally obligated to register with the Department under this article and the act.

Research—One of the following:

(i) Theoretical analysis, exploration or experimentation.

(ii) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental testing of models, devices, equipment, materials and processes. The term includes the external administration of X-ray radiation to human beings for diagnostic or therapeutic purposes or in an equivalent manner as a diagnostic or therapeutic procedure.

Response time—The time required for an instrument system to reach 90% of its final reading when the instrument system is exposed to a step change from zero radiation flux to a flux sufficient to provide a steady state midscale reading.

SSD—The distance between the source and the skin of the patient.

SID—Source-image receptor distance—The distance from the source to the center of the input surface of the image receptor.

Scattered radiation—Radiation that, during passage through matter, has been deviated in direction.

Screening—See the definition of "healing arts screening."

Serial radiography—Radiographic images produced in regular sequence.

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

Source—The focal spot of the X-ray tube.

Specific prescription—A written or oral directive authorizing a radiographic or fluoroscopic examination of a specified individual.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Spot film—A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device—A device intended to transport or position a radiographic image receptor between the X-ray source and fluoroscopic image receptor. The term includes a device intended to hold a cassette in front of the input end of an image intensifier for the purpose of making a radiograph.

Stray radiation—The sum of leakage and scattered radiation.

Technique factors—The following conditions of operation:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV, number of X-ray pulses and either tube current or product of tube current and time.

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(iii) For other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

Therapeutic X-ray system—A system design for irradiation of a part of the human body for the purpose of treatment or alleviation of symptoms of disease.

Timer—An electronic device which is capable of measuring an X-ray exposure.

Tube—An X-ray tube, unless otherwise specified.

Tube housing assembly—The tube housing with the X-ray tube installed. The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device—A beam-limiting device which has capacity for stepless adjustment of the X-ray field size.

Visible area—The portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray control—A device which controls input power to the X-ray high-voltage generator or the X-ray tube, or both. The term includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an X-ray exposure.

X-ray equipment—An X-ray system, subsystem or component thereof. Types of X-ray equipment are as follows:

(i) *Mobile X-ray equipment*—X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(ii) *Portable X-ray equipment*—X-ray equipment designed to be hand-carried.

(iii) *Stationary X-ray equipment*—X-ray equipment which is installed in a fixed location or vehicle.

X-ray field—The area defined by the intersection of the useful beam with a plane parallel with the plane of the image receptor. The edge of the field is defined by the points at which the exposure rate is 25% of the maximum exposure rate in the plane.

X-ray high-voltage generator—A device which transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential.

X-ray subsystem—A combination of two or more components of an X-ray system.

X-ray system—An assembly of components for the controlled production of X-rays. The term includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device and the necessary

supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray tube—An electron tube which is designed to be used primarily for the production of X-rays.

Authority

The provisions of this § 221.2 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282389) to (282390) and (249277) to (249282).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.201 (relating to definitions).

§ 221.3. Sale and installation.

No person may sell or install a radiation–producing machine that does not meet the provisions of this article.

Authority

The provisions of this § 221.3 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4881).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

(a) The registrant is responsible for directing the operation of X-ray systems under his administrative control and shall assure that the requirements of this article are met in the operation of the X-ray systems.

(b) An individual who operates an X-ray system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include items included in Appendix A (relat-

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ing to determination of competence) and there shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

(c) A chart, which specifies the techniques for examinations performed with the system, shall be provided in the vicinity of each diagnostic X-ray system's control panel. This chart shall include information pertinent to the particular examination, such as:

(1) The patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized.

(2) The type and size of the film or film-screen combination.

(3) The type of grid, if any.

(4) The type and location of placement of patient shielding-for example, gonad, and the like.

(5) For mammography, indication of kVp/target/filter combination.

(6) Source to image receptor distance to be used, except for dental intraoral radiography.

(d) Written safety procedures and rules shall be available at a facility including restrictions of the operating technique required for the safe operation of the particular X-ray system. The operator shall be able to demonstrate familiarity with the rules.

(e) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. The following apply for individuals other than the patient being examined:

(1) Individuals shall be positioned so that no part of the body will be struck by the useful beam unless protected by at least 0.5 millimeter lead equivalent material. The lead equivalent of the material is to be determined at 60 kV.

(2) All persons required for the medical procedure shall be protected from the stray radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be so positioned that the persons are not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(3) A patient who cannot be removed from the room shall be protected from the stray radiation by protective barriers of at least 0.25 millimeter lead equivalent material unless the shield would compromise the health of the individual or shall be so positioned that the patient is not in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(4) No individual, other than the patient being examined, may be in the useful beam, unless required to conduct the procedure.

(f) During diagnostic procedures in which the gonads are in the useful beam, gonad shielding of at least 0.5 millimeter lead equivalent shall be used for patients except for cases in which this would interfere with the diagnostic procedure.

(g) An individual may not be exposed to the useful beam except for healing arts purposes or under § 221.15 (relating to use of X-rays in research on humans). An exposure shall be authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration or other nonhealing arts purposes.

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by the Department. When requesting authorization, the registrant shall submit the information outlined in § 221.13 (relating to information to be submitted by persons requesting approval to conduct healing arts screening).

(h) If a patient or image receptor requires auxiliary support during a radiation exposure the following apply:

(1) Mechanical holding devices shall be used when the technique permits.

(2) The human holder shall be protected as required by subsection (e).

(3) An individual may not be used routinely to hold image receptors or patients.

(i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(j) The screen and film system used shall be spectrally compatible. Defective screens may not be used for diagnostic radiological imaging.

(k) With the exception of intraoral dental radiography, film may not be used without intensifying screens for routine diagnostic radiological imaging.

(l) The registrant shall have a quality assurance program. This quality assurance program shall be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address repeat rate; image recording, processing and viewing; and maintenance and modifications to the quality assurance program. Records shall be maintained by the registrant for inspection by the Department for 3 years. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

(m) Neither the X-ray tube housing nor the collimating device may be handheld during the exposure.

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Authority

The provisions of this § 221.11 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249282), (285667) to (285669).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.42a (relating to control of scattered radiation).

§ 221.12. Records, maintenance and associated information.

The registrant shall maintain records of surveys, calibrations, maintenance and modifications performed on the X-ray systems including the names of persons who performed the services. The registrant shall keep these records for inspection by the Department for 5 years.

Authority

The provisions of this § 221.12 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123681).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.13. Information to be submitted by persons requesting approval to conduct healing arts screening.

(a) The Department will consider efficacy as a factor in evaluating healing arts screening procedures. In its review, the Department will consider National medical organization consensus statements as well as peer reviewed scientific and medical literature that addresses the efficacy of the proposed screening procedures. The review may also consider relevant information from appropriate Federal agencies. For procedures that result in an individual organ dose or deep dose equivalent greater than 1 mSv (100 mrem) to a screened individual the Department will consult with the Department of Health (DOH) for assistance in review-

ing the efficacy of the proposed procedures but the final decision will remain that of the Department. The DOH will have access to all relevant materials when rendering its review.

(b) A person requesting that the Department approve a healing arts screening program shall submit in writing the following information for evaluation by the Department. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) The diseases or conditions for which the X-ray examinations are to be used.

(3) The description in detail of the X-ray examinations proposed in the screening program.

(4) A description of the population to be examined in the screening program—age, sex, physical condition and other appropriate information.

(5) An evaluation of all known alternate methods that could achieve the goals of the screening program and why these methods are not used in preference to the proposed X-ray examinations.

(6) An evaluation by a qualified expert of the X-ray systems to be used in the screening program. The evaluation shall show that the systems satisfy the requirements of this article. The evaluation shall include a measurement of patient entrance exposures and calculation of the maximum shallow dose, deep dose equivalent and organ dose from the X-ray examinations to be performed.

(7) A description of the diagnostic X-ray quality control program.

(8) A copy of the technique chart for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(9) The qualifications of all individuals who will be operating the X-ray systems.

(10) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(11) The name, address and qualifications of the individual who will interpret the screening procedure results.

(12) A description of the information and procedure for advising the individuals screened of the potential for false positive or negative results and the implications for the patient; the procedure for recording informed consent for the procedure following disclosure of this information; and the procedure for advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and further medical needs indicated.

(13) A description of the procedures for the retention or disposition of the diagnostic images, data and other records pertaining to the X-ray examination.

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(14) Mammography facilities shall comply with 21 CFR Part 900 (relating to mammography).

(15) An approximation of the frequency of screening activities and duration of the entire screening program.

Authority

The provisions of this § 221.13 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285669) to (285670).

Cross References

This section cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities); and 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.14. [Reserved].

Source

The provisions of this § 221.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

§ 221.15. Use of X-rays in research on humans.

(a) Registrants conducting research using X-rays involving human subjects are exempted from the requirements of this section if the research is conducted, funded, regulated or supported by a Federal agency which has implemented the Federal policy for the protection of human subjects or if the research is carried out in an institution which conducts other Federally funded or supported human research and follows all Federal requirements for protocol review and research subject protection.

(b) If not exempted under subsection (a), a person shall submit, in writing, the following information and evaluation to the Department and receive approval by the Department before conducting the research. If the information submitted to the Department becomes invalid or outdated, the person shall immediately, in writing, notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) A description of the population to be examined in the research program, age, sex, physical condition and other appropriate information.

(3) An evaluation of all known alternate methods that could achieve the goals of the research program and why these methods are not used in preference to the X-ray examinations.

(4) An evaluation by a qualified expert of the X-ray system to be used in the research program. This evaluation shall show that the system satisfies the requirements of this article. The evaluation shall include a projected measurement of individual and cumulative patient exposures from the X-ray examinations to be performed.

(5) A description of the diagnostic X-ray quality control program.

(6) A copy of the technique chart which specifies the information for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(7) The qualifications of all individuals who will be operating the X-ray system.

(8) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(9) The name, address and qualifications of the individual who will interpret the data.

(10) A copy of the research protocol authorized by a committee consisting of at least three qualified persons. At least one of the committee members shall be knowledgeable in radiation effects on humans.

(11) The provisions for independent institutional review.

(c) Proposed subjects or their legal representative shall sign a statement acknowledging that they have been informed of their anticipated radiation exposure and possible consequences arising from this exposure.

Authority

The provisions of this § 221.15 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.15 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3238. Immediately preceeding text appears at serial pages (249287) to (249288).

Cross References

This section cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities); and 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

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DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.21. Diagnostic equipment requirements.

Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30—1020.33.

Authority

The provisions of this § 221.21 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123683).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.22. Battery charge indicator.

On battery-powered X-ray generators, the control panel shall have means to indicate visually whether the battery is adequately charged for proper operation.

Authority

The provisions of this § 221.22 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.23. Leakage radiation from the diagnostic source assembly.

The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Authority

The provisions of this § 221.23 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4882).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.24. Radiation from components other than the diagnostic source assembly.

The radiation emitted by a component other than the diagnostic source assembly may not exceed 2 milliroentgens (.516 μC/kg) in 1 hour at 5 centimeters from an accessible surface of the component when it is operated in an assembled X-ray system under conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

Authority

The provisions of this § 221.24 amended under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4882) to (4883).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.25. Beam quality.

(a) Diagnostic X-ray systems shall have filtration that satisfies the requirements of Table I. The requirements of this section shall be considered to have been met if it can be demonstrated that the half value layer of the primary beam is not less than that shown in Table II.

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TABLE I

Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	*Total Filtration (inherent plus added) (millimeters aluminum equivalent)*
Below 50	.5 millimeters
50—70	1.5 millimeters
Above 70	2.5 millimeters

TABLE II

Design operating range (Kilovolts peak)	*Measured potential (Kilovolts peak)*	*Minimum half-value layer (millimeters of aluminum)*	
		Specified dental systems*	All other X-ray systems
Below 51	30	1.5	0.3
	40	1.5	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

Note: Half-value layers for kilovoltages not listed in Table II may be determined by interpolation or extrapolation.

* Dental systems manufactured after December 1, 1980, designed for use with intraoral image receptors.

(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(c) For capacitor energy storage equipment, compliance with this section shall be determined with the maximum quantity of charge per exposure.

(d) The required minimal aluminum equivalent filtration shall include the filtration contributed by materials which are always present between the source and the patient.

(e) For X-ray systems having variable filtration in the useful beam, a means shall be provided to prohibit exposure unless the filtration requirements of subsection (a) are met for the kVp selected.

Authority

The provisions of this § 221.25 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.25 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3238. Immediately preceeding text appears at serial pages (249290) and (285671).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.26. Multiple tubes.

If two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

Authority

The provisions of this § 221.26 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.26 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.27. Mechanical support of tube head.

The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

Authority

The provisions of this § 221.27 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

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Source

The provisions of this § 221.27 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.28. Technique indicators.

(a) The technique factors for radiographic systems shall be indicated before exposure except for units utilizing automatic exposure controls, in which case the maximum mAs shall be indicated.

(b) The requirement of subsection (a) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by a fluoroscopist.

Authority

The provisions of this § 221.28 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.27 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123686).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.29. Kilovoltage (kV) accuracy.

(a) For variable kV units, the kV output may not vary from the set-indicated value by more than 10% over the range of technique factors normally used. Discrepancies of more than 10% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

(b) For fixed kV units, the kV output may not vary from the set-indicated value by more than 20% over the range of technique factors normally used. Discrepancies of more than 20% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

Authority

The provisions of this § 221.29 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.29 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285672) to (285673).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.30. Exposure reproducibility.

The coefficient of variation of exposure reproducibility may not exceed 0.10 when technique factors are held constant. This requirement shall be deemed to have been met when four exposures are made. This requirement applies when either manual techniques or automatic exposure control is used.

Authority

The provisions of this § 221.30 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.30 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.31. [Reserved].

Source

The provisions of this § 221.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123686) to (123688).

§ 221.31a. Locks.

Position locking, holding and centering devices on X-ray systems shall function as intended.

Authority

The provisions of this § 221.31a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.31a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

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Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.32. [Reserved].

Source

The provisions of this § 221.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123688).

§ 221.32a. Radiographic beam limitation.

(a) The useful beam shall be limited to the area of clinical interest.

(b) The beam limiting device shall do one of the following:

(1) Indicate numerically the field size in the plane of the image receptor to which it is adjusted to within 2% of the SID.

(2) Provide for visually defining the perimeter of the X-ray field except for systems designed for one image receptor size. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field may not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

(c) A means shall be provided for stepless (continuous) adjustment of the size of the X-ray field except for systems which use removable fixed operation beam limiting devices.

(d) A means shall be provided to:

(1) Indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor if the angle between the axis of the X-ray beam and the plane of the image receptor is variable. This paragraph does not apply to portable, mobile or intraoral dental units.

(2) Align the center of the X-ray field with respect to the center of the image receptor to within 2% of the SID.

(3) Indicate the SID to within 2%.

(e) Intraoral dental X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD to not less than either of the following:

(1) Eighteen centimeters if operable above 50 kVp.

(2) Ten centimeters if not operable above 50 kVp.

(f) Indication of field size dimensions and SIDs shall be specified so that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(g) Intraoral dental systems designed for use with an intraoral image receptor shall be provided with a means to limit the X-ray beam so that:

(1) Eighteen centimeters or more, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

(2) Less than 18 centimeters, the X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(h) When positive beam limitation is used, the following conditions shall be met:

(1) The radiation beam may not be larger than the linear dimensions of the image receptor being used.

(2) The positive beam limitation device shall allow the operator to further reduce the size of the radiation field.

(i) Mobile or portable radiographic systems, other than intraoral dental X-ray systems, shall be provided with a means to limit the source-to-skin distance to at least 30 centimeters.

(j) Radiographic equipment designed for one or more image receptor sizes at a fixed SID shall be provided with a means to accomplish one of the following:

(1) Limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and align the center of the X-ray field with the center of the image receptor to within 2% of the SID.

(2) The X-ray field shall be sized and aligned so that at the plane of the image receptor, it does not extend beyond the edge of the image receptor by more than 2% of the SID.

Authority

The provisions of this § 221.32a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.32a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (254508) and (249295).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.33. [Reserved].

Source

The provisions of this § 221.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123688) to (123689).

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§ 221.33a. Radiation from capacitor energy storage equipment in standby status.

Radiation emitted from an X-ray tube when the exposure switch or timer in not activated may not exceed a rate of 2 milliroentgens (0.516 μC/kg) per hour at 5 centimeters from an accessible surface of a fully charged diagnostic source assembly, with the beam-limiting device fully open.

Authority

The provisions of this § 221.33a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.33a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (249295) to (249296).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.34. [Reserved].

Source

The provisions of this § 221.34 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123690).

§ 221.34a. Radiation exposure control.

(a) *Radiation exposure control.* A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure may not be initiated without such an action.

(b) *Visual indication and audible signal.* A means shall be provided for visual indication observable from the operator's protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) *Termination of exposure.* A means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the time to its initial setting or to "zero."

(d) *Manual exposure control.* An X-ray control shall be incorporated into each X-ray system which allows the operator to terminate an exposure at any time except for one or more of the following:

(1) Exposure of 1/2 second or less.

(2) During serial radiography in which case a means shall be provided to permit completion of any single exposure of the series in process.

(e) *Automatic exposure control.*

(1) Indication shall be made on the control panel when this mode of operation is selected.

(i) A means shall be provided to terminate irradiation at an appropriate exposure for the projection if the automatic exposure control fails to terminate irradiation.

(ii) A visible signal shall indicate when an exposure has been terminated at the limits required by subparagraph (i), and manual resetting shall be required before further automatically timed exposures can be made.

(2) For X-ray systems operating in automatic exposure control mode, and which lack engineered safeguards that prevent exposure in the event of either a malfunction or a mispositioned X-ray beam with respect to film cassette sensors, the back-up or default mAs shall be set by the operator to an appropriate maximum value for the projection.

(3) X-ray systems utilizing automatic exposure control, in which the back-up mAs values are preset and cannot be selected by the operator, shall prominently indicate the preset mAs value on the console, along with an appropriate warning notice to the operator.

(f) *Exposure control location.*

(1) Stationary X-ray systems shall have X-ray controls permanently mounted in a protected area and situated so that the operator is required to remain in that protected area during the entire exposure.

(2) For mobile and portable X-ray systems the exposure switch shall be arranged so that the operator can stand at least 2 meters from the patient and from the tube head and away from the direction of the useful X-ray beam.

Authority

The provisions of this § 221.34a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.34a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems).

§ 221.35. [Reserved].

Source

The provisions of this § 221.35 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123690) to (123691).

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§ 221.35a. Fluoroscopic X-ray systems.

Fluoroscopic X-ray systems shall use an image intensifier and in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

Authority

The provisions of this § 221.35a issued under sections 301 and 302 of the Radiation Protection Act (31 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.35a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.36. [Reserved].

Source

The provisions of this § 221.36 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123691).

§ 221.36a. Limitation of useful beam of fluoroscopic equipment.

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

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless a barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(c) A means shall be provided for stepless (continuous) adjustment of the field size.

(d) The minimum field size at the greatest source to image receptor distance shall be containable in a square of 5 centimeters by 5 centimeters unless otherwise provided in 21 CFR 1020.32(b) (relating to fluoroscopic equipment).

(e) Equipment may not be operated at a source to skin distance less than 30 centimeters or as required under 21 CFR 1020.32(g).

(f) The width of the X-ray field in the plane of the image receptor may not exceed that of the visible area of the image receptor by more than 3% of the source to image receptor distance. The sum of the excess length and the excess width may not be greater than 4% of the source to image receptor distance.

(g) For rectangular X-ray fields used with a circular image receptor, the error in alignment shall be determined along the length and width dimensions of the X-ray field which passes through the center of the visible area of the image receptor.

(h) Compliance with subsections (a)—(g) shall be determined with the beam axis perpendicular to the plane of the image receptor.

(i) Spot-film devices shall meet the following additional requirements:

(1) A means shall be provided between the source and the patient for adjustment of the X-ray field size to the size of the portion of film which has been selected on the spot-film selector.

(2) The adjustments shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the film.

(3) The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor may not exceed 3% of the source-to image receptor when adjusted for full coverage of the selected portion of the image receptor.

(4) The sum, without regard to sign, of the misalignment along any two orthogonal dimensions, may not exceed 4% of the source to image receptor distance.

(5) The center of the X-ray field in the plane of the film shall be aligned with the center of the film within 2% of the source to image receptor distance.

Authority

The provisions of this § 221.36a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.36a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285678) to (285679).

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.37. [Reserved].

Source

The provisions of this § 221.37 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123691) to (123692).

§ 221.37a. Activation of fluoroscopic tube.

X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of the exposure (dead-man switch). When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate X-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

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Authority

The provisions of this § 221.37a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.37a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.38. [Reserved].

Source

The provisions of this § 221.38 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123692).

§ 221.38a. Entrance exposure rate.

(a) *Fluoroscopic systems without high level control.* The exposure rate may not exceed 10 roentgens (2.58 mC/kg) per minute except during recording of fluoroscopic images.

(b) *Fluoroscopic systems with high level control.*

(1) When the high level control is activated, the maximum exposure rate shall be 20 roentgens (5.16 mC/kg) per minute.

(2) When the high level control is not activated, the maximum exposure rate shall be 10 roentgens (2.58 mC/kg) per minute.

(3) Special means of activation of high level controls are required. The high level control shall only be operable when continuous manual activation is provided by the operator.

(4) There shall be an indication to the fluoroscopist that the high level control is being used.

(c) *Frequency of output measurements.* Output measurements to show compliance with this section shall be made at least annually and after maintenance that could affect the output of the machine.

(d) *Compliance requirements.* Compliance with subsections (a)—(c) shall be determined as follows:

(1) If the source is below the table, the exposure rate shall be expressed for the center of the useful beam 1 centimeter above the tabletop or cradle with the image intensifier 30 centimeters above the tabletop or cradle.

(2) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(3) In a c-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source at its closest possible position of operation.

(4) The tube potential and current shall be set to give the maximum exposure possible from the X-ray system. For systems with automatic exposure control, at least 3 millimeters of lead shall be placed between the measuring device and image receptor.

(5) The measurement shall be made at the center of the useful beam.

Authority

The provisions of this § 221.38a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.38a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); and 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.39. [Reserved].

Source

The provisions of this § 221.39 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123692) to (123693).

§ 221.39a. Barrier transmitted radiation rate limits.

The protective barrier may not transmit more than 2 milliroentgens (.516 μmC/kg) per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly for each roentgen per minute of entrance exposure rate.

Authority

The provisions of this § 221.39a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.39a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.40. [Reserved].

Source

The provisions of this § 221.40 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123693).

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§ 221.40a. Indication of tube voltage and current.

During fluoroscopy and cinefluorography, the voltage and the current shall be continuously indicated.

Authority

The provisions of this § 221.40a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.40a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.41. [Reserved].

Source

The provisions of this § 221.41 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123693).

§ 221.41a. Fluoroscopic timer.

A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

Authority

The provisions of this § 221.41a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.41a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.35a (relating to fluoroscopic X-ray systems); 25 Pa. Code § 221.43a (relating to mobile fluoroscopes); and 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems).

§ 221.42. [Reserved].

Source

The provisions of this § 221.42 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (123694).

§ 221.42a. Control of scattered radiation.

(a) Fluoroscopic table designs when combined with normal operating procedures shall be of a type so no unprotected part of the staff or an ancillary individual's whole body is exposed to unattenuated scattered radiation which originates from under the table. The attenuation required may be not less than .25 millimeter lead equivalent.

(b) Equipment configuration when combined with normal operating procedures shall be of a type so that no portion of the staff or an ancillary individual's whole body, except the extremities, is exposed to the unattenuated scattered radiation emanating from above the table top unless one of the following criteria is met:

(1) The individual is at least 120 centimeters from the center of the useful beam.

(2) The radiation has passed through at least .25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover (film-tray cover panel), sliding or folding panel or self supporting curtains—in addition to lead equivalency provided by the protective apron referred to in § 221.11(e) (relating to registrant responsibilities).

Authority

The provisions of this § 221.42a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.42a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.43a (relating to mobile fluoroscopes).

§ 221.43. [Reserved].

Source

The provisions of this § 221.43 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123694) to (123695).

§ 221.43a. Mobile fluoroscopes.

In addition to the other requirements of §§ 221.35a—221.42a, mobile fluoroscopes shall provide image intensification.

Authority

The provisions of this § 221.43a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.43a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

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§§ 221.44—221.49. [Reserved].

Source

The provisions of these §§ 221.44—221.49 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123694) to (123698).

§§ 221.51—221.55. [Reserved].

Source

The provisions of these §§ 221.51—221.55 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123698) to (123701).

§ 221.56. [Reserved].

Source

The provisions of this § 221.56 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (249304) and (254511).

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

(a) Fluoroscopic systems used solely for radiation therapy simulations shall comply with §§ 221.35a, 221.37a, 221.40a and 221.41a. The requirements in § 221.41a (relating to fluoroscopic timer) may also be satisfied if a means is provided to indicate the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.

(b) CT units used solely for therapy simulations shall comply with §§ 221.202(f)(1), (7) and (8) and 221.203 (relating to equipment requirements; and facility design requirements).

Authority

The provisions of this § 221.61 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.61 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (285683).

§ 221.62. [Reserved].

Source

The provisions of this § 221.62 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123701) to (123702).

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.71. Equipment requirements.

(a) When the tube is operated at its leakage technique factors, the leakage radiation may not exceed:

(1) One hundred milliroentgens (25.8μC/kg) per hour at 5 centimeters from the surface of the tube housing assembly for contact therapy systems.

(2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured or installed prior to December 19, 1987.

(3) One hundred milliroentgens (25.8μC/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured on or after December 19, 1987.

(4) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 151 to 500 kVp systems.

(5) One-tenth percent of the exposure rate of the useful beam 1 meter from the source for 501 to 999 kVp systems at 1 meter from the source.

(b) Fixed diaphragms or cones used for limiting the useful beam shall provide at least the same protection as required by the tube housing assembly.

(c) Beam limiting devices may, for the portion of the useful beam blocked by these devices, transmit not more than 5% of the original X-ray beam intensity at the maximum voltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(d) The filter system shall be designed so that:

(1) Filters cannot be accidentally displaced from the useful beam at any possible tube orientation.

(2) The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under operating conditions.

(3) A filter is marked as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.

(4) On equipment purchased after January 1, 1971, a filter indication system shall be used on therapy machines using changeable filters. The system shall indicate from the control panel the presence or absence of a filter and shall be designed to permit easy recognition of an added filter in place.

(5) An X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(e) The tube housing assembly shall be immobilized during stationary treatments.

(f) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and the marking shall be readily accessible for use during calibration procedures.

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(g) Contact therapy tube housing assemblies shall have a removable shield of at least .5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(h) Systems of greater than 150 kVp manufactured after December 19, 1987, shall have a beam monitor system which shall meet the following requirements:

(1) Not allow irradiation until a preselected value of exposure has been made at the treatment control panel.

(2) Independently terminate irradiation when the preselected exposure has been reached.

(3) Be designed so that, in the event of a system malfunction or electrical power failure or other interruption, the dose administered to a patient prior to the interruption can be accurately determined.

(4) Have a control panel display which maintains the reading until intentionally reset to zero.

(5) Have a control panel display which does not have scale multiplying factors and utilizes a design so that increasing dose is displayed by increasing numbers.

(i) The following apply to times on the equipment:

(1) A timer shall be provided which has a display at the control panel. The timer shall be graduated in minutes and fractions of minutes. The timer shall have a preset time selector and an elapsed time indicator.

(2) The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer to zero.

(3) The timer shall terminate irradiation when a preselected time has elapsed if a dose monitoring system present has not previously terminated irradiation.

(4) The timer shall permit accurate presetting and determination of exposure time as short as 1 second.

(5) The timer may not permit an exposure if set at zero.

(6) The timer may not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

(j) The control panel, in addition to the displays required in this section, shall have:

(1) An indication of power status.

(2) An indication of X-ray production.

(3) The means of indicating X-ray tube current and voltage.

(4) The means of terminating an exposure.

(k) When a control panel may energize more than one X-ray tube, the following requirements shall be met:

(1) It shall be possible to activate only one X-ray tube at one time.

(2) There shall be an indication at the control panel identifying which X-ray tube is energized.

(3) There shall be an indication at the tube housing assembly when that tube is energized.

(l) There shall be a means of determining the SSD to within 5 millimeters.

(m) Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

(1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

(2) An indication of shutter position shall appear at the control panel.

Authority

The provisions of this § 221.71 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.71 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§ 221.72. Facility design requirements for systems capable of operating above 50 kVp.

(a) Provision shall be made to permit continuous observation of and communication with the patient during irradiation.

(b) Windows, mirror systems or closed-circuit television viewing screens used for observing the patient shall be so located that the operator can maintain direct surveillance over both the control panel and the patient.

(c) Treatment rooms which contain an X-ray system capable of operating above 150 kVp shall meet the following additional requirements:

(1) Necessary shielding, except for a beam interceptor, shall be provided by fixed barriers.

(2) The control panel shall be outside the treatment room or in a shielded booth.

(3) Doors of the treatment room shall be electrically interlocked to the control panel so that X-ray production cannot occur unless entrance doors are closed.

(4) Interlocks shall be provided so that, when a door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than two milliroentgens (.52 μC/kg) per hour and a maximum of ten milliroentgens (2.58 μC/kg) per hour at a distance of 1 meter in any direction from the target; or interlocks shall energize a conspicuous visible or audible alarm signal so that the individual entering and the operator are made aware of the entry. After a shut-off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

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(5) Treatment room entrances shall be provided with warning lights, which will indicate when the useful beam is on, in a readily observable position near the outside of access doors.

Authority

The provisions of this § 221.72 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.72 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§ 221.73. Surveys.

(a) A facility shall have a survey made by, or under the direction of, a qualified expert. The survey shall also be done after a change in the facility or equipment which might cause a change in radiation levels.

(b) The qualified expert or radiological physicist shall report the survey results in writing to the individual in charge of the facility and a copy of the report shall be maintained by the registrant for inspection by the Department. The facility shall be operated in compliance with limitations indicated by the survey.

Authority

The provisions of this § 221.73 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.73 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (249309).

§ 221.74. Calibration.

(a) The calibration of an X-ray system shall be performed at intervals not to exceed 1 year and after a change of replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation output of the X-ray system shall be performed by or under the direction of a qualified expert for radiation therapy calibration who is physically present at the facility during the calibration.

(c) The calibration of the radiation output of an X-ray system shall be performed with a calibrated instrument. The calibration of the instrument shall be traceable to a National standard. The instrument shall have been calibrated within the preceding 2 years.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

(e) The calibration of the X-ray system shall include, but is not limited to, the following determinations:

(1) The exposure rates for each combination of field size, technique factors, filter and treatment distance used.

(2) The degree of congruence between the radiation field and the field indicated by the localizing device if a device is present.

(3) An evaluation of the uniformity of the largest radiation field used.

(f) Records of calibration performed under this section shall be maintained by the registrant for at least 5 years after completion of the calibration.

(g) A copy of the most recent X-ray system calibration shall be available at the control panel.

Authority

The provisions of this § 221.74 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.74 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249309) to (249310).

Cross References

This section cited in 25 Pa. Code § 221.75 (relating to spot checks).

§ 221.75. Spot checks.

Spot checks shall be performed on X-ray systems capable of operation at greater than 150 kVp. The spot checks shall meet the following requirements:

(1) The procedures shall be in writing and shall have been developed by a qualified expert for radiation therapy calibration.

(2) If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within 15 days.

(3) The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the X-ray system.

(4) The spot-check procedure shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in § 221.74 (relating to calibration).

(5) The procedure shall also note conditions which require that the system be recalibrated under § 221.74.

(6) Records of spot-check measurements performed under this section shall be maintained by the registrant for 5 years following the measurement.

(7) Spot check measurements shall be performed using a dosimetry system that has been calibrated under § 221.74(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated under § 221.74(c). The alternative calibration method shall have been performed within the previous year and after each servicing that may have affected the system calibration.

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Authority

The provisions of this § 221.75 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.75 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249310) to (249311).

§ 221.76. Operating procedures.

(a) Therapeutic X-ray systems shall be secured to prevent unauthorized use whenever the system is unattended.

(b) If a patient is held in position for radiation therapy, mechanical supporting or restraining devices shall be used.

(c) The tube housing assembly may not be held by an individual during exposures.

(d) No individual other than the patient may be in the treatment room during irradiation unless protected by a shielded booth.

(e) Interlocks, on-off beam control mechanisms and safety and warning devices shall be checked and appropriately serviced at least once in a calendar year.

Authority

The provisions of this § 221.76 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.76 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

§§ 221.81—221.102. [Reserved].

Source

The provisions of these §§ 221.81—221.102 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (123709) to (123726).

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

In addition to the definitions in §§ 215.2 and 221.2 (relating to definitions), the following words and terms when used in this section and §§ 221.202—221.205, have the following meanings, unless the context clearly indicates otherwise:

CS—Contrast scale—The change in the linear attenuation coefficient per CT number relative to water; that is:

$$CS = (U_x - U_w)/((CT)_x - (CT)_w)$$

Where:
U_x = Linear attenuation coefficient of the material of interest
U_w = Linear attenuation coefficient of water
$(CT)_x$ = CT number of the material of interest
$(CT)_w$ = CT number of water

CT number—The number used to represent the X-ray attenuation associated with each elemental area of the CT image.

CT—Computed tomography—The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

CTDI—Computed tomography dose index—The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

CT conditions of operation—The selectable parameters governing the operation of a CT X-ray system including, but not limited to, nominal tomographic section thickness, filtration and the technique factors as defined in this chapter.

Elemental area—The smallest area within a tomogram for which the X-ray attenuation properties of a body are depicted.

Gantry—The tube housing assemblies, beam-limiting devices, detectors, transformers, if applicable, and the supporting structures and frames which hold these components.

Lux—A unit illumination equivalent to 1 lumen per square centimeter or .0929 foot-candles.

MSAD—Multiple scan average dose—The calculated average dose to the tissue within each slice in a series utilizing an ion chamber. The MSAD is calculated using the following equation:

$$MSAD = (F \times K \times L \times E)/(T \times N)$$

Where
F = Factor to convert exposure in air to absorbed dose in lucite in RADS/mR
K = Calibration factor to account for the ion chamber's response and volume.
L = Effective length of ion chamber in millimeters (mm)
E = Exposure reading in milliroentgen (mR)
T = Nominal slice thickness in millimeters (mm) and
N = Number of slices per scan

Multiple tomogram system—A computed tomography X-ray system which obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise—The standard deviation of the fluctuations in the CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = 100 \times CS \times S/U_w$$

Where:
CS = Contrast scale

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U_w = Linear attenuation coefficient of water.

S = Estimated standard deviation of the CT number of picture elements in a specified area of the CT image.

Nominal tomographic section thickness—The full-width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which X-ray transmission data are collected.

Performance phantom—A phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the CT system for low and high contrast objects, and measuring the mean CT number for water or other reference materials.

Picture element—See elemental area.

Pixel—See elemental area.

Reference plane—A plane which is at a known fixed distance—which could be zero—to the tomographic plane and parallel to it.

Scan—The complete process of collecting X-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan increment—The amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of the displacement.

Scan sequence—A preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

Scan time—The period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

Sensitivity profile—The relative response of the CT X-ray system as a function of position along a line perpendicular to the tomographic plane.

Single tomogram system—A CT X-ray system which obtains X-ray transmission data during a scan to produce a single tomogram.

Technique factors—The conditions of operation, specified as follows:

(i) For CT equipment designed for pulsed operations, peak tube potential, scan time in seconds, X-ray pulse width in seconds and the number of X-ray pulses per second or per mAs.

(ii) For CT equipment not designed for pulsed operation, peak tube potential, and either tube current and scan time in seconds or the product of tube current and exposure time in mAs.

Tomogram—The depiction of the X-ray attenuation properties of a section through a body.

Tomographic plane—The geometric plane which is identified as corresponding to the output tomogram.

Tomographic section—The volume of an object whose X-ray attenuation properties are imaged in a tomogram.

Authority

The provisions of this § 221.201 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.201 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.204 (relating to radiation measurements and performance evaluations).

§ 221.202. Equipment requirements.

(a) *Termination of exposure.* The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under X-ray system control, of greater than 0.5 second duration. Termination of the X-ray exposure shall necessitate resetting of the conditions of operation prior to initiation of another scan.

(b) *Tomographic plane indication and alignment.*

(1) For any single tomogram system, a means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, a means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic plane.

(c) *Status indicators and control switches.*

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) The emergency buttons or switches shall be clearly labeled as to their function.

(3) Each individual scan or series of scans shall require initiation by the operator.

(d) *Indication of CT conditions of operation.* The CT X-ray system shall be designed so that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(e) *Leakage radiation.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is

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operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(f) *Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.*

(1) The total error in the indicated location of the tomographic plane or reference plane by the light field or laser indicator may not exceed 5 millimeters.

(2) If the X-ray production period is less than 0.5 second, the indication of X-ray production shall be actuated for at least 0.5 second. Beam-on and shutter status indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The CT X-ray system shall be normalized to water.

(4) The CT number for water for a region of interest, not exceeding 100 square millimeters, shall be 0 ± 10.0 CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the qualified expert, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the qualified expert may establish and maintain an equivalent value.

(5) With the performance phantom, the mean CT number of water of one group of pixels may not differ from the mean CT number of water of a second group of pixels equal size within the same image by more than the manufacturer's published specifications.

(6) The noise, utilizing the facility's performance phantom, may not exceed the manufacturer's published specifications.

(7) The total error between the indicated and actual slice thickness may not exceed 2.0 millimeters.

(8) A distance of at least 100 millimeters measured in a CT image shall agree with the actual distance to within ± 5%.

(9) Premature termination of the X-ray exposure by the operator shall necessitate resetting the CT conditions of operation prior to the initiation of another scan.

Authority

The provisions of this § 221.202 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.202 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285686) to (285688).

Cross References

This section cited in 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems); 25 Pa. Code § 221.201 (relating to definitions); and 25 Pa. Code § 221.204 (relating to radiation measurements and performance evaluations).

§ 221.203. Facility design requirements.

(a) *Oral communication.* Provision shall be made for oral communication between the patient and the operator at the control panel.

(b) *Viewing systems.*

(1) A means shall be provided to permit continuous observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

(2) If the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

Authority

The provisions of this § 221.203 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.203 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 221.61 (relating to radiation therapy simulation systems); and 25 Pa. Code § 221.201 (relating to definitions).

§ 221.204. Radiation measurements and performance evaluations.

(a) *Radiation measurements.*

(1) The CTDI or MSAD along the two axes specified in paragraph (2)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry at the point of maximum surface exposure identified. The CT conditions of operation shall be reproducible and correspond to typical values used by the registrant. If the point of maximum surface exposure constantly changes due to system design, then measurements shall be taken at four different locations-top left, top right, bottom left, bottom right—1 centimeter from the outer surface of the phantom.

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(2) CT dosimetry phantoms shall be used in determining the radiation output of a CT X-ray system. The phantoms shall meet the definition for a CT dosimetry phantom under 21 CFR 1020.33(b)(6) (relating to computed tomography (CT) equipment).

(i) The phantoms shall be specifically designed for CT dosimetry and deemed appropriate by the facility's qualified expert and the Department.

(ii) CT dosimetry phantoms shall provide a means for the placement of dosimeters along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. The means for the placement of dosimeters or alignment devices at other locations may be provided.

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(iv) Dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(3) In addition to the items in subsection (b), the following items shall be evaluated annually or after any component repair or change which in the opinion of the qualified expert may effect the performance of the CT unit:

(i) HVL (half value layer) determination at the most commonly used kVp or 120 kVp.

(ii) CTDI or MSAD as specified in § 221.201 (relating to definitions) for commonly used techniques.

(iii) Tomographic plane indication (light/laser alignment).

(iv) Slice thickness as specified in § 221.202(g)(7) (relating to equipment requirements).

(v) Distance readout calibration.

(4) The measurement of the radiation output of a CT X-ray system shall be performed with a dosimetry system that has calibration traceable to National Institute of Standards and Technology. The calibration of the system shall be in accordance with an established calibration protocol. The calibration protocol published by the AAPM is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent.

(5) An mR/mAs value shall be determined at least annually for the head and body.

(6) Procedures and results shall be maintained for 5 years and be available for review by the Department.

(b) *Performance evaluations.*

(1) Written performance evaluation procedures shall be developed by a qualified expert. These procedures shall be available for review by the Department.

(2) The performance evaluation procedures shall include at least the following using the facility's performance phantom:

(i) Noise.

(ii) Contrast scale.

(iii) Spatial resolution (low and high contrast).

(iv) Mean CT number for water.

(v) Acceptable tolerances.

(3) The performance evaluation shall be performed at intervals not to exceed 3 months by the qualified expert or an individual designated by the qualified expert.

(4) The qualified expert need not be present during the performance evaluation, but shall be informed within 48 hours of any problems or unacceptable deviations.

(5) Performance evaluations shall include acquisition of images obtained with the performance phantom using the same processing mode and CT conditions of operation as are used to perform the measurements required by subsection (a).

(6) Records of the performance evaluations shall be maintained for inspection by the Department for at least 4 years.

Authority

The provisions of this § 221.204 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.204 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285688) and (249317) to (249318).

Cross References

This section cited in 25 Pa. Code § 221.201 (relating to definitions).

§ 221.205. Operating procedures.

(a) Information shall be available at the control panel regarding the operation and performance evaluations of the system. The information shall include the following:

(1) The dates of the latest radiation measurements and performance evaluation and the location within the facility where the results of those tests may be obtained.

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(2) Instructions on the use of the CT phantoms including a schedule of performance evaluations appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent performance evaluation conducted on the system.

(3) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(b) If the radiation measurements and performance evaluation of the CT X-ray system indicates that a system operating parameter has exceeded a tolerance established by the qualified expert, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

Authority

The provisions of this § 221.205 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 221.205 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249318) to (249319).

Cross References

This section cited in 25 Pa. Code § 221.201 (relating to definitions).

APPENDIX A
DETERMINATION OF COMPETENCE

The registrant shall ensure that individuals who operate diagnostic X-ray equipment have received training on the subjects listed in this appendix. The individual shall be trained and competent in the general operation of the X-ray equipment, and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

(1) Basic properties of radiation.
(2) Units of measurement.
(3) Sources of radiation exposure.
(4) Methods of radiation protection.
(5) Biological effects of radiation exposure.
(6) X-ray equipment.
(7) Image recording and processing.
(8) Patient exposure and positioning.
(9) Procedures.
(10) Quality assurance.
(11) Regulations.

Authority

The provisions of this Appendix A issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this Appendix A adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (249320).

Cross References

This appendix cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities).

[Next page is 222-1.]

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CHAPTER 222. [Reserved]

Source

The provisions of this Chapter 222 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial pages (123727) to (123735).

§ 222.1. [Reserved].

Source

The provisions of this § 222.1 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123728).

§ 222.2. [Reserved].

Source

The provisions of this § 222.2 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123728).

§ 222.11. [Reserved].

Source

The provisions of this § 222.11 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123728).

§ 222.12. [Reserved].

Source

The provisions of this § 222.12 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123728).

§ 222.13. [Reserved].

Source

The provisions of this § 222.13 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123729).

§ 222.14. [Reserved].

Source

The provisions of this § 222.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123729).

§ 222.15. [Reserved].

Source

The provisions of this § 222.15 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123730).

§ 222.16. [Reserved].

Source

The provisions of this § 222.16 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123730).

§ 222.17. [Reserved].

Source

The provisions of this § 222.17 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123730).

§ 222.21. [Reserved].

Source

The provisions of this § 222.21 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial pages (123731) to (123732).

§ 222.22. [Reserved].

Source

The provisions of this § 222.22 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123732).

§ 222.23. [Reserved].

Source

The provisions of this § 222.23 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial pages (123732) to (123733).

§ 222.24. [Reserved].

Source

The provisions of this § 222.24 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial page (123733).

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§ 222.25. [Reserved].

Source

The provisions of this § 222.25 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; reserved June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135. Immediately preceding text appears at serial pages (123733) to (123735).

[Next page is 223-1.]

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CHAPTER 223. VETERINARY MEDICINE

GENERAL PROVISIONS

Sec.
223.1. Purpose and scope.
223.2. [Reserved].
223.2a. Definitions.
223.3—223.6. [Reserved].
223.7. Structural shielding.
223.8. Operating procedures.

X-RAYS

223.11. Radiographic equipment.
223.12. [Reserved].
223.12a. Fluoroscopic equipment.
223.13. [Reserved].
223.13a. Therapeutic systems.

RADIOACTIVE MATERIAL

223.21. In vitro testing.
223.22. Sealed sources.

Authority

The provisions of this Chapter 223 issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 223 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL PROVISIONS

§ 223.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons utilizing radiation sources in veterinary medicine. Persons who use radiation sources for veterinary medicine shall comply with this chapter. The requirements of this chapter are in addition to and not in substitution for other applicable requirements of this article.

Source

The provisions of this § 223.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119229).

§ 223.2. [Reserved].

Source

The provisions of this § 223.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119229).

§ 223.2a. Definitions.

As used in this chapter, the following words and terms have the following meanings, unless the context clearly indicates otherwise:

C—Coefficient of variation—The ratio of the standard deviation to the mean value of a population of observations.

Dead-man switch—A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Fluoroscopic imaging assembly—A subsystem in which X-ray photons produce a fluoroscopic image. The term includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Image receptor—A device, such as a fluorescent screen or radiographic film, which 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.

Leakage radiation—Radiation emanating from the diagnostic or therapeutic source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

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Authority

The provisions of this § 223.2a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.2a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§§ 223.3—223.6. [Reserved].

Source

The provisions of these §§ 223.3—223.6 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119230).

§ 223.7. Structural shielding.

Facilities regularly used for diagnostic or therapeutic veterinary X-ray procedures shall have protective barriers sufficient to assure compliance with § 219.51 (Reserved).

Authority

The provisions of this § 223.7 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110-301 and 7110-302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.7 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 223.8. Operating procedures.

(a) Individuals, whose presence is not necessary to conduct the X-ray procedures, shall be located in a shielded area or at least 2 meters from the primary X-ray beam and X-ray tubehead.

(b) Mechanical supporting or restraining devices shall be used during X-ray procedures to hold the animal patient or films in position, when the technique permits.

(c) Individuals whose presence is necessary to conduct X-ray procedures and who are not located behind protective barriers or at least 2 meters from the X-ray tubehead and primary X-ray beam shall be protected with appropriate shielding devices such as lead aprons and gloves, and be positioned so that no part of their body except hands and forearms will be exposed to the primary beam. Appropriate shielding devices shall have a lead equivalent at least 0.25 millimeters of lead.

(d) X-ray exposures shall be authorized by a veterinarian.

Authority

The provisions of this § 223.8 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.8 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 223.12a (relating to fluoroscopic equipment).

X-RAYS

§ 223.11. Radiographic equipment.

(a) *Leakage radiation.*

(1) The leakage radiation from the tube housing assembly with a beam-limiting device attached measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8 μC/kg) in 1 hour when the X-ray tube is operated at its maximum technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) The radiation emitted by a component other than the tube housing assembly with a beam-limiting device attached may not exceed 2 milliroentgens (0.516 μC/kg) in 1 hour at 5 centimeters from an accessible surface of the component when it is operated in an assembled X-ray system under conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(b) *X-ray beam restriction.*

(1) The primary X-ray beam shall be restricted to the area of clinical interest and equal to or smaller than the image receptor.

(2) Collimating devices capable of limiting the primary beam to the appropriate image receptor to within 2% of the source to image distance shall be provided and used. They shall provide the same degree of protection as is required in subsection (a)(1) for a diagnostic source assembly.

(3) A means shall be provided to align the center of the X-ray field to the center of the image receptor to within 2% of the source to image distance.

(c) *X-ray beam filtration.* The total filtration permanently in the useful beam may not be less than .5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50—70 kVp and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(d) *Exposure control devices.*

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(1) An exposure control device shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to zero. It may not be possible to initiate an exposure with the exposure control device in the zero or off position, if either position is available, unless equipped for current adjustment.

(2) A means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator such as the depression of a switch. The switch shall be of the dead man type.

(e) The coefficient of variation for exposure may not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure (a) is greater than or equal to 5 times the maximum exposure (e(max)) minus the minimum exposure (e(min)).

(f) Veterinary portable X-ray units shall be supported by a tube stand when the technique permits unless the unit is designed to be hand held during X-ray procedures.

(g) The X-ray control shall provide indication of the production of X-rays that is observable from the operator's position. The technique factors that are set prior to the exposure shall be indicated on the X-ray control and shall be visible to the operator from the operator's position.

Authority

The provisions of this § 223.11 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.11 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203901).

Cross References

This section cited in 25 Pa. Code § 223.12a (relating to fluoroscopic equipment).

§ 223.12. [Reserved].

Source

The provisions of this § 223.11 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203901).

§ 223.12a. Fluoroscopic equipment.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the primary beam at the maximum source to image receptor distance.

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless the primary barrier is in position to intercept the entire primary beam.

(c) X-ray production in the fluoroscopic mode shall be controlled by a deadman switch for the duration of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposures at any time. A means may be provided to permit completion of a single exposure of the series in process.

(d) The protective barrier may not transmit more than 2 milliroentgens (.516 μC/kg) per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly for each roentgen per minute of entrance exposure rate.

(e) During fluoroscopy and cinefluorography, the voltage and the current shall be continuously indicated.

(f) A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

(g) Fluoroscopic table designs when combined with normal operating procedures shall be of a type that no unprotected part of the staff or an ancillary individual's whole body is exposed to unattenuated scattered radiation which originates from under the table. The attenuation required may be not less than 0.25 millimeter lead equivalent.

(h) Equipment configuration when combined with normal operating procedures shall be of a type that no portion of the staff or an ancillary individual's whole body, except the extremities, is exposed to the unattenuated scattered radiation emanating from above the tabletop unless one of the following criteria is met:

(1) The individual is at least 120 centimeters from the center of the primary beam.

(2) The radiation has passed through at least 0.25 millimeter of lead equivalent material—for example, drapes, bucky-slot cover (film-tray cover panel), sliding or folding panel or self-supporting curtains—in addition to the lead equivalency provided by the protective apron referred to in § 223.8(c) (relating to operating procedures).

(i) In addition to the other requirements of this section, mobile fluoroscopes shall have image intensification.

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Authority

The provisions of this § 223.12a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.12a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 223.13. [Reserved].

Source

The provisions of this § 223.13 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203902).

§ 223.13a. Therapeutic systems.

(a) When the tube is operated at its maximum technique factors, the leakage radiation may not exceed any of the following:

(1) One hundred milliroentgens (25.8 μC/kg) per hour at 5 centimeters from the surface of the tube housing assembly for contact therapy systems.

(2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-500 kVp systems.

(3) One-tenth percent of the exposure rate of the primary beam at 1 meter from the source for 501-999 kVp systems.

(b) Beam limiting devices used for limiting the primary beam shall provide at least the same protection as required by the tube housing assembly.

(c) Therapeutic X-ray systems shall be secured to prevent unauthorized use whenever the system is unattended.

(d) Interlocks shall be provided so that, when a door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than 2 milliroentgens (0.516 μC/kg) per hour and a maximum of 10 milliroentgens (2.58 μC/kg) per hour at a distance of 1 meter in any direction from the target; or interlocks will energize a conspicuous visible or audible alarm signal so that the individual entering and the operator are made aware of the entry. After a shut-off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

(e) Interlocks, on-off beam control mechanisms and safety and warning devices shall be checked and appropriately serviced at least once in a calendar year.

(f) Treatment room entrances shall be provided with warning lights, which will indicate when the primary beam is on, in a readily observable position near the outside of access doors.

(g) Exposure factors shall be displayed on the control panel.

(h) Provision shall be made to permit continuous observation of the animal patient from the control panel during irradiation.

(i) A registrant may not permit an individual to operate a therapeutic X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the system and has demonstrated understanding of the operating procedures and competence in the use of the system.

Authority

The provisions of this § 223.13a issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.13a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

RADIOACTIVE MATERIAL

§ 223.21. In vitro testing.

A veterinarian who uses radioactive material for in vitro testing shall comply with 10 CFR 31.11 (relating to general license for use of by-product material for certain in vitro clinical or laboratory testing) but is exempt from 10 CFR Part 20 Subpart K (relating to waste disposal).

Authority

The provisions of this § 223.21 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.906); and sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.21 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282396).

§ 223.22. Sealed sources.

A veterinarian who uses sealed sources for therapeutic treatment of animals shall comply with 10 CFR Part 35, Subparts F, G, H and K but is exempt from 10 CFR 35.632—35.645 and 35.2632—35.2645.

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Authority

The provisions of this § 223.22 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.906); and sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 223.22 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282396) and (249329).

[Next page is 224-1.]

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CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

Subch.		Sec.
A.	GENERAL	224.1
B.	OTHER REQUIREMENTS	224.21
C.	[Reserved]	224.101
D.	[Reserved]	224.151
E.	[Reserved]	224.201
F.	[Reserved]	224.251
G.	[Reserved]	224.301
H.	[Reserved]	224.351
I.	[Reserved]	224.401
J.	[Reserved]	224.451
K.	[Reserved]	224.501

Authority

The provisions of this Chapter 224 issued under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.906); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 224 adopted June 19, 1992, effective June 20, 1992, 22 Pa.B. 3135, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); and 25 Pa. Code § 217.1 (relating to purpose and scope).

Subchapter A. GENERAL

Sec.	
224.1.	Purpose and scope.
224.2—224.9.	[Reserved].
224.10.	Incorporation by reference.
224.11.	Effect of incorporation of 10 CFR Part 35.

§ 224.1. Purpose and scope.

This chapter prescribes requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of radioactive material. These requirements and provisions provide for the protection of the public health and safety. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements in this article. Unless specifically exempted, the requirements of Chapters 215, 217—220 and 230 apply to applicants and licensees subject to this article.

Source

The provisions of this § 224.1 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206. Immediately preceding text appears at serial page (170454).

§§ 224.2—224.9. [Reserved].

Source

The provisions of these §§ 224.2—224.9 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203906) to (203910).

§ 224.10. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 35 (relating to medical use of byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 35.8, 35.4001 and 35.4002 (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

Authority

The provisions of this § 224.10 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 224.10 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282398).

§ 224.11. Effect of incorporation of 10 CFR Part 35.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 35 (relating to medical use of byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 35 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) A reference to "byproduct material" includes NARM.

(4) The definition of "sealed source" includes NARM.

(5) A reference to the Advisory Committee on the Medical Uses of Isotopes is synonymous with the Department's Radiation Protection Advisory Committee.

(6) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 224.11 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

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Subchapter B. OTHER REQUIREMENTS

Sec.
224.21. [Reserved].
224.22. Authorization for calibration, transmission and reference sources.
224.23. Decay-in-storage.
224.51—224.60. [Reserved].

§ 224.21. [Reserved].

Source

The provisions of this § 224.21 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; reserved July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282399).

§ 224.22. Authorization for calibration, transmission and reference sources.

Notwithstanding the incorporation by reference of 10 CFR 35.65 (relating to authorization for calibration, transmission, and reference sources), a licensee authorized for medical use radioactive materials may not receive, possess or use radium in total quantity of 3.7 MBq (100 μci) or more for check, calibration, transmission and reference use except as specifically authorized by the Department.

Authority

The provisions of this § 224.22 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 224.22 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282399).

§ 224.23. Decay-in-storage.

Notwithstanding the incorporation by reference of 10 CFR Part 35 (relating to medical use of byproduct material), a licensee may hold sealed sources of radioactive material with a physical half-life of up to 300 days for decay-in-storage before disposal in ordinary trash.

Authority

The provisions of this § 224.23 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 224.23 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282399).

§§ 224.51—224.60. [Reserved].

Source

The provisions of these §§ 224.51—224.60 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203910) to (203915).

Subchapter C. [Reserved]

§§ 224.101—224.111. [Reserved].

Source

The provisions of these §§ 224.101—224.111 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203916) to (203924).

§ 224.112. [Reserved].

Source

The provisions of this § 224.112 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203924).

Subchapter D. [Reserved]

§§ 224.151 and 224.152. [Reserved].

Source

The provisions of these §§ 224.151 and 224.152 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203924) to (203925).

Subchapter E. [Reserved]

§§ 224.201 and 224.202. [Reserved].

Source

The provisions of these §§ 224.201 and 224.202 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203925) to (203926).

§ 224.203. [Reserved].

Source

The provisions of this § 224.203 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203926).

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§ 224.204. [Reserved].

Source

The provisions of this § 224.204 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203927).

Subchapter F. [Reserved]

§§ 224.251 and 224.252. [Reserved].

Source

The provisions of these §§ 224.251 and 224.252 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203927) to (203928).

§ 224.253. [Reserved].

Source

The provisions of this § 224.253 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203928) to (203929).

§ 224.254. [Reserved].

Source

The provisions of this § 224.254 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203929).

Subchapter G. [Reserved]

§§ 224.301—224.304. [Reserved].

Source

The provisions of these §§ 224.301 and 224.304 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203929) to (203931).

§ 224.305. [Reserved].

Source

The provisions of this § 224.305 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203931) to (203932).

§ 224.306. [Reserved].

Source

The provisions of this § 224.306 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203932).

Subchapter H. [Reserved]

§§ 224.351 and 224.352. [Reserved].

Source

The provisions of these §§ 224.351 and 224.352 reserved September 14, 2001, reserved September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203932) to (203933).

Subchapter I. [Reserved]

§§ 224.401—224.411. [Reserved].

Source

The provisions of these §§ 224.401 and 224.411 reserved September 14, 2001, reserved September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203933) to (203942).

§ 224.412. [Reserved].

Source

The provisions of this § 224.412 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203942).

§§ 224.413 and 224.414. [Reserved].

Source

The provisions of these §§ 224.413 and 224.414 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203942) to (203943).

Subchapter J. [Reserved]

§§ 224.451—224.465. [Reserved].

Source

The provisions of these §§ 224.451 and 224.465 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203944) to (203953).

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Subchapter K. [Reserved]

§ 224.501. [Reserved].

Source

The provisions of this § 224.501 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (903953) to (203954).

[Next page is 225-1.]

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CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subch.		Sec.
A.	GENERAL PROVISIONS	225.1
B.	RADIATION-PRODUCING MACHINES	225.71

Authority

The provisions of this Chapter 225 issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed); and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 225 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 78.111 (relating to abandonment); 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 228.45 (relating to portable or mobile accelerators); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

Subchapter A. GENERAL PROVISIONS

Sec.	
225.1.	Purpose and scope.
225.2.	[Reserved].
225.2a.	Incorporation by reference.
225.3.	[Reserved].
225.3a.	Effect of incorporation of 10 CFR Part 34.
225.4.	[Reserved].
225.4a.	Radiation safety program.
225.5.	[Reserved].
225.5a.	Reciprocity.
225.6.	[Reserved].
225.6a.	Prohibitions.
225.7.	[Reserved].
225.8.	[Reserved].
225.9.	[Reserved].
225.11—225.13.	[Reserved].
225.14.	[Reserved].
225.15—225.18.	[Reserved].
225.21.	[Reserved].
225.22.	[Reserved].
225.23.	[Reserved].
225.31—225.33.	[Reserved].
225.34—225.36.	[Reserved].
225.41—225.43.	[Reserved].

225.44. [Reserved].
225.51—225.53. [Reserved].
225.54—225.65. [Reserved].

§ 225.1. Purpose and scope.

(a) This chapter establishes radiation safety requirements for persons utilizing radiation sources for industrial radiography. Licensees and registrants who use radiation sources for industrial radiography shall comply with this chapter. The requirements of this chapter are in addition to and not in substitution for other applicable requirements in this article, in particular, the requirements and provisions of Chapters 215, 217—220, 228 and 230.

(b) Persons using only radiation-producing machines for industrial radiographic operations need not comply with § 225.2a (relating to incorporation by reference) unless otherwise specified in Subchapter B (relating to radiation-producing machines).

(c) This chapter does not apply to the use of radiation sources for medical diagnosis or therapy.

Source

The provisions of this § 225.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial page (282406).

§ 225.2. [Reserved].

Source

The provisions of this § 225.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203957) to (203958).

§ 225.2a. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 34 (relating to licenses for industrial radiography and radiation safety requirements for industrial radiographic operations) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 34.5, 34.8, 34.121 and 34.123 are not incorporated by reference.

Source

The provisions of this § 225.2a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Cross References

This section cited in 25 Pa. Code § 225.1 (relating to purpose and scope).

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§ 225.3. [Reserved].

Source

The provisions of this § 225.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4895) to (4896).

§ 225.3a. Effect of incorporation of 10 CFR Part 34.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 34, the following words and phrases shall be substituted for the language in 10 CFR Part 34 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 225.3a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 225.4. [Reserved].

Source

The provisions of this § 225.4 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4896).

§ 225.4a. Radiation safety program.

(a) A person who intends to use radiation-producing machines for industrial radiography shall have a program for training personnel, written operating procedures and emergency procedures, an internal review system and an organizational structure for radiographic operations which includes specified delegations of authority and responsibility for operation of the program. This program shall be approved by the Department before commencing industrial radiographic operations.

(b) The registrant shall notify the Department of intended changes to the registrant's radiation safety program and obtain Departmental approval.

Source

The provisions of this § 225.4a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282407).

Cross References

This section cited in 25 Pa. Code § 225.102 (relating to shielded room X-ray radiography).

§ 225.5. [Reserved].

Source

The provisions of this § 225.5 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4896).

§ 225.5a. Reciprocity.

Out-of-State users of radiation producing machines shall meet the requirements of § 216.7 (relating to out-of-State radiation-producing machines).

Source

The provisions of this § 225.5a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 225.6. [Reserved].

Source

The provisions of this § 225.6 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4896).

§ 225.6a. Prohibitions.

Use of radiation sources covered under this chapter for diagnosis or therapy on humans or animals is not permitted.

Source

The provisions of this § 225.6a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 225.7. [Reserved].

Source

The provisions of this § 225.7 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4896) to (4897).

§ 225.8. [Reserved].

Source

The provisions of this § 225.8 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4897).

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§ 225.9. [Reserved].

Source

The provisions of this § 225.9 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4897).

§§ 225.11—225.13. [Reserved].

Source

The provisions of these § 225.11—225.13 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203959) to (203960).

§ 225.14. [Reserved].

Source

The provisions of this § 225.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203960) to (203961).

§§ 225.15—225.18. [Reserved].

Source

The provisions of these §§ 225.15—225.18 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial text pages (203962) to (203964).

§ 225.21. [Reserved].

Source

The provisions of this § 225.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203964).

§ 225.22. [Reserved].

Source

The provisions of this § 225.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203965).

§ 225.23. [Reserved].

Source

The provisions of this § 225.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203965) to (203966).

§§ 225.31—225.33. [Reserved].

Source

The provisions of these §§ 225.31—225.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203966) to (203967).

§§ 225.34—225.36. [Reserved].

Source

The provisions of these §§ 225.34—225.36 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (4902) to (4904).

§§ 225.41—225.43. [Reserved].

Source

The provisions of these §§ 225.41—225.43 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203968) to (203970).

§ 225.44. [Reserved].

Source

The provisions of this § 225.44 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203970) to (203971).

§§ 225.51—225.53. [Reserved].

Source

The provisions of these §§ 225.51—225.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203971) to (203972).

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§§ 225.54—225.65. [Reserved].

Source

The provisions of these §§ 225.54—225.65 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4908) to (4916).

Subchapter B. RADIATION-PRODUCING MACHINES

GENERAL ADMINISTRATIVE REQUIREMENTS

Sec.
225.71. Definitions.
225.72. Duties of personnel.
225.73. Training of personnel.
225.74. Training and testing.
225.75. Audits and safety reviews of radiographers and radiographer's assistants.
225.76. Reporting requirements.

GENERAL TECHNICAL REQUIREMENTS

225.81. Permanent radiographic installations.
225.82. Operating requirements.
225.83. Records required at field radiography sites.
225.84. Operating and emergency procedures.
225.85. Surveys and survey records.
225.86. Utilization logs.
225.87. Security.
225.88. Posting.

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

225.91. Radiation survey meter requirements.
225.92. Radiation survey meter calibration requirements.
225.93. Personnel monitoring control.

RADIATION-PRODUCING MACHINE REQUIREMENTS

225.101. Cabinet X-ray systems and baggage/package X-ray systems.
225.102. Shielded room X-ray radiography.
225.103. Field site radiography.
225.104. X-ray detection systems for explosives, weapons and illegal items.

Source

The provisions of this Subchapter B adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239, unless otherwise noted.

Cross References

This subchapter cited in 25 Pa. Code § 225.1 (relating to purpose and scope).

GENERAL ADMINISTRATIVE REQUIREMENTS

§ 225.71. Definitions.

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

Cabinet radiography—Industrial radiography conducted in an enclosure or cabinet (not a room) so shielded that doses to individual members of the public at every location on the exterior meet the limitations specified in 10 CFR 20.1301 (relating to dose limits for individual members of the public).

Cabinet X-ray system—An X-ray system with the X-ray tube installed in an interlocked enclosure or cabinet, designed to exclude personnel from its interior during operation.

(i) Included are all X-ray systems designed primarily for the inspection of baggage or packages.

(ii) An X-ray tube used within a shielded part of a building or X-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet X-ray system.

Certified cabinet X-ray system—An X-ray system which has been certified under 21 CFR 1010.2 (relating to certification) as being manufactured and assembled under 21 CFR 1020.40 (relating to cabinet x-ray systems).

DRD—Direct reading dosimeter—

(i) As used in this subchapter, means an "individual monitoring device" (see 10 CFR 20.1003 (relating to definitions)) that does not require additional processing to measure an individual's dose.

(ii) The term also includes the direct reading personnel (individual) monitoring devices known as pocket dosimeter, pocket ionization chamber and electronic personal dosimeter (EPD).

Field radiography—A location where radiographic operations are conducted (onsite or offsite) other than those designated as a permanent radiographic facility.

Industrial radiography—An examination of the structure of materials by nondestructive methods, including fluoroscopy, which utilizes radiation producing machines to make radiographic images.

NVLAP—National Voluntary Laboratory Accreditation Program.

Permanent radiographic installation—A shielded installation or structure designed or intended for radiography in which radiography is regularly performed.

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Personal supervision—The provision of guidance and instruction to a radiographer's assistant given by a radiographer who is:

(i) Physically present at the site.

(ii) In visual contact with the radiographer's assistant while the assistant is using radiation sources.

(iii) In proximity so that immediate assistance can be given if required.

Personnel dosimeter—As used in this subchapter, means any of the "individual monitoring devices" (see 10 CFR 20.1003) that shall be processed and evaluated to generate a permanent record of an individual's dose, for example, a film badge, thermoluminescent dosimeter (TLD) or optically stimulated luminescent dosimeter (OSLD).

RSO—radiation safety officer—An individual who ensures that, in the daily operation of the registrant's or licensee's radiation safety program, activities are being performed in accordance with approved procedures and are in compliance with Department requirements.

Radiographer—An individual who performs radiographic operations or an individual in attendance at a site where radiation producing machines are being used who personally supervises industrial radiographic operations.

Radiographer's assistant—An individual who, under the personal supervision of a radiographer, uses radiation producing machines or radiation survey instrumentation.

Radiographer trainee—An individual who is in the process of becoming a radiographer's assistant or a radiographer.

Radiographic operations—The activities associated with a radiation producing machine during use of the machine, to include surveys to confirm adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

Safety device—As applied to radiation-producing machines in this subchapter, a device or component that causes the unit to de-energize or interrupt the beam.

Shielded room radiography—Industrial radiography that is conducted in an enclosed room, the interior of which is not occupied during radiographic operations.

Source

The provisions of this § 225.71 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282412) to (282413).

§ 225.72. Duties of personnel.

(a) The RSO shall assure that the radiation safety program of the registrant or licensee is implemented and suspend or terminate operations that are not being conducted in accordance with approved procedures or the Department's requirements.

(b) The radiographer is responsible to the registrant or licensee for following the procedures of the registrant or licensee and for complying with the Department's requirements while industrial radiographic operations are being conducted.

(c) The radiographer's assistant shall only use radiation producing machines or radiation survey instrumentation under the personal supervision of a radiographer.

(d) The radiographer trainee is not permitted to operate radiation producing machines or radiation survey instrumentation.

§ 225.73. Training of personnel.

(a) A registrant may not allow an individual to act as a radiographer or radiographer's assistant unless that individual meets the requirements of § 225.74 (relating to training and testing).

(b) Persons performing field radiography shall comply with the training requirements in Appendix A (relating to subjects to be covered during the instruction of radiographers).

Source

The provisions of this 225.73 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282414).

§ 225.74. Training and testing.

(a) The registrant may not permit an individual to act as a radiographer until that individual has:

(1) Been instructed in the subjects outlined in Appendix A.

(2) Received copies of this chapter, Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations), and copies of the license or certificate of registration and the operating and emergency procedures of the registrant or licensee.

(3) Received instruction covering regulatory requirements, operating and emergency procedures and the use of radiation-producing machines and radiation survey instruments of the registrant or licensee.

(4) Demonstrated competency and understanding of the information in this subsection to the satisfaction of the registrant or licensee as evidenced by the successful completion of a written test and a field examination.

(b) The registrant or licensee may not permit an individual to act as a radiographer's assistant until that individual has:

(1) Received copies of, and instruction in, the applicable operating and emergency procedures and has been instructed in the use of sources of radiation and radiation survey instruments of the registrant or licensee.

(2) Demonstrated that, under direct personal supervision of a radiographer, the individual is competent to use sources of radiation and radiation survey

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instruments as evidenced by the successful completion of a written or oral test and a field examination on the subjects relevant to being an assistant radiographer.

(c) Records of the training required under subsections (a) and (b), including copies of written tests, dates of oral tests and field examinations, shall be maintained for inspection by the Department for 3 years following termination of employment by the individual or until the registration or license is terminated.

Cross References

This section cited in 25 Pa. Code § 225.73 (relating to training and testing).

§ 225.75. Audits and safety reviews of radiographers and radiographer's assistants.

(a) The registrant or licensee shall review and provide for the safety and ongoing training needs of radiographers and radiographer's assistants at least once during each calendar year.

(b) The registrant or licensee shall conduct an annual inspection program of the job performance of each radiographer and radiographer's assistant to ensure that operating and emergency procedures and this article and registration or license requirements for the registrant or licensee are followed. This audit program shall:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed 1 calendar year.

(2) Provide that, if a radiographer or radiographer's assistant has not participated in a radiographic operation for more than 6 months since the last annual inspection, the individual's performance shall be observed and recorded when the individual next participates in a radiographic operation.

(c) The registrant or licensee shall maintain records of the training set forth in subsection (b) to include certification documents, written and field examinations, annual safety reviews and annual audits of job performance. Records shall be available for inspection by the Department for 3 years following the termination of employment of the individual or until the registration or license is terminated.

§ 225.76. Reporting requirements.

(a) In addition to the reporting requirements in §§ 219.221 and 219.222 (relating to reports of stolen, lost or missing licensed or registered sources of radiation; and notification of incidents and reportable events), each registrant or licensee shall provide to the Department, within 30 days of its occurrence, a written report on any of the following incidents involving machines or equipment used in radiographic operations:

(1) The inability to terminate irradiation from a radiation producing machine.

(2) An interlock failure during shielded room radiography.

(b) The registrant or licensee shall include the following information in each report submitted under subsection (a):

(1) A description of the equipment problem.

(2) The cause of the incident, if known or determined.

(3) The manufacturer and model number of the equipment involved.

(4) The place, date and time of the incident.

(5) Actions taken to reestablish normal operations.

(6) Corrective actions taken or planned to prevent reoccurrence.

(7) The names and qualifications of personnel involved.

(c) Reports of overexposures, required under 10 CFR 20.2202 (relating to notification of incidents) or of excessive exposures, required under 10 CFR 20.2203 (relating to reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits) which involve the failure of safety components of radiography equipment shall also include, to the extent known, the information specified under subsection (b). Complete information required in subsection (b) shall be available in the 30-day follow-up report rule under 10 CFR 20.2203(a).

GENERAL TECHNICAL REQUIREMENTS

§ 225.81. Permanent radiographic installations.

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in 10 CFR 20.1601 and 20.1902 (relating to control of access to high radiation areas; and posting requirements) shall also meet the following requirements.

(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the X-ray source is energized. The audible signal shall be actuated when an attempt is made to enter the installation while the X-ray source is energized.

(2) The entrance control device or alarm system shall be tested for proper function prior to beginning operations on each day of use.

(3) The radiographic exposure system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used provided that the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.52 (relating to surveillance; posting), § 225.83 (relating to records required at field radiography sites) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the radiation safety officer or an individual designated by the radiation safety officer shall validate the repair.

(b) Records of the tests performed under subsection (a) shall be maintained for inspection by the Department for 3 years.

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§ 225.82. Operating requirements.

(a) When radiographic operations are performed at a location other than a permanent radiographic installation, a minimum of two radiographic personnel shall be present to operate the X-ray device. At least one of the radiographic personnel shall be qualified as a radiographer. The other individual may be either a radiographer, a radiographer's assistant or a radiographer trainee.

(b) Other than a radiographer, or a radiographer's assistant who is under the personal supervision of a radiographer, an individual may not manipulate the controls or operate the equipment used in industrial radiographic operations.

(c) At each job site, the following shall be supplied by the registrant or licensee:

(1) The appropriate barrier ropes and warning signs.

(2) At least one operable, calibrated radiation survey instrument.

(3) For each worker requiring monitoring, an individual personnel dosimeter that is processed and evaluated by an NVLAP processor.

(4) An operable, calibrated direct reading dosimeter with a range of zero to 51.6 μC/kg (200 milliroentgen) for each worker requiring monitoring.

(d) An industrial radiographic operation may not be performed if any of the items in subsection (c) is not available at the job site or is inoperable.

Source

The provisions of this § 225.82 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282416) to (282417).

§ 225.83. Records required at field radiography sites.

Each registrant or licensee conducting radiographic operations at a field radiography site shall maintain and have available for inspection by the Department at that job site, the following records or documents:

(1) The certificate of registration, license or equivalent document which authorizes radiographic operations, and radiographic personnel certifications.

(2) Operating and emergency procedures.

(3) Relevant regulations of the Department.

(4) Survey records required under this chapter for the period of operation at the site.

(5) Daily direct reading dosimeter records for the period of operation at the site.

(6) The current radiation survey meter calibration records for meters in use at the site. Acceptable records include tags or labels that are affixed to the survey meter.

Source

The provisions of this § 225.83 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282417).

Cross References

This section cited in 25 Pa. Code § 225.81 (relating to permanent radiographic installations).

§ 225.84. Operating and emergency procedures.

The operating and emergency procedures of the registrant or licensee shall include instruction in at least the following:

(1) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation in excess of the limits established in Chapter 219 (relating to standards for protection against radiation).

(2) Methods and occasions for conducting radiation surveys and the proper use of survey meters.

(3) Methods for controlling access to areas where radiographic operations are being conducted.

(4) Methods and occasions for locking and securing sources of radiation.

(5) Personnel monitoring and the use of individual monitoring devices, including steps that are to be taken immediately by radiographic personnel when a direct reading dosimeter is found to be off-scale.

(6) Methods and procedures for minimizing exposure to individuals in the event of an accident.

(7) The procedure for notifying proper personnel in the event of an accident.

(8) Maintenance of records required by the Department.

(9) The inspection and maintenance of radiation-producing machines and survey meters.

Cross References

This section cited in 25 Pa. Code § 225.102 (relating to shielded room X-ray radiography).

§ 225.85. Surveys and survey records.

(a) A survey with a calibrated radiation survey instrument shall be made after each radiographic exposure to determine that the emission of radiation has terminated.

(b) Records of the surveys required by subsection (a) shall be maintained (for inspection by the Department) for 3 years. If the survey has been used to determine an individual's exposure, the records of the survey shall be maintained until the Department terminates the registration or license.

§ 225.86. Utilization logs.

A registrant or licensee shall maintain current logs, which shall be kept available for inspection by the Department for 3 years from the date of the event, showing for each radiation-producing machine, the following applicable information:

(1) The identity (name and signature) of the operator to whom the radiation-producing machine is assigned.

(2) The model and serial number of the radiation-producing machine.

(3) The locations and dates of use.

(4) The technique factors (tube kilovoltage, tube current, exposure time) used for each radiographic exposure.

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§ 225.87. Security.

During each radiographic operation, the radiographer or radiographer's assistant shall maintain direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except when one of the following exists:

(1) The high radiation area is equipped with a control device or an alarm system as described in 10 CFR 20.1601 and 20.1902(b) (relating to control of access to high radiation areas; and posting of high radiation areas).

(2) The high radiation area is locked to protect against unauthorized or accidental entry.

§ 225.88. Posting.

Areas in which radiographic operations are being performed shall be conspicuously posted as required by 10 CFR 20.1902 (relating to posting requirements).

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

§ 225.91. Radiation survey meter requirements.

(a) A registrant or licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this chapter and Chapter 219 (relating to standards for the protection against radiation).

(b) A radiographic operation may not be conducted unless calibrated and operable radiation survey instrumentation is available and used at each site where radiographic operations are conducted.

(c) Immediately prior to first use at a site where radiographic operations are conducted and at the beginning of work shift changes thereafter, a radiation survey instrument shall be checked to ensure that it is operating properly by exposing the instrument to a reference source of radiation and observing its response. Instruments that fail to respond as expected may not be used.

Cross References

This section cited in 25 Pa. Code § 225.92 (relating to radiation survey meter calibration requirements).

§ 225.92. Radiation survey meter calibration requirements.

(a) In addition to the requirements of § 225.91 (relating to survey meter requirements), instruments required by this chapter shall have a range so that 0.516 μC/kg (2 mR) per hour through 258 μc/kg (1 R) per hour can be measured.

(b) Each radiation instrument shall be calibrated:

(1) At energies appropriate for use.

(2) At intervals not to exceed 6 months.

(3) After each instrument servicing, other than battery replacement.

(4) To within an accuracy of +/- 20%.

(5) At two points located approximately one-third and two-thirds of full scale on each scale of linear scale instruments; at mid-range of each decade and at two points of at least 1 decade for logarithmic scale instruments; and for digital instruments, at three points between 0.516 μC/kg (2 mR) and 258 μC/kg (1000 mR) per hour.

(6) By a person authorized by the Department, the NRC or an agreement state.

(c) Calibration records shall be maintained for inspection by the Department for 3 years after the date of calibration.

§ 225.93. Personnel monitoring control.

(a) The registrant or licensee may not permit an individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each individual wears a direct reading dosimeter and a personnel dosimeter that is processed and evaluated by an NVLAP processor.

(1) Personnel monitoring devices used to determine compliance with dose limits for the whole body shall be worn on the trunk of the body over the area most likely to receive exposure.

(2) This does not relieve the registrant or licensee from providing peripheral monitoring devices such as ring finger TLDs when appropriate.

(3) Each personnel monitoring device shall be assigned to and worn by only one individual.

(b) Film badges shall be replaced at intervals not to exceed 1 month. Other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at intervals not to exceed 3 months.

(c) Direct reading dosimeters shall meet the criteria as in ANSI N13.5-1972, "Performance Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma-Radiation" published in 1972, exclusive of subsequent amendments or additions.

(d) The use of DRDs is subject to the following requirements:

(1) DRDs shall have a range of zero to 51.6 μC/kg (200 mR) and shall be rezeroed at the start of each work shift.

(2) As a minimum, at the beginning and the end of each worker's shift involving the use of a source of radiation, DRDs shall be read and the exposure values recorded.

(3) Direct reading dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. A dosimeter may not be used for personnel monitoring unless the response is accurate within +/- 20% of the true radiation exposure. Records of dosimeter response checks shall be maintained for inspection by the Department for 3 years.

(4) If an individual's DRD indicates exposure that is "off-scale" beyond the range it can measure, industrial radiographic operations by that individual

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shall cease immediately and the individual's personnel dosimeter shall be sent immediately for processing. The individual may not use any sources of radiation until the individual's radiation dose has been determined.

(e) Data on personnel exposure reported or recorded from personnel monitoring devices shall be kept for inspection by the Department until the certificate of registration or license is terminated or until the Department authorizes their disposition, in writing, following a determination by the Department that the records contain inaccurate personnel monitoring information.

RADIATION-PRODUCING MACHINE REQUIREMENTS

§ 225.101. Cabinet X-ray systems and baggage/package X-ray systems.

(a) Cabinet and baggage/package X-ray systems that are certified under 21 CFR Chapter I, Subchapter J (relating to radiological health) shall also meet the requirement of 21 CFR 1020.40 (relating to cabinet X-ray systems).

(b) A cabinet X-ray system may not be energized unless all openings are securely closed and exposure to radiation from the system does not exceed the limits in 10 CFR 20.1301 (relating to dose limits for individual members of the public). Each access door to the cabinet shall have an interlock that terminates the exposure whenever the door is opened. The enclosure shall be shielded so that every location on the exterior meets the conditions for an unrestricted area.

(c) A registrant may not permit an individual to operate a cabinet X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the X-ray system and has demonstrated competency in the use of the cabinet X-ray system and an understanding of the operating procedures.

(d) The registrant shall perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 and maintain records of these surveys for inspection by the Department for 3 years:

(1) Upon installation of the equipment.

(2) Following a change in the initial arrangement, relocation of the unit, or following any maintenance requiring the disassembly or removal of any shielding component.

(3) When a visual inspection reveals an abnormal condition.

(e) The registrant shall test on-off switches, interlocks and safety devices at intervals not exceeding 1 year, and make repairs as necessary to maintain all safety features including warning labels. Records of these tests shall be maintained for inspection by the Department for 3 years.

(f) Cabinet X-ray systems and baggage/package X-ray systems are exempt from all other provisions of this chapter.

Source

The provisions of this § 225.101 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282421).

Cross References

This section cited in 25 Pa. Code § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items).

§ 225.102. Shielded room X-ray radiography.

(a) A room used for shielded room X-ray radiography shall be shielded so that every location on the exterior meets conditions for an unrestricted area and the only access to the room is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

(b) The operator shall conduct a physical radiation survey to determine that the radiation source is deenergized prior to each entry into the radiographic exposure area.

(c) As an alternative to subsection (b), the registrant may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels.

(d) With the exception of the provisions of §§ 225.4a and 225.84 (relating to radiation safety program; and operating and emergency procedures), shielded room radiography is exempt from all other provisions of this chapter.

Source

The provisions of this § 225.102 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282421) to (282422).

§ 225.103. Field site radiography.

(a) The operator shall conduct a physical radiation survey to determine that the radiation source is de-energized prior to each entry into the radiographic exposure area. Survey results and records of the boundary location shall be maintained and kept available for inspection by the Department for 3 years.

(b) Mobile or portable radiation producing machines shall be physically secured to prevent tampering or removal by unauthorized personnel.

Source

The provisions of this § 225.103 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282422).

§ 225.104. X-ray detection systems for explosives, weapons and illegal items.

(a) This section applies to X-ray systems that produce an image that may be used to screen for the presence of explosive devices or components, weapons, contraband or prohibited items. This section does not apply to cabinet and baggage/package X-ray systems covered under § 225.101 (relating to cabinet X-ray systems and baggage/package X-ray systems).

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(b) An X-ray system used for detection of explosives, weapons or illegal items may not be used on human beings or animals without specific permission of the Department. X-ray systems that irradiate human beings for medical diagnosis are covered under Chapter 221 (relating to human use of X-ray machines). X-ray systems that irradiate animals for diagnosis or therapy are covered under Chapter 223 (relating to veterinary medicine).

(c) Radiographic X-ray detection systems shall conform to the following:

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) Portable X-ray systems shall be equipped with collimators which are capable of restricting the useful beam to the area of interest. Collimators shall provide the same degree of protection required in paragraph (1).

(3) A means shall be provided to terminate the exposure after a preset time, a preset to image receptor or a preset product of exposure time and tube current.

(4) The X-ray control shall have a dead-man type exposure switch.

(5) The X-ray controls shall indicate the technique factors, (that is, kilovoltage, tube current and exposure time or the product of tube current and exposure time).

(6) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the words, "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.

(7) For fixed radiographic equipment, an easily visible warning light shall be located adjacent to the X-ray tube and labeled with the words "X-RAY ON" or words having a similar intent. The warning light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(d) Fluoroscopic X-ray detection systems shall conform to the following:

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the words, "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.

(3) To the extent practicable, the X-ray system (X-ray tube, imaging system and the object being irradiated) shall be completely enclosed so that every location on the exterior meets conditions for an unrestricted area and the only

access to the room or enclosure is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

(4) The equipment shall be constructed so that, under conditions of normal use, the entire cross-section of the useful beam shall be attenuated by a primary protective barrier permanently incorporated into the equipment.

(5) The X-ray control shall have a dead-man type exposure switch. Activation of the X-ray beam shall be possible only by continuous pressure on the exposure switch.

(6) An easily visible warning light shall be located adjacent to the X-ray tube or on the outside of the enclosure and be labeled with the words "X-RAY ON" or words having a similar intent. This light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(e) Operating procedures for portable radiographic X-ray detection systems are as follows:

(1) To the extent practicable, portable X-ray tube heads shall be supported by a stand.

(2) To the extent practicable, supporting or positioning devices for the image receptor shall be used during radiation exposures.

(3) Individuals, other than those whose presence is necessary to conduct the X-ray procedure, shall be located at least 2 meters away from the X-ray tube and the object being irradiated during exposures.

(4) An individual may not be regularly employed to support the image receptor or object during radiation exposures.

(f) Operating procedures for fixed radiographic X-ray detection systems are as follows:

(1) A registrant shall test the safety and warning devices, including interlocks, at intervals not to exceed 12 months. Test records shall be maintained for inspection by the Department for 3 years after the test has been conducted.

(2) Safety or warning devices that do not function properly shall be repaired in a timely manner.

(3) If an X-ray detection system is required to be operated while in need of repair, procedures shall be modified to maintain the design level equivalent of safety or else the equipment may not be used.

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APPENDIX A

Subjects to be Covered During the
Instruction of Radiographers

I. *Fundamentals of Radiation Safety*
   A. Characteristics of radiation
   B. Units of radiation dose and quantity of radioactivity
   C. Significance of radiation dose
      1. Radiation protection standards
      2. Biological effects of radiation dose
   D. Levels of radiation from radiation sources
   E. Methods of controlling radiation dose
      1. Working time
      2. Working distances
      3. Shielding

II. *Radiation Detection Instrumentation to be Used*
   A. Use of radiation survey instruments
      1. Operation
      2. Calibration
      3. Limitations
   B. Survey techniques
   C. Use of personnel monitoring equipment
      1. Film badges
      2. Thermoluminescent dosimeters
      3. Pocket dosimeters

III. *Radiographic Equipment to be Used*
   A. Remote handling equipment
   B. Radiographic exposures devices and sealed sources
   C. Storage containers
   D. Operation and control of X-ray equipment

IV. *The Requirements of Pertinent Federal and State Regulations*

V. *The Licensee's or Registrant's Written Operating and Emergency Procedures*

VI. *Inspection and Maintenance Performed by the Radiographers*

VII. *Case Histories of Radiography Incidents*

Source

The provisions of this Appendix A adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235.

Cross References

This appendix cited in 25 Pa. Code § 225.73 (relating to training of personnel).

[Next page is 226-1.]

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CHAPTER 226. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

GENERAL

Sec.
226.1. Purpose and scope.
226.2. [Reserved].
226.3. [Reserved].
226.3a. Abandonment of a sealed source.
226.4. Incorporation by references.
226.5. Effect of incorporation of 10 CFR Part 39.
226.11. [Reserved].
226.12. [Reserved].
226.13. [Reserved].
226.14. [Reserved].
226.15—226.19. [Reserved].
226.21—226.23. [Reserved].
226.31—226.33. [Reserved].
226.34. [Reserved].
226.41—226.43. [Reserved].
226.51. [Reserved].

PARTICLE ACCELERATORS

226.61. Particle accelerators.

Authority

The provisions of this Chapter 226 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. § 7110.301 and § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 226 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 78.111 (relating to abandonment); 25 Pa. Code § 215.32 (relating to exemption qualifications); and 25 Pa. Code § 217.1 (relating to purpose and scope).

GENERAL

§ 226.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons using radiation sources for well logging in a single well, radioactive markers, uranium sinker bars and subsurface tracer studies. Persons who use radiation sources for well

logging operations shall comply with this chapter, which is in addition to and not in substitution for other applicable requirements of this article, in particular, the requirements of Chapters 215, 217—220, 228 and 230.

Source

The provisions of this § 226.1 amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203978).

§ 226.2. [Reserved].

Source

The provisions of this § 226.2 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203978) to (203979).

§ 226.3. [Reserved].

Source

The provisions of this § 226.3 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203979).

§ 226.3a. Abandonment of a sealed source.

In addition to incorporation by reference of 10 CFR 39.15 and 39.77 (relating to agreement with well owner or operator; and notification of incidents and lost sources; abandonment procedures for irretrievable sources), the requirements of § 78.111 (relating to abandonment) shall also be met.

Source

The provisions of this § 226.3a adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282428).

§ 226.4. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 39 (relating to licenses and radiation safety requirements for well logging) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 39.5, 39.8, 39.101 and 39.103 are not incorporated by reference.

Source

The provisions of this § 226.4 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 226.5. Effect of incorporation of 10 CFR Part 39.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 39, the following words and phrases shall be substituted for the language in 10 CFR Part 39 as follows:

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(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 226.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 226.11. [Reserved].

Source

The provisions of this § 226.11 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203979) to (203980).

§ 226.12. [Reserved].

Source

The provisions of this § 226.12 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203980).

§ 226.13. [Reserved].

Source

The provisions of this § 226.13 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203980).

§ 226.14. [Reserved].

Source

The provisions of this § 226.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203980) to (203981).

§§ 226.15—226.19. [Reserved].

Source

The provisions of these §§ 226.15—226.19 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203982) to (203984).

§§ 226.21—226.23. [Reserved].

Source

The provisions of these §§ 226.21—226.23 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203984) to (203985).

§§ 226.31—226.33. [Reserved].

Source

The provisions of these §§ 226.31—226.33 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203985).

§ 226.34. [Reserved].

Source

The provisions of this § 226.34 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203985) to (203986).

§§ 226.41—226.43. [Reserved].

Source

The provisions of these §§ 226.41—226.43 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203986) to (203987).

§ 226.51. [Reserved].

Source

The provisions of this § 226.51 adopted December 18, 1987, effective December 19, 1987, 17 Pa. B. 5235; amended June 19, 1992, effective June 20, 1992, 22 Pa. B. 3135; reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (203987) to (203989).

PARTICLE ACCELERATORS

§ 226.61. Particle accelerators.

(a) A licensee or registrant may not permit aboveground testing of particle accelerators designed for use in well logging which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of 10 CFR 20.1301 (relating to radiation dose to dose limits for individual members of the public) are met.

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(b) The use of particle accelerators for well logging shall be conducted under the licensing provisions of Chapter 228 (relating to radiation safety requirements for particle accelerators).

Source

The provisions of this § 226.61 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

APPENDIX A. [Reserved]

Source

The provisions of this Appendix A reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203990).

APPENDIX B. [Reserved]

Source

The provisions of this Appendix B reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (203991).

[Next page is 227-1.]

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CHAPTER 227. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT, X-RAY GAUGING EQUIPMENT, ELECTRON MICROSCOPES AND X-RAY CALIBRATION SYSTEMS

GENERAL PROVISIONS

Sec.
227.1. Purpose and scope.
227.2. Definitions.
227.3. [Reserved].

ANALYTICAL X-RAY EQUIPMENT

227.11. [Reserved].
227.11a. Equipment requirements.
227.12. [Reserved].
227.12a. Area requirements.
227.13. [Reserved].
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X-RAY GAUGING EQUIPMENT

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227.31. Warnings.
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227.61—227.71. [Reserved].
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X-RAY CALIBRATION SYSTEMS

227.101. Scope.
227.102. Area requirements.
227.103. Operating requirements.
227.104. Personal requirements.

Authority

The provisions of this Chapter 227 issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed); and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 227 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL PROVISIONS

§ 227.1. Purpose and scope.

This chapter establishes the requirements for the use of analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration sys-

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tems. Registrants who use analytical X-ray equipment, X-ray gauging equipment, electron microscopes or X-ray calibration systems shall comply with this chapter. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of this article.

Source

The provisions of this § 227.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249334).

§ 227.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Analytical X-ray machine—An assembly of components utilizing X-rays to determine the elemental or chemical composition or to examine the microstructure of materials usually by X-ray diffraction or fluorescence.

Electron microscope—Equipment utilizing the wave characteristics of electrons that have been accelerated by an electric field to visualize the microscopic structure of material.

Fail-safe characteristics—A design feature which causes X-ray production to cease, beam port shutters to close or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

Local components—Parts of an analytical X-ray system, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, that contain or are in the path of the X-ray beam. The term does not include power supplies, transformers, amplifiers, readout devices and control panels.

Open-beam configuration—An analytical X-ray system in which the beam is not enclosed or shielded so any portion of an individual's body could accidentally be placed in the beam path during normal operation.

Operating procedures—Step-by-step instructions necessary to accomplish the analysis.

Primary beam—Radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

X-ray calibration systems—Radiation-producing machines and equipment used to calibrate radiation detection or measuring devices.

X-ray gauging equipment—A machine utilizing X-rays to detect, measure, gauge or control thickness, density, level or interface location.

Source

The provisions of this § 227.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249335).

§ 227.3. [Reserved].

Source

The provisions of this § 227.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119234) and (4919).

ANALYTICAL X-RAY EQUIPMENT

§ 227.11. [Reserved].

Source

The provisions of this § 227.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203996).

§ 227.11a. Equipment requirements.

(a) Open-beam configurations shall have a safety device which either prevents the entry of any portion of an individual's body into the primary X-ray beam path, or causes the beam to be terminated or interrupted upon entry into the path. A registrant may apply to the Department for an exemption from the requirement of a safety device. The application for an exemption shall include the following:

(1) A description of the various safety devices that have been evaluated.

(2) The reason each of these safety devices cannot be used.

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Open-beam configurations shall be provided with a readily discernible indication of one or both of the following:

(1) X-ray tube status (on-off) located near the radiation source housing, if the primary beam is controlled in this manner.

(2) Shutter status (open-closed) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified. In addition, equipment manufactured after December 17, 1987, shall have fail-safe characteristics.

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(d) An easily visible warning light located immediately adjacent to the tube head or port and labeled with the words "X-ray on," or words containing a similar warning, shall be provided and shall be illuminated when the X-ray tube is energized.

(e) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(f) Analytical X-ray equipment shall be labeled with a readily discernible sign bearing the radiation symbol and both of the following:

(1) "CAUTION—HIGH INTENSITY X-RAY BEAM" or words having a similar intent on the X-ray source housing.

(2) "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X-ray tube.

(g) On equipment with an open-beam configuration manufactured and installed after December 19, 1987, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or coupling has been connected to the port.

(h) Equipment exclusively designed and exclusively used for vacuum spectroscopy where the tube housing and sample chamber is located behind all external surfaces of the unit shall be exempt from the requirements of this section, §§ 227.12a and 227.13a (relating to area requirements; and operating requirements), but shall meet the requirements of § 227.14 (relating to personnel procedures) and the following:

(1) The unit shall be designed so that when the unit is operating at the maximum kilovoltage and current ratings, the leakage radiation will not be in excess of 0.5 milliroentgens (.129 μC/kg) per hour at a distance of 4 centimeters from any external surface.

(2) Radiation surveys using appropriate radiation survey equipment shall be performed on the analytical X-ray unit upon installation, after moving the unit to a new location, and after maintenance or repair requiring the disassembly or removal of a local component or radiation shielding.

(3) Safety and warning devices shall be tested for proper operation at least annually. If the test reveals that a safety or warning device is not working properly, the unit may not be operated until the warning device is repaired or replaced.

(4) Records of all tests and surveys sufficient to show compliance with subsection (h) shall be maintained and kept available for inspection by the Department for 4 years.

(5) A sign bearing the radiation symbol and the words "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words of similar intent shall be placed next to any switch or device that activates the X-ray tube.

(6) A sign bearing the radiation symbol and the words "CAUTION—RADIATION," or words of similar intent shall be placed next to the opening of the sample chamber.

Authority

The provisions of this § 227.11a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.11a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285692) to (285693) and (282433).

§ 227.12. [Reserved].

Source

The provisions of this § 227.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203997).

§ 227.12a. Area requirements.

(a) The source housing construction shall be of a type that when all the shutters are closed and the source is in any possible operating mode, the leakage radiation will not be in excess of 2.5 milliroentgens (.645 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(b) The X-ray generator shall have a protective cabinet constructed so that the leakage radiation will not be in excess of 0.5 milliroentgen (.129 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(c) The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in 10 CFR 20.1301 (relating to dose limits for individual members of the public). For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.

(d) To show compliance with subsections (a)—(c), the registrant shall perform radiation surveys:

(1) Upon installation of the equipment and at least every 12 months thereafter.

(2) Following a change in the initial arrangement, number or type of local components in the system.

(3) Following maintenance requiring the disassembly or removal of a local component in the system.

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(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when a local component in the system is disassembled or removed.

(5) When a visual inspection of the local components in the system reveals an abnormal condition.

(6) When personnel monitoring devices show a significant increase in radiation exposure over the previous monitoring period or the readings are approaching the radiation dose limits.

(7) When the machine is operated in a manner other than the routine manner specified in § 227.13a (relating to operating requirements).

(e) The registrant shall test and inspect all safety and warning devices at least annually to insure their proper operation. If a safety or warning device is found to be malfunctioning, the machine shall be removed from service until repairs to the malfunctioning device are completed.

(f) Records of surveys and tests sufficient to show compliance with this chapter shall be maintained for 4 years and kept available for inspection by the Department.

(g) The equipment used to conduct the surveys and tests required in this chapter shall be adequate to measure the radiation produced by the radiation source.

Authority

The provisions of this § 227.12a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.12a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282434) and (249339).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements); and 25 Pa. Code § 227.14 (relating to personnel requirements).

§ 227.13. [Reserved].

Source

The provisions of this § 227.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (203997) to (203998).

§ 227.13a. Operating requirements.

(a) Operating procedures shall be written and available to the analytical X-ray equipment operators. These procedures shall include instructions for sample insertion and manipulation, equipment alignment, routine maintenance and data recording procedures which are related to radiation safety. An individual may not operate analytical X-ray equipment in a manner other than that specified in the operating procedures unless the individual has obtained written approval from the radiation safety officer.

(b) An individual may not bypass or otherwise circumvent a safety device unless the individual has obtained the prior written approval of the radiation safety officer. The radiation safety officer may grant the permission only if the following conditions are met:

(1) The radiation safety officer establishes administrative controls and procedures to assure the radiation safety of individuals working around the system.

(2) The period for the bypass of the safety device is not more than 30 days unless written permission is obtained from the Department for a longer period.

(3) A readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words containing a similar warning, is placed on the radiation source housing.

(c) Except as specified in subsection (b), an operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops may not be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Emergency procedures shall be written and posted near the equipment and shall list the names and telephone numbers of personnel to contact. The emergency procedures shall also provide information necessary to de-energize the equipment, such as location and operation of the power supply or circuit breakers.

Authority

The provisions of this § 227.13a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.13a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249339) to (249340).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements); and 25 Pa. Code § 227.12a (relating to area requirements).

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§ 227.14. Personnel requirements.

(a) An individual may not operate or maintain analytical X-ray equipment unless the individual has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment.

(2) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions necessary if the devices are absent or bypassed.

(3) Written operating and emergency procedures for the equipment.

(4) Symptoms of an acute localized radiation exposure.

(5) Procedures for reporting an actual or suspected exposure.

(6) Use of survey and personnel monitoring equipment.

(7) The applicable regulations of this article and those incorporated by reference.

(b) Finger or wrist personnel monitoring devices shall be provided to and shall be used by:

(1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device as described in § 227.12a(c) (relating to area requirements).

(2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when a local component in the analytical X-ray system is disassembled or removed or when safety devices are bypassed.

(c) Reported dose values may not be used for the purpose of determining compliance with 10 CFR 20.1201 (relating to occupational dose limits for adults) unless they are evaluated by a qualified expert.

(d) The registrant or licensee shall notify the Department within 5 days of a suspected radiation overexposure to an individual from analytical X-ray machines. This notification is required even if subsequent investigation reveals no actual over-exposure actually occurred.

Authority

The provisions of this § 227.14 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. 510-20).

Source

The provisions of this § 227.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249340) to (249341).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements).

§ 227.15. [Reserved].

Source

The provisions of this § 227.15 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (203999) to (204000).

X-RAY GAUGING EQUIPMENT

§ 227.21. Warnings.

X-ray gauging equipment shall be labeled with a readily discernable sign or signs bearing the radiation symbol and the words, "Caution Radiation—This Equipment Produces Radiation When Energized," or words containing a similar warning.

Source

The provisions of this § 227.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4922).

§ 227.22. Radiation levels.

An X-ray tube housing shall be constructed so that, with the unit in normal operation, the leakage radiation measured 5 centimeters from a surface is no more than 2.5 milliroentgens (645 nC/kg) per hour.

Source

The provisions of this § 227.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4922).

§ 227.23. Personnel requirements.

No registrant may permit an individual to operate or conduct maintenance upon X-ray gauging equipment until the individual has received a copy of and instruction in, and demonstrated an understanding of, the operating procedures necessary to ensure radiation safety.

Source

The provisions of this § 227.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4922) to (4923).

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§ 227.24. [Reserved].

Source

The provisions of this § 227.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4923) to (4924).

§ 227.25. [Reserved].

Source

The provisions of this § 227.25 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4924) to (4937).

ELECTRON MICROSCOPES

§ 227.31. Warnings.

An electron microscope shall be labeled with a readily discernable sign bearing the words, "Caution Radiation—This Equipment Produces Radiation When Energized," or words containing a similar warning.

Source

The provisions of this § 227.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4937).

§ 227.32. Radiation levels.

Radiation levels measured 5 centimeters from any accessible surface of an electron microscope may not exceed .5 milliroentgen (129 nC/kg) per hour.

Source

The provisions of this § 227.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4938).

§ 227.33. Personnel requirements.

A registrant may not permit an individual to operate or conduct maintenance upon any electron microscope until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to insure radiation safety.

Authority

The provisions of this § 227.33 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.33 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204002).

§§ 227.41—227.44. [Reserved].

Source

The provisions of these §§ 227.41—227.44 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4938) to (4941).

§§ 227.51—227.53. [Reserved].

Source

The provisions of these §§ 227.51—227.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4941) to (4942).

§§ 227.61—227.71. [Reserved].

Source

The provisions of these §§ 227.61—227.71 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4942) to (4948).

§§ 227.81—227.85. [Reserved].

Source

The provisions of these §§ 227.81—227.85 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4949) to (4951).

§§ 227.91—227.97. [Reserved].

Source

The provisions of these §§ 227.91—227.97 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4951) to (4955).

X-RAY CALIBRATION SYSTEMS

§ 227.101. Scope.

This section and §§ 227.102—227.104 apply to registrants who use X-ray producing machines to calibrate or test radiation detection or measuring devices.

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Authority

The provisions of this § 227.101 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.101 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

§ 227.102. Area requirements.

A room or enclosure used for testing or calibration shall be shielded so that every location on the exterior meets conditions for an unrestricted area, and the only access to the room or enclosure is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

Authority

The provisions of this § 227.102 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.102 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

§ 227.103. Operating requirements.

(a) The operator shall conduct a physical radiation survey to determine that the radiation machine X-ray tube is de-energized prior to each entry of any body part into the X-ray exposure area.

(b) As an alternative to subsection (a), the registrant may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels.

Authority

The provisions of this § 227.103 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.103 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

§ 227.104. Personnel requirements.

A registrant may not permit an individual to operate or conduct maintenance on any X-ray calibration system until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to ensure radiation safety.

Authority

The provisions of this § 227.104 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.104 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

[Next page is 228-1.]

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CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

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Authority

The provisions of this Chapter 228 issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. § 7110.301 and § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 228 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 216.1 (relating to purpose and scope); 25 Pa. Code § 216.3 (relating to exemptions); 25 Pa. Code § 218.1 (relating to purpose and scope); 25 Pa. Code § 218.11 (relating to registration, renewal of registration and license fees); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 266.61 (relating to particle accelerators).

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GENERAL PROVISIONS

§ 228.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons utilizing particle accelerators for industrial, research or medical purposes. Persons who use particle accelerators shall comply with this chapter. The requirements in this chapter are in addition to and not in substitution for other applicable requirements of this article.

§ 228.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Accelerator or *particle accelerator*—A radiation-producing machine that imparts kinetic energies of one of the following:

(i) One-tenth of one MeV or greater to electrons if the electron beam is brought out of the evacuated region of the unit.

(ii) One MeV or greater to electrons if the electrons are utilized for X-ray production.

(iii) One-tenth of one MeV or greater to other particles.

Applicator—A structure which determines the extent of the treatment field at a given distance from the virtual source.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

Beam scattering filter—A filter used to scatter a beam of electrons.

Central axis of the beam—A line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

Dose monitoring system—A system of devices for the detection, measurement and display of quantities of radiation.

Dose monitor unit—A unit response from the dose monitoring system from which the absorbed dose can be calculated.

Existing equipment—Systems manufactured on or before October 3, 1998.

Field flattening filter—A filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

Field size—The configuration of the radiation field along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50% isodose line.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and remove radiation that does not contribute to the efficacy of the useful beam.

Isocenter—A fixed point in space located at the center of the smallest sphere through which the central axes of the beams pass.

Leakage radiation—Radiation emanating from the source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

Moving beam therapy—Radiation therapy with relative displacement of the useful beam and the patient during irradiation.

New equipment—Systems manufactured after January 1, 1985.

Normal treatment distance—

(i) For isocentric equipment, the isocenter.

(ii) For nonisocentric equipment, the target to patient skin distance along the central axis as specified by the manufacturer.

Particle accelerator—See the definition of "accelerator."

Phantom—A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Primary dose monitoring system—A system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been attained.

Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Radiation head—The structure from which the useful beam emerges.

Secondary dose monitoring system—A system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Shadow tray—A device attached to the radiation head to support auxiliary beam limiting material.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Stationary beam therapy—Radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subsystem—A combination of two or more components of an accelerator.

Target—The part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

Tube housing assembly—The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Virtual source—The nominal location of either the first scattering foil (for equipment providing electrons only) or the photon focal spot (for equipment capable of delivering both photons and electrons).

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.

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Source

The provisions of this § 228.2 amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249347) to (249349).

Cross References

This section cited in 25 Pa. Code § 216.1 (relating to purpose and scope).

§ 228.3. Sale and installation.

A person may not sell or install an accelerator that does not meet the provisions of this article.

Source

The provisions of this § 228.3 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

ADMINISTRATIVE CONTROLS

§ 228.11. [Reserved].

Source

The provisions of this § 228.11 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204010).

§ 228.11a. Licensee responsibilities.

(a) A person may not possess, operate or permit the operation of an accelerator unless the accelerator and installation meet the applicable requirements of this article.

(b) Written safety procedures and rules shall be available at a facility, including restrictions of the operating technique required for the safe operation of the particular accelerator. The operator shall be able to demonstrate familiarity with the rules.

(c) An individual may not be exposed to the useful beam except for healing arts purposes. An exposure shall be authorized by a licensed practitioner of the healing arts.

Source

The provisions of this § 228.11a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249349) to (249350).

§ 228.12. Information and maintenance record and associated information.

The licensee shall maintain records of surveys, calibrations, maintenance, machine malfunctions and modifications performed on the accelerators, including

the names of persons who performed the services. The licensee shall keep these records for inspection by the Department for 5 years.

Source

The provisions of this § 228.12 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (249530).

NOTIFICATION AND LICENSING PROCEDURES

§ 228.21. [Reserved].

Source

The provisions of this § 228.21 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204011).

§ 228.21a. Notification and license requirements.

(a) A person who intends to purchase, construct or acquire an accelerator shall notify the Department of this intent by filing an application for a specific license within 30 days after the initial order is issued to obtain any or all parts of the accelerator.

(1) The application shall be filed in duplicate on a form prescribed by the Department and shall be accompanied by the required fee as described in § 218.11(d) (relating to registration, renewal of registration and license fees).

(2) The application shall contain pertinent information to permit the Department to evaluate the accelerator facility for compliance with the act and this article.

(b) In addition to the notification requirement in subsection (a), a person who intends to install an accelerator shall notify the Department within 30 days after the initial construction or installation begins.

(c) Except as provided in subsection (d), a person may not operate a particle accelerator after October 3, 1998, without having obtained a license from the Department.

(d) A registrant possessing an accelerator before October 3, 1998, may continue to operate the accelerator provided an application for a license is filed in duplicate with the Department by October 4, 1999.

(e) The Department may, after the filing of an original application, and before the expiration of the license, require further information to enable the Department to determine whether the application will be granted or denied or whether a license will be modified or revoked.

(f) The application shall be signed by the applicant or licensee or an individual authorized by the applicant or licensee.

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(g) A license issued under this chapter may not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, to any person except through submission of a written request by the licensee to the Department for approval.

Source

The provisions of this § 228.21a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249350) and (285701).

Cross References

This section cited in 25 Pa. Code § 228.24a (relating to renewal of licenses); and 25 Pa. Code § 228.25a (relating to amendment of license at the request of the licensee).

§ 228.22. [Reserved].

Source

The provisions of this § 228.22 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204011).

§ 228.22a. Issuance of specific licenses.

(a) Upon determination that an application meets the requirements of the act and this article, the Department will issue a specific license authorizing the proposed activity and containing conditions and limitations as it deems appropriate or necessary.

(b) After the issuance of the license, the Department may, by appropriate regulations or order, incorporate additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of the accelerator subject to this chapter as it deems appropriate or necessary in order to:

(1) Protect the public health and safety or property.

(2) Prevent loss or theft of material subject to this chapter.

Source

The provisions of this § 228.22a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249351).

§ 228.23. [Reserved].

Source

The provisions of this § 228.23 amended November 17, 1995, effective November 28, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (204011) to (204012).

§ 228.23a. Expiration and termination of a license.

(a) Except as provided in § 228.24a (relating to renewal of licenses), and subject to subsection (d)(5)(ii), a specific license expires on the date specified in the license. A license is effective for 5 years.

(b) A licensee shall notify the Department in writing when the licensee decides to permanently discontinue activities involving the accelerator authorized under the license and request termination of the license. The notification and request for termination shall include the reports and information specified in subsection (d)(3)—(5). The licensee is subject to subsections (d) and (e), as applicable, until termination.

(c) At least 30 days before the expiration date specified in a specific license, the licensee shall do one of the following:

(1) Submit an application for license renewal under § 228.24a.

(2) Notify the Department in writing if the licensee decides not to renew the license.

(d) If the licensee does not submit an application for license renewal under § 228.24a on or before the expiration date specified in the license, the licensee shall:

(1) Terminate the use of, and transfer or dispose of the accelerator.

(2) Properly dispose of incidental radioactive material generated by the operation of the accelerator.

(3) Submit a completed Department Form 2900-PM-RP0314, "Certificate of Disposition of Materials," describing the disposition of materials in paragraph (2).

(4) Submit a radiation survey report to confirm the absence of radioactive materials or establish the levels of residual radioactive contamination unless the Department determines a radiation survey report is not necessary. This report shall include:

(i) The levels of beta and gamma radiation (in units of microrems or microsieverts, or in microrads or micrograys per hour) at 1 centimeter and gamma radiation at 1 meter from surfaces, levels of removable and fixed alpha, beta and gamma contamination on surfaces (in becquerels or microcuries per 100 square centimeters), and concentrations of contamination in soils (in units of picocuries or becquerels per gram) or in water (in units of picocuries or becquerels per liter) where soil and water concentrations are reported.

(ii) The survey instrumentation used to perform these surveys.

(5) Proceed with one of the following:

(i) Submit a certification that no detectable radioactive contamination was found if no residual contamination attributable to activities conducted

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under the license is detected. If the information submitted under this section is adequate, the Department will notify the licensee in writing that the license is terminated.

(ii) Continue the license in effect beyond the expiration date. If necessary, with respect to possession of residual radioactive material present as contamination if detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall comply with subsection (e), in addition to the information submitted under paragraphs (3) and (4) and this paragraph, the licensee shall submit a plan for decontamination, if necessary.

(e) A licensee who possesses residual radioactive material under subsection (d)(5)(ii) following the expiration date specified in the license, shall:

(1) Limit activities involving radioactive materials to those activities which are solely related to decontamination and other activities related to preparation for release for unrestricted use.

(2) Continue to control entry to restricted areas until the restricted areas are suitable for release for unrestricted use and until the Department notifies the licensee in writing that the license is terminated.

Source

The provisions of this § 228.23a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285702) and (249353).

§ 228.24. [Reserved].

Source

The provisions of this § 228.24 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204012).

§ 228.24a. Renewal of licenses.

(a) An application for renewal of a specific license shall be filed under § 228.21a (relating to notification and license requirements).

(b) If a renewal application is filed prior to 30 days before the expiration of a license, the existing license does not expire until definitive notice has been given by the Department of its action on the renewal application. This subsection also applies to new license applications incorporating other licenses.

Source

The provisions of this § 228.24a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 228.23a (relating to expiration and termination of a license).

§ 228.25. [Reserved].

Source

The provisions of this § 228.25 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (204012) to (204013).

§ 228.25a. Amendment of license at the request of the licensee.

A licensee filing an application for an amendment shall utilize the procedures in § 228.21a (relating to notification and license requirements). The application shall specify the requested amendment and the reason for the amendment.

Source

The provisions of this § 228.25a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.26. [Reserved].

Source

The provisions of this § 228.26 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.26a. Department action on applications to renew and amend.

In considering an application by a licensee to renew or amend a license, the Department will apply criteria in the act and this article.

Source

The provisions of this § 228.26a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.31. [Reserved].

Source

The provisions of this § 228.31 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.31a. Limitations.

(a) The facility shall operate within the terms and conditions of the license issued for the operation of the accelerator.

(b) A licensee may not permit an individual to act as an operator of an accelerator until the individual:

(1) Has been instructed in radiation safety and has demonstrated an understanding thereof.

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(2) Has received copies of and instruction in this chapter and Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations), pertinent license conditions and the licensee's operating and emergency procedures and demonstrated understanding thereof.

(3) Has demonstrated competence to use the accelerator, related equipment and survey instruments which will be utilized in that individual's assignment.

(c) The radiation safety officer shall have the authority to restrict or terminate operations at an accelerator facility if the action is necessary to minimize danger to health and safety, property or the environment.

Source

The provisions of this § 228.31a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249354) and (282437).

§ 228.32. [Reserved].

Source

The provisions of this § 228.32 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.32a. Shielding and safety design requirements.

(a) The licensee shall consult a qualified expert for radiation protection concerning the shielding design of an accelerator installation.

(b) An accelerator facility shall have primary and secondary protective barriers that are necessary to assure compliance with 10 CFR Part 20, Subpart D (relating to dose limits for individual members of the public).

Source

The provisions of this § 228.32a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282437).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.33. [Reserved].

Source

The provisions of this § 228.33 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204013).

§ 228.33a. Facility and shielding requirements.

In addition to the requirements in Chapter 219 (relating to standards for protection against radiation), the following are required:

(1) The control panel shall be located outside the treatment or irradiation room.

(2) For accelerators not used in the healing arts, provision shall be made to permit continuous observation of the material being irradiated and any transfer or conveyance of material within the irradiation room.

(3) For accelerators used in the healing arts, provision shall be made to permit continuous observation of and communication with the patient during irradiation.

(4) Windows, mirror systems or closed-circuit television viewing screens used for observing the patient or the material being irradiated shall be located so that the operator can maintain direct surveillance over both the control panel and the patient or the material being irradiated.

(5) If the surveillance conducted under paragraph (4) is provided solely by electronic means, and if a malfunction of this surveillance equipment occurs, irradiation activities shall cease until repair of that surveillance equipment is performed and the equipment is found to be functioning normally.

(6) Irradiation or treatment room entrances shall be provided with warning lights in a readily observable position near the outside of access doors. These will indicate when the useful beam is on.

(7) Interlocks shall be provided so that entrance or access doors are closed before irradiation or treatment can be initiated or continued.

(8) For accelerators used to irradiate materials by means of a transfer or conveyance system, a means shall be provided which either terminates the irradiation or prevents entry if an individual attempts access to the irradiation room.

Source

The provisions of this § 228.33a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.34. [Reserved].

Source

The provisions of this § 228.34 amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204014).

§ 228.34a. Accelerator controls and interlock systems.

(a) Instrumentation, readouts and controls on the accelerator control console shall be clearly identified and easily discernible.

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(b) Entrances into a target room or high radiation areas shall have interlocks that meet the requirements of 10 CFR Part 20, Subpart G (relating to control of exposure from external sources in restricted areas) and 10 CFR 20.1902 (relating to posting requirements). If the radiation beam is interrupted by a door opening, it shall be possible to reinitiate the radiation exposure only by closing the door first and then by manual action at the control panel.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the interlock position, and lastly at the main control console.

(d) Safety interlocks shall be fail-safe, that is, designed so that a defect or component failure in the interlock system prevents operation of the accelerator.

(e) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. The cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

Source

The provisions of this § 228.34a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282438) and (285703).

§ 228.35. Operating procedures.

(a) Accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) An interlock may not be used to turn off the accelerator beam except in an emergency or for testing the interlock.

(c) Each safety and warning device, including interlocks, shall be checked at least every 3 months for proper functioning and shall be repaired as necessary. Results of these checks and records of repairs shall be maintained for 4 years at the accelerator facility for inspection by the Department.

(d) In the event of a malfunction of a safety or warning device, the accelerator may not be operated unless appropriate interim precautions are instituted to provide equivalent protection.

(e) If it is necessary to intentionally bypass a safety interlock system or component thereof, the action shall be the following:

(1) Authorized in writing by the radiation safety officer.

(2) Recorded in a permanent log and a notice posted at the accelerator operator's position.

(3) Terminated as soon as possible.

(f) A copy of the current operating and emergency procedures shall be maintained in the accelerator operator area.

(g) For accelerators used in the healing arts, operating procedures shall meet the following requirements:

(1) No individual other than the patient is in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system may not be used in the administration of radiation therapy unless the requirements of this chapter have been met.

(4) A medical reportable event for radiation-producing machine therapy, as defined in § 219.3 (relating to definitions), shall be reported as required under § 219.228 (relating to reports of medical reportable events for radiation-producing machine therapy).

(5) An individual who operates an accelerator system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include, but not be limited to, items included in Appendix A (relating to determination of competence). There shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

Source

The provisions of this § 228.35 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (285703) to (285704).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.36. Radiation monitoring requirements.

An independent radiation monitoring system shall be provided so that the individuals entering or present in a potential very high radiation area become aware of the existence of the hazard. Independent radiation monitors shall be tested for response at least annually and after each servicing or repair.

Source

The provisions of this § 228.36 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial pages (282440) to (282441).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.37. Production of radioactive material.

(a) A licensee who produces radioactive material incidental to the operation of an accelerator shall comply with the general license requirements of § 217.144 (relating to incidental radioactive material produced by a particle accelerator).

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(b) A licensee possessing radioactive material intentionally produced by bombarding nonradioactive material with the accelerator beam shall comply with the specific license requirements of Chapter 217 (relating to licensing of radioactive material).

Source

The provisions of this § 228.37 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282441).

§ 228.38. Radiation safety surveys.

(a) Prior to first use, a facility shall have a survey made by, or under the direction of, a qualified expert for radiation protection. A survey shall also be done after a change in the facility or equipment, including a relocation of the equipment within the irradiation or treatment room.

(b) The qualified expert shall report the survey results in writing to the individual in charge of the facility and a copy of the initial report shall be maintained by the licensee for inspection by the Department for the life of the facility. Other survey reports shall be maintained for inspection by the Department for 4 years. The facility shall be operated in compliance with limitations indicated by the survey.

(c) The report of the survey results shall include:

(1) The date of the measurements.

(2) The reason the survey is required.

(3) The manufacturer's name, model number and serial number of the therapeutic radiation machine accelerator.

(4) The instrument used to measure radiation levels.

(5) A plan of the areas surrounding the treatment room that were surveyed.

(6) The measured dose rate at several points in each area expressed in microsieverts or millirems per hour.

(7) The calculated maximum level of radiation over a period of 1 year for each restricted and unrestricted area.

(8) The signature of the individual who conducted or is responsible for conducting the survey.

(d) If the survey required by subsection (a) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 10 CFR 20.1201 (relating to occupational dose limits for adults) or 10 CFR 20.1301 (relating to dose limits for individual members of the public), the licensee shall do the following:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Chapter 219 (relating to standards for protection against radiation).

(2) Perform the survey required by subsection (a) again.

(3) Prepare and submit the report required by subsection (a). The report shall also include:

(i) The results of the initial survey.

(ii) A description of the modification made to comply with this section.

(iii) The results of the second survey.

Source

The provisions of this § 228.38 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282441) to (282442).

Cross References

This section cited in 25 Pa. Code § 228.39 (relating to records).

§ 228.39. Records.

In addition to the requirements of 10 CFR Part 20, Subpart L (relating to records), the licensee shall maintain:

(1) Records of the tests and safety and warning devices described in § 228.35 (relating to operating procedures).

(2) The surveys described in §§ 228.32a and 228.38 (relating to shielding and safety design requirements; and radiation safety survey).

(3) The radiation monitoring equipment calibrations and repairs of that equipment under § 228.36 (relating to radiation monitoring requirements).

Source

The provisions of this § 228.39 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282442).

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL AND RESEARCH ACCELERATORS

§ 228.41. [Reserved].

Source

The provisions of this § 228.41 reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204014).

§ 228.41a. Warning devices.

(a) A location designated as a high radiation area and an entrance to the location shall be equipped with easily observable warning lights that operate only when radiation is being produced.

(b) A high radiation area shall meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

Source

The provisions of this § 228.41a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282443).

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§ 228.42. Circuit diagrams.

Electrical circuit diagrams of the accelerator and the associated safety, warning and interlock systems shall be kept current and maintained for inspection by the Department and shall be available to the operator at an accelerator facility.

Source

The provisions of this § 228.42 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.43. Radiation surveys.

(a) Periodic surveys shall be made to determine the amount of airborne radioactivity present in areas of airborne hazards.

(b) Periodic smear surveys shall be made to determine the amount of contamination in target and other pertinent areas.

(c) Area surveys shall be made in accordance with the written procedures established by a qualified expert for radiation protection or the radiation safety officer of the accelerator facility.

(d) Records of surveys shall be kept current and on file at an accelerator facility. Records of surveys shall be maintained as described in 10 CFR Part 20, Subpart L (relating to records).

Source

The provisions of this § 228.43 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282443).

§ 228.44. Ventilation systems.

(a) A licensee shall control the concentration of radioactive material in air to meet the requirements of 10 CFR 20.1204 (relating to determination of internal exposure).

(b) A licensee may not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which does not meet the requirements of 10 CFR 20.1301 (relating to dose limits for individual members of the public). Every reasonable effort shall be made to maintain releases of radioactive material to uncontrolled areas as far below these limits as practicable. Compliance with this section shall be demonstrated as described in 10 CFR 20.1302 (relating to compliance with dose limits for individual members of the public).

Source

The provisions of this § 228.44 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282443) to (282444).

§ 228.45. Portable or mobile accelerators.

Portable or mobile accelerators used for industrial radiography or research shall comply with Chapter 225 (relating to radiation safety requirements for industrial radiographic operations).

Source

The provisions of this § 228.45 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

§ 228.61. Leakage radiation to the patient area.

(a) New equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the dose due to leakage radiation, including X-rays, electrons and neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, may not exceed 0.1% of the maximum dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

(2) For each system, the licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records for 5 years on leakage radiation measurements for inspection by the Department.

(b) Existing equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, including neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam 1 meter from the virtual source, may not exceed 0.1% of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(2) For each system, the licensee shall have available the leakage radiation data existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records on radiation leakage for 5 years for inspection by the Department.

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Source

The provisions of this § 228.61 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (282444) and (249363).

Cross References

This section cited in 25 Pa. Code § 228.62 (relating to leakage radiation outside the patient area for new equipment).

§ 228.62. Leakage radiation outside the patient area for new equipment.

(a) The absorbed dose due to leakage radiation except in the area specified in § 228.61(a)(1) (relating to leakage radiation to the patient area) when measured at any point 1 meter from the path of the charged particles, before the charged particles strike the target or window, may not exceed 0.1% for X-ray leakage nor 0.5% for neutron leakage of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in § 228.61(a)(1).

(b) The licensee shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in subsection (a) for specified operating conditions. Radiation measurements, including neutrons, shall be averaged over an area up to but not exceeding 200 square centimeters.

Source

The provisions of this § 228.62 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.63. Beam limiting devices.

Adjustable or interchangeable beam limiting devices shall be provided and the devices may transmit no more than 5% of the useful beam at the normal treatment distance. The neutron component of the useful beam may not be included to comply with this requirement.

Source

The provisions of this § 228.63 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.64. Filters.

(a) A filter which is removable from the system shall be clearly identified. Documentation shall contain a description of the filter which includes a drawing showing dimensions and noting materials of construction.

(b) For new equipment which utilizes a system of wedge filters, interchangeable field flattening filters or interchangeable beam scattering filters the following apply:

(1) Irradiation may not be possible until a selection of a filter has been made at the control panel.

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(3) An interlock shall be provided to prevent irradiation if a filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the control panel.

Source

The provisions of this § 228.64 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.65. Electron beam quality.

The licensee shall determine that the following beam quality requirements are met:

(1) The absorbed dose resulting from X-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons may not exceed the values in Table I. Linear interpolation shall be used for values not stated.

Table I

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 paragraph (1) 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.

(iii) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

(3) The licensee shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose due to stray neutrons in the useful beam for specified operating conditions.

Source

The provisions of this § 228.65 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

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§ 228.66. Beam monitors.

(a) Therapy systems shall be provided with radiation detectors in the radiation head.

(b) New equipment shall be provided with at least two radiation detectors incorporated into two separate dose monitoring systems.

(c) Existing equipment shall be provided with at least one radiation detector incorporated into a primary dose monitoring system.

(d) The detector in a dose monitoring system shall be:

(1) Permanently installed and interlocked to prevent incorrect positioning.

(2) Part of a dose monitoring system that provides readings in dose monitor units which can be used to calculate the absorbed dose at a reference point in the treatment volume.

(3) Capable of independently monitoring and controlling the useful beam.

(e) For new equipment, the design of dose monitoring systems shall assure that:

(1) The malfunctioning of one system does not affect the correct functioning of the second system.

(2) The failure of an element common to both systems which could affect the correct function of both systems terminates irradiation.

(f) A dose monitoring system shall have a legible display at the control panel. For new equipment, a display shall:

(1) Maintain a reading until intentionally reset to zero.

(2) Have only one scale and no scale multiplying factors.

(3) Utilize a design so that increasing dose is displayed by increasing numbers and that the absorbed dose may be accurately determined under all conditions of use.

(4) Provide that, in the event of a power failure, the dose monitoring information required in this subsection displayed at the control panel at the time of failure shall be retrievable.

Source

The provisions of this § 228.66 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 228.74 (relating to absorbed dose rate).

§ 228.67. Beam symmetry.

(a) In new equipment inherently capable of producing useful beams with asymmetry exceeding 5%, at least four different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device.

(b) If the difference in dose rates between two of the different parts required in subsection (a) exceeds 10%, the irradiation shall be terminated.

Source

The provisions of this § 228.67 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.68. Selection and display of dose monitor units.

(a) Irradiation may not be possible until a selection of a number of dose monitor units has been made at the control panel.

(b) The preselected number of dose monitor units shall be displayed at the control panel until reset manually to zero before subsequent treatment can be initiated.

Source

The provisions of this § 228.68 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.69. Termination of irradiation by the dose monitoring system or systems.

(a) A dose monitoring system shall be capable of independently terminating irradiation.

(b) A primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(c) A secondary dose monitoring system shall terminate irradiation when either 110% of the preselected number of dose monitor units or 10 dose monitor units (whichever is greater) has been detected by the secondary dose monitoring system.

(d) For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

Source

The provisions of this § 228.69 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.70. Interruption and termination switches.

The operator shall be able to interrupt or terminate irradiation and equipment movement at any time from the control panel. Following an interruption, the operator shall be able to resume irradiation without reselection of operating conditions.

Source

The provisions of this § 228.70 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

Cross References

This section cited in 25 Pa. Code § 228.73 (relating to selection of stationary beam therapy or moving beam therapy).

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§ 228.71. Timer.

(a) The control panel shall have a timer that is graduated in minutes and fractions of minutes or seconds. The timer shall have a preset time selector and an elapsed time indicator.

(b) The timer shall be cumulative and activated only during irradiation and shall retain its reading after irradiation is interrupted or terminated.

(c) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.

Source

The provisions of this § 228.71 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.72. Selection of radiation type.

Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation may not be possible until a selection of radiation type and appropriate energy has been made and displayed at the control panel.

(2) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

(3) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the control panel.

(4) An interlock system shall be provided to prevent:

(i) Irradiation with X-rays except to obtain a port film when electron applicators are fitted.

(ii) Irradiation with electrons when accessories specific for X-ray therapy are fitted.

(5) For new equipment, a system shall be provided to terminate irradiation if the energy of the electrons striking either the X-ray target or electron window deviates by more than +20% or 3 MeV, whichever is smaller, from the selected nominal energy.

Source

The provisions of this § 228.72 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.73. Selection of stationary beam therapy or moving beam therapy.

Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following additional requirements:

(1) Irradiation may not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the control panel.

(2) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

(3) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment rooms do not agree with the selected operations carried out at the control panel.

(4) The mode of operation shall be displayed at the control panel.

(5) An interlock system shall be provided to terminate irradiation if one of the following occurs:

(i) Movement of the gantry during stationary beam therapy.

(ii) Movement of the gantry stops during moving beam therapy unless the stoppage is a preplanned function.

(6) An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered along an arc differs by more than 10% from the selected value. Termination of irradiation shall be as required by § 228.70 (relating to interruption and termination switches).

Source

The provisions of this § 228.73 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.74. Absorbed dose rate.

New equipment shall have a system that provides information from which the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in § 228.66 (relating to beam monitors) may form part of this system. The dose monitor unit rate shall be displayed at the control panel.

Source

The provisions of this § 228.74 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894.

§ 228.75. Calibrations.

(a) The calibration of systems subject to this subchapter shall be performed in accordance with an established calibration protocol. The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent. The calibration shall be performed as follows:

(1) Before the system is first used for irradiation of a patient and, at time intervals which do not exceed 1 year.

(2) After a change which alters the calibration, spatial distribution or other characteristics of the therapy beam.

(b) The calibration shall be performed by, or under the direct supervision of, a qualified expert for radiation therapy calibrations.

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(c) Calibration radiation measurements required by subsection (a) shall be performed using a dosimetry system meeting the following specifications:

(1) The system has an exposure calibration factor appropriate to the beam energy measured and traceable to a National standard.

(2) The system has been calibrated within the previous 2 years and after servicing that may have affected its calibration.

(3) The system has been calibrated so that an uncertainty can be stated for the radiation quantities monitored by the system.

(4) The system has had constancy checks performed on the system as specified by a qualified expert for radiation therapy calibrations.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

(e) The calibration of the therapy beam shall include, but is not limited to, the following determinations:

(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and beam limiting device (collimator) system.

(2) The absorbed dose rate at various depths (depth dose) and beam profile measured in water and the beam flatness and symmetry for the range of field sizes used, for each beam energy.

(3) The uniformity of the radiation field and a dependency upon the direction of the useful beam.

(4) Verification of depth-dose data and isodose curves applicable to the specific machine.

(5) Verification of the applicability of transmission factors of accessories such as wedges, shadow trays, compensators and their effects on electron buildup.

(6) The dose per monitor unit, end effect, linearity and dose rate dependence of the dose monitor systems.

(7) For photon beams, the congruence of the light field and the radiation field.

(8) For electron beams, the validity of commissioning data for virtual source distances or effective source-to-skin distances is to be verified at a single electron energy with a beam restriction device. When the replacement of a beam restriction device occurs, the determination will be required for each electron energy.

(f) Records of calibration measurements under subsection (a) and dosimetry system calibrations under subsection (c) shall be preserved for 5 years.

(g) A copy of the latest calibration performed under subsection (a) shall be available at the facility.

Source

The provisions of this § 228.75 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249369) to (249370).

Cross References

This section cited in 25 Pa. Code § 228.76 (relating to spot checks).

§ 228.76. Spot checks.

Spot checks shall be performed on systems subject to this subchapter during full calibrations and thereafter once in each calendar month. The spot checks shall meet the following requirements:

(1) The procedures shall be in writing and developed by a qualified expert for radiation therapy calibrations.

(2) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a qualified expert within 15 days of the completion of the spot check.

(3) 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.

(4) The spot-check procedures shall specify the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the full calibration.

(5) If a spot check indicates a change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in § 228.75 (relating to calibrations).

(6) Records of spot-check measurements performed under this section shall be maintained by the licensee for 5 years after completion of the spot-check measurements and necessary corrective actions.

(7) Spot check measurements shall be performed using a dosimetry system that has been calibrated in accordance with § 228.75(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with § 228.75(c). This alternative calibration method shall have been performed within the previous year and after a servicing that may have affected the system calibration.

Source

The provisions of this § 228.76 adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249370) to (249371).

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APPENDIX A
DETERMINATION OF COMPETENCE

The licensee shall ensure training on the subjects listed in Appendix A has been conducted. The individual shall be trained and competent in the general operation of the radiation therapy equipment and its functions, and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

(1) Basic properties of radiation.
(2) Units of measurement.
(3) Sources of radiation exposure.
(4) Methods of radiation protection.
(5) Biological effects of radiation exposure.
(6) Medical accelerator operation.
(7) Treatment planning and execution.
(8) Patient positioning and protection.
(9) Operating and emergency procedures.
(10) Quality assurance.
(11) Regulations.

Source

The provisions of this Appendix A adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (249371) to (249372).

Cross References

This appendix cited in 25 Pa. Code § 228.35 (relating to operating procedures).

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CHAPTER 229. [Reserved].

Source

The provisions of this Chapter 229 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4956), (119235) to (119236), (26466) to (26468), (4962) to (4968) and (119237).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 229.1. [Reserved].

Source

The provisions of this § 229.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended February 27, 1976, effective March 15, 1976, 6 Pa.B. 391; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119235) to (119236) and (26466).

§ 229.2. [Reserved].

Source

The provisions of this § 229.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.3. [Reserved].

Source

The provisions of this § 229.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.4. [Reserved].

Source

The provisions of this § 229.4 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.5. [Reserved].

Source

The provisions of this § 229.5 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26466).

§ 229.6. [Reserved].

Source

The provisions of this § 229.6 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended February 27, 1976, effective March 15, 1976, 6 Pa.B. 391; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26467).

§ 229.11. [Reserved].

Source

The provisions of this § 229.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26467).

§ 229.12. [Reserved].

Source

The provisions of this § 229.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (26467) to (26468).

§ 229.13. [Reserved].

Source

The provisions of this § 229.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26468).

§ 229.14. [Reserved].

Source

The provisions of this § 229.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26468).

§ 229.15. [Reserved].

Source

The provisions of this § 229.15 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (26468).

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§ 229.16. [Reserved].

Source

The provisions of this § 229.16 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4962).

§ 229.17. [Reserved].

Source

The provisions of this § 229.17 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4962).

§ 229.21. [Reserved].

Source

The provisions of this § 229.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4962).

§ 229.22. [Reserved].

Source

The provisions of this § 229.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4963).

§ 229.23. [Reserved].

Source

The provisions of this § 229.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4963).

§ 229.24. [Reserved].

Source

The provisions of this § 229.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4964).

§ 229.25. [Reserved].

Source

The provisions of this § 229.25 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4964).

§ 229.31. [Reserved].

Source

The provisions of this § 229.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4964).

§ 229.32. [Reserved].

Source

The provisions of this § 229.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.33. [Reserved].

Source

The provisions of this § 229.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.34. [Reserved].

Source

The provisions of this § 229.34 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.41. [Reserved].

Source

The provisions of this § 229.41 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4965).

§ 229.42. [Reserved].

Source

The provisions of this § 229.42 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4965) to (4966).

§ 229.43. [Reserved].

Source

The provisions of this § 229.43 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

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§ 229.44. [Reserved].

Source

The provisions of this § 229.44 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

§ 229.45. [Reserved].

Source

The provisions of this § 229.45 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

§ 229.46. [Reserved].

Source

The provisions of this § 229.46 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4966).

§ 229.51. [Reserved].

Source

The provisions of this § 229.51 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4967).

§ 229.52. [Reserved].

Source

The provisions of this § 229.52 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4967).

§ 229.53. [Reserved].

Source

The provisions of this § 229.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4967).

§ 229.54. [Reserved].

Source

The provisions of this § 229.54 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.55. [Reserved].

Source

The provisions of this § 229.55 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.56. [Reserved].

Source

The provisions of this § 229.56 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.57. [Reserved].

Source

The provisions of this § 229.57 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4968).

§ 229.58. [Reserved].

Source

The provisions of this § 229.58 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119237).

§ 229.59. [Reserved].

Source

The provisions of this § 229.59 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119237).

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CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subch.		Sec.
A.	SCOPE AND DEFINITIONS	230.1
B.	GENERAL	230.11
C.	[Reserved]	230.21
D.	OPERATING CONTROLS AND PROCEDURES	230.41
E.	[Reserved]	230.51

Authority

The provisions of this Chapter 230 issued under the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703); the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20); amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 230 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5206, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 226.1 (relating to purpose and scope); and 25 Pa. Code § 232.1 (relating to purpose and scope).

Subchapter A. SCOPE AND DEFINITIONS

Sec.
230.1. Purpose and scope.
230.2. [Reserved].
230.3. Incorporation by reference.
230.4. Effect of incorporation of 10 CFR Part 71.
230.5. Communications.

§ 230.1. Purpose and scope.

This chapter establishes requirements for packaging, preparation for shipment and transportation of radioactive material. This chapter applies to a person who transports radioactive material or delivers radioactive material to a carrier for transport.

§ 230.2. [Reserved].

Source

The provisions of this § 230.2 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204173) to (204176).

§ 230.3. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100 are not incorporated by reference.

Source

The provisions of this § 230.3 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial page (282446).

§ 230.4. Effect of incorporation of 10 CFR Part 71.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), the following words and phrases shall be substituted for the language in 10 CFR Part 71 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or agreement state.

(3) The definition of "sealed source" includes NARM.

(4) The definition of "licensed material" includes NARM.

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Source

The provisions of this § 230.4 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 230.5. Communications.

Notwithstanding the incorporation by reference of 10 CFR 71.1 (relating to communications and records), all communications concerning the requirements of this chapter should be sent to the address listed under § 215.41 (relating to address).

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Source

The provisions of this § 230.5 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Subchapter B. GENERAL

Sec.
230.11 and 230.12. [Reserved].
230.13. Transportation of licensed material.
230.14. [Reserved].

§§ 230.11 and 230.12. [Reserved].

Source

The provisions of these §§ 230.11 and 230.12 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (245185).

§ 230.13. Transportation of licensed material.

In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), if 67 Pa. Code Chapters 229, 231 and 403 (relating to interstate motor carrier safety requirements; intrastate motor carrier requirements; and hazardous materials transportation) or the regulations of the United States Department of Transportation in 49 CFR Parts 171—180 and 388—397 do not apply to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

Source

The provisions of this § 230.13 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

§ 230.14. [Reserved].

Source

The provisions of this § 230.14 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial page (243186).

Subchapter C. [Reserved]

§§ 230.21—230.26. [Reserved].

Source

The provisions of these §§ 230.21—230.26 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204179) to (204183).

Subchapter D. OPERATING CONTROLS AND PROCEDURES

Sec.
230.41—230.46. [Reserved].
230.47. Advance notification of transport of nuclear waste.

§§ 230.41—230.46. [Reserved].

Source

The provisions of these §§ 230.41—230.46 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204184) to (204188).

§ 230.47. Advance notification of transport of nuclear waste.

In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive materials), the licensee is responsible for the following:

(1) Prior to the transport of nuclear waste specified in 10 CFR 71.97(b) (relating to advance notification of shipment of irradiated reactor fuel and nuclear waste) outside the licensee's facility or other place of use or storage, or prior to delivery to a carrier for transport, each licensee shall provide advance notification of the transport to the Governor, or the Governor's designee, of each state through which the waste will be transported, and to the Department.

(2) The notification required by paragraph (1) shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Department. A notification delivered by mail shall be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger shall reach the office of the governor, or governor's designee, and the Department, at least 4 days before the beginning of the 7-day period during which the departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 3 years.

(3) The licensee shall notify each appropriate governor, or governor's designee, and the Department of changes to schedule information provided under paragraph (1). The notification shall be by telephone to a responsible individual in the office of each appropriate governor, or governor's designee, and the Department. The licensee shall maintain for 3 years a record of the individual contacted.

(4) Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to each appropriate governor, or governor's designee, and to the Department. A copy of the notice shall be retained by the licensee for 3 years.

(5) A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, United States Nuclear Regulatory Commission, Washington, DC 20555.

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Source

The provisions of this § 230.47 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239.

Subchapter E. [Reserved]

§ 230.51. [Reserved].

Source

The provisions of this § 230.51 reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204189) to (204190).

APPENDIX A. [Reserved]

Source

The provisions of this Appendix A reserved September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Immediately preceding text appears at serial pages (204191) to (204202).

[Next page is 231-1.]

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CHAPTER 231. [Reserved]

Source

The provisions of this Chapter 231 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119239) to (119243).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 231.1. [Reserved].

Source

The provisions of this § 231.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119239).

§ 231.2. [Reserved].

Source

The provisions of this § 231.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.11. [Reserved].

Source

The provisions of this § 231.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.12. [Reserved].

Source

The provisions of this § 231.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.13. [Reserved].

Source

The provisions of this § 231.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.21. [Reserved].

Source

The provisions of this § 231.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119240).

§ 231.22. [Reserved].

Source

The provisions of this § 231.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119241).

§ 231.31. [Reserved].

Source

The provisions of this § 231.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119241).

§ 231.32. [Reserved].

Source

The provisions of this § 231.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119241) to (119242).

§ 231.33. [Reserved].

Source

The provisions of this § 231.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119243).

§ 231.34. [Reserved].

Source

The provisions of this § 231.34 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119243).

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CHAPTER 232. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Sec.
232.1. Purpose and scope.
232.2. Incorporation by reference.
232.3. Effect of incorporation of 10 CFR Part 36.

Authority

The provisions of this Chapter 232 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 232 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239. Unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualification); and 25 Pa. Code § 217.1 (relating to purpose and scope).

§ 232.1. Purpose and scope.

(a) This chapter contains the requirements for the issuance of a license authorizing the use of radioactive materials in sealed sources to irradiate objects or materials with gamma radiation.

(b) The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements in this article, in particular, the requirements and provisions of Chapters 215, 217—220 and 230.

§ 232.2. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, §§ 36.5, 36.8, 36.91 and 36.93 are not incorporated by reference.

§ 232.3. Effect of incorporation of 10 CFR Part 36.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators), the following words and phrases shall be substituted for the language in 10 CFR Part 36 as follows:

(1) A reference to "NRC" or "Commission" means Department.

(2) A reference to "NRC or agreement state" means Department, NRC or Agreement State.

(3) The definition of "sealed source" includes NARM.

(4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

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CHAPTER 233. [Reserved]

Source

The provisions of this Chapter 233 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119245) to (119247), (4977) to (4982) and (119249) to (119250).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 233.1. [Reserved].

Source

The provisions of this § 233.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119246) to (119247).

§ 233.2. [Reserved].

Source

The provisions of this § 233.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119247).

§ 233.11. [Reserved].

Source

The provisions of this § 233.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119247) and (4977).

§ 233.12. [Reserved].

Source

The provisions of this § 233.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4977).

§ 233.13. [Reserved].

Source

The provisions of this § 233.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4977).

§ 233.14. [Reserved].

Source

The provisions of this § 233.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4978).

§ 233.15. [Reserved].

Source

The provisions of this § 233.15 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4978) to (4979).

§ 233.21. [Reserved].

Source

The provisions of this § 233.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4979).

§ 233.22. [Reserved].

Source

The provisions of this § 233.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4979).

§ 233.23. [Reserved].

Source

The provisions of this § 233.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4979) to (4980).

§ 233.31. [Reserved].

Source

The provisions of this § 233.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4980).

§ 233.32. [Reserved].

Source

The provisions of this § 233.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4980) to (4981).

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§ 233.41. [Reserved].

Source

The provisions of this § 233.41 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4981) to (4982).

§ 233.42. [Reserved].

Source

The provisions of this § 233.42 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4982) and (119249).

§ 233.43. [Reserved].

Source

The provisions of this § 233.43 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119249).

§ 233.51. [Reserved].

Source

The provisions of this § 233.51 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119249).

§ 233.52. [Reserved].

Source

The provisions of this § 233.52 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119250).

§ 233.53. [Reserved].

Source

The provisions of this § 233.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119250).

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CHAPTER 235. [Reserved]

Source

The provisions of this Chapter 235 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119251) to (119256).

Cross References

This chapter cited in 28 Pa. Code § 501.4 (relating to regulations).

§ 235.1. [Reserved].

Source

The provisions of this § 235.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119251).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.11. [Reserved].

Source

The provisions of this § 235.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119251) to (119252).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.12. [Reserved].

Source

The provisions of this § 235.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119252).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.13. [Reserved].

Source

The provisions of this § 235.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119252).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.14. [Reserved].

Source

The provisions of this § 235.14 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119253).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.15. [Reserved].

Source

The provisions of this § 235.15 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119253).

Cross References

This section cited in 28 Pa. Code § 565.12 (relating to radiology service policy).

§ 235.21. [Reserved].

Source

The provisions of this § 235.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119253).

§ 235.22. [Reserved].

Source

The provisions of this § 235.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119253) to (119254).

§ 235.23. [Reserved].

Source

The provisions of this § 235.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119254).

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§ 235.24. [Reserved].

Source

The provisions of this § 235.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119254).

§ 235.31. [Reserved].

Source

The provisions of this § 235.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119255).

§ 235.32. [Reserved].

Source

The provisions of this § 235.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (119255).

§ 235.33. [Reserved].

Source

The provisions of this § 235.33 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119255) to (119256).

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CHAPTER 236. LOW-LEVEL RADIOACTIVE WASTE MANAGEMENT AND DISPOSAL

Subchap.		Sec.
A.	GENERAL PROVISIONS	236.1
B.	REQUIREMENTS FOR SITING THE REGIONAL DISPOSAL FACILITY	236.101
C.	REGIONAL FACILITY LICENSE	236.201
D.	DESIGN REQUIREMENTS FOR THE REGIONAL DISPOSAL FACILITY	236.301
E.	REQUIREMENTS FOR THE CONSTRUCTION, OPERATION AND CLOSURE OF THE REGIONAL DISPOSAL FACILITY	236.401
F.	WASTE CLASSIFICATION, WASTE CHARACTERISTICS, LABELING AND MANIFESTS	236.501
G.	FINANCIAL ASSURANCES AND LIABILITY	236.601
H.	INSPECTIONS, TESTS AND RECORDS	236.701

Authority

The provisions of this Chapter 236 issued under section 302 of the Radiation Protection Act (35 P. S. § 7110.302); section 5 of The Clean Streams Law (35 P. S. § 691.5); section 302 of the Low-Level Radioactive Waste Disposal Act (35 P. S. § 7130.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 236 adopted October 27, 1989, effective October 28, 1989, 19 Pa.B. 4665, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 217.1 (relating to purpose and scope); and 25 Pa. Code § 287.2 (relating to scope).

Subchapter A. GENERAL PROVISIONS

GENERAL

Sec.
236.1. Purpose and scope.
236.2. Definitions.

DISPOSAL SITE PERFORMANCE OBJECTIVES

236.11. Scope.
236.12. General requirement.
236.13. Protection of the general population and environment from releases of radioactivity.

236.14. Protection of individuals from inadvertent intrusion.
236.15. Protection of individuals during operations.
236.16. Stability of the disposal site.

Cross References

This subchapter cited in 25 Pa. Code § 236.108 (relating to site justification); 25 Pa. Code § 236.141 (relating to general requirements); 25 Pa. Code § 236.143 (relating to demography and land use); 25 Pa. Code § 236.145 (relating to meteorology and climatology); 25 Pa. Code § 236.146 (relating to seismology); 25 Pa. Code § 236.147 (relating to surface geology and hydrology); 25 Pa. Code § 236.148 (relating to subsurface geology and hydrology); 25 Pa. Code § 236.149 (relating to natural resources); 25 Pa. Code § 236.208 (relating to specific technical information); 25 Pa. Code § 236.209 (relating to technical analyses); 25 Pa. Code § 236.245 (relating to content of license application for closure); 25 Pa. Code § 236.246 (relating to application and transfer of license to the Commonwealth); 25 Pa. Code § 236.301 (relating to scope and purpose); 25 Pa. Code § 236.311 (relating to general requirements); 25 Pa. Code § 236.312 (relating to compatibility with site); 25 Pa. Code § 236.315 (relating to recoverability); 25 Pa. Code § 236.326 (relating to remedial measures); 25 Pa. Code § 236.330 (relating to performance assessment); 25 Pa. Code § 236.403 (relating to facility operation plan); and 25 Pa. Code § 236.409 (relating to monitoring plan).

GENERAL

§ 236.1. Purpose and scope.

(a) This chapter establishes procedures, criteria and terms and conditions upon which the Department issues a license for the disposal of low-level radioactive wastes received from other persons. The requirements of this chapter are in addition to other applicable requirements of this article.

(b) This chapter establishes performance objectives, and technical and procedural requirements which are applicable to any method of disposal except shallow land burial, as defined in § 236.2 (relating to definitions).

(c) This chapter does not apply to disposal of byproduct material, as defined in section 11(e)(2) of the Atomic Energy Act of 1954 (42 U.S.C.A. § 2014(e)(2)) in quantities greater than 10,000 kilograms containing more than 5 millicuries of radium-226.

§ 236.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Account—The Long Term Care Account.

Act—The Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

Active fault—A fault along which there is recurrent movement that is demonstrated by measurable periodic displacements or seismic activity.

Active institutional control period—See the definition of time periods.

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Active maintenance—Significant activity needed during the long term care period to maintain reasonable assurance that the performance objectives in this subchapter are met. The term includes major remedial actions such as replacement of disposal unit covers. The term does not include custodial activities, such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor repair of disposal unit covers and general disposal site upkeep such as mowing grass.

Affected municipality—A unit of local government other than the host municipality designated as an affected municipality under section 318 of the act (35 P. S. § 7130.318). The term may include a county, city, borough, township or school district.

Broker—An intermediate person who collects, consolidates, handles, treats, processes, stores, packages, ships or otherwise has responsibility for or possesses low-level radioactive waste.

Buffer zone—A portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

Capable fault—A fault which exhibited movement at or near the ground surface within the past 35,000 years.

Carrier—A person who transports low-level radioactive waste from or to a generator or waste management facility or to the regional disposal facility.

Chelating agent—An organic chemical that bonds with a central metal atom or ion at two or more points such as amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acids and polycarboxylic acids.

Commencement of construction—Clearing of land, excavation or other substantial action that would adversely affect the environment of the disposal facility. The term does not include disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.

Commission—The Appalachian States Low-Level Radioactive Waste Commission.

Compact—The Compact entered into by the Commonwealth under the terms of the Low-Level Radioactive Waste Policy Act of 1980 (42 U.S.C.A. §§ 2021b—2021j) and as contained in the act of December 22, 1985 (P. L. 539, No. 120), known as the Appalachian State Low-Level Radioactive Waste Compact Law (35 P. S. §§ 7125.1—7125.4).

Compact states—The combined states, including the Commonwealth, which have entered into the Compact.

Container—The first enclosure which encompasses the radioactive waste.

Containment—The function of isolating radioactive waste from the biosphere by emplacement of the waste within a container, waste module or disposal unit.

Custodial agency—An agency of the government designated by the Governor to act on behalf of the government owner of the disposal site. The agency is responsible for the long term monitoring and care of the disposal site. The term does not include the Department.

Disposal—The isolation of low-level radioactive wastes from the biosphere.

Disposal facility—The buildings, equipment and other engineered features, including disposal units and temporary holding facilities, within the disposal site which are used for the disposal of low-level radioactive waste.

Disposal site—The property, including improvements thereon, which is used for disposal of low-level radioactive waste. The term consists of the disposal units and the buffer zone.

Disposal Unit—A discrete portion of the disposal site into which waste is placed for disposal.

Disqualifying criteria—Conditions which would eliminate an area from further consideration for disposal.

Engineered barrier—A manmade structure or device that is intended to improve the disposal facility's ability to meet the performance objectives in this chapter.

Engineered cover—A manmade structure constructed over the disposal facility.

Engineered structure—A manmade state-of-the-art barrier designed to:

(i) Provide additional measures for containment of radioactive waste from the environment.

(ii) Provide protection for an inadvertent intruder.

(iii) Provide stability of the disposal facility.

(iv) Prevent radioactive release.

Enhanced containment—Additional isolation of the radioactive waste from the environment as provided by engineered structures.

Explosive material—A chemical compound, mixture or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

Fund—The Low-Level Waste Fund.

Generate—To produce low-level radioactive waste requiring disposal.

Generator—A person whose activity results in the production of low-level radioactive waste requiring disposal.

Groundwater—The part of the subsurface water that is in the zone of saturation, perennial or otherwise.

Hazardous life—The time required for radioactive materials to decay to safe levels of radioactivity, as defined by the time period for the concentration of radioactive materials within a given container or package to decay to maximum

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permissible concentrations as defined by Federal law or by standards to be set by the host state, whichever is more restrictive.

Hazardous wastes—Wastes as defined in section 103 of the Solid Waste Management Act (35 P. S. § 6018.103) and regulations thereunder.

Host municipality—A city, borough, incorporated town or township, excluding a county, in which the low-level waste disposal facility will be constructed, as designated by the Department under section 318 of the act (35 P. S. § 7130.318).

Inadvertent intruder—A person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction or other pursuits in which an individual might be unknowingly exposed to radiation from the waste.

Intruder barrier—A manmade structure or sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the requirements under § 236.320 (relating to protection from inadvertent intruders) and the performance objectives in this subchapter.

Isolation—Protection of the public and the environment from inadvertent intrusion or direct release of radioactive material from the disposal site.

Leak resistance—The material properties of the disposal facility design which retard or prevent migration of water.

Long term care period—See the definition of time periods.

Low-level radioactive waste—Radioactive waste that meets one of the following criteria:

(i) Is not high-level radioactive waste, spent nuclear fuel or by-product material as defined in section 11(e)(2) of the Atomic Energy Act of 1954 (42 U.S.C.A. § 2014(e)(2)), waste generated as a result of atomic energy defense activities of the Federal government and waste for which the Federal government is responsible under section 3(b)(1) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (42 U.S.C.A. § 2021c(b)(1)).

(ii) Is classified by the Federal government as low-level waste, consistent with the Low-Level Radioactive Waste Policy Amendments Act of 1985 or waste that contains naturally occurring or accelerator produced radioactive material which is not excluded by subparagraph (i).

Management—The reduction, collection, consolidation, storage, processing, incineration, separation, minimization, compaction, segregation, solidification, evaporation, packaging or treatment of low-level radioactive waste.

Mixed waste—Waste that is low-level radioactive waste, as defined in this subchapter, and either contains a hazardous waste or exhibits a hazardous characteristic as contained in the Solid Waste Management Act (35 P. S. §§ 6018.101—6018.1003).

Monitoring—Observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

Municipality—A county, city, borough, home rule or incorporated town or township as defined in 1 Pa.C.S. § 1991 (relating to definitions).

Passive institutional control period—See the definition of time periods.

Person—Includes the following:

(i) The definition contained in § 215.2 (relating to definitions).

(ii) An individual, corporation, partnership, association, public or private institution, cooperative enterprise, municipal authority, public utility, trust, estate, group, Federal government or agency, other than the United States Nuclear Regulatory Commission or a successor thereto, State institution and agency or other legal entity which is recognized by law as the subject of rights and duties. The term includes officers and directors of a corporation or other legal entity having officers and directors.

Postclosure observation and maintenance period—See the definition of time periods.

Potentially suitable site—An area containing approximately 500 acres, for the disposal site, that meets the screening requirements in Subchapter B (relating to requirements for siting the regional disposal facility) and would reasonably be expected to meet the performance objectives in this subchapter and site suitability requirements in Subchapter B.

Protection fund—The Regional Facility Protection Fund.

Public water system—A water system which provides water to the public for human consumption and which has at least 15 service connections or regularly services an average of at least 25 individuals daily, at least 60 days out of the year.

Pyrophoric material—aterial that ignites spontaneously. The term includes any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.5°C), or a solid, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious transportation, handling or disposal hazard. The term also includes spontaneously combustible and water reactive materials.

Shallow land burial—The disposal of low-level radioactive waste directly in subsurface trenches without additional confinement in engineered structures and in proper packaging as determined in the act.

Site closure and stabilization—Actions that are taken upon completion of operations that prepare the disposal site for custodial care and that assure that the disposal site will remain stable and will not need ongoing active maintenance.

Stability—Structural stability.

Surveillance—onitoring and observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion and compliance with other license, permit and regulatory requirements.

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Time periods—Specific periods of time associated with the life of the disposal facility. The term includes the following time periods presented in chronological order:

(i) *Postclosure observation and maintenance period*—The period of time following site closure during which the site operator is preparing the site for transfer to the custodial agency.

(ii) *Long term care period*—The period of time which includes both the active and passive institutional control periods.

(iii) *Active institutional control period*—The period of time following site closure and the postclosure observation and maintenance period during which active access control, surveillance, monitoring and custodial care is maintained. This period will last for a minimum of 100 years.

(iv) *Passive institutional control period*—The period of time after the active institutional control period during which monitoring and passive access control of the facility is maintained. This period will be at least as long as the hazardous life of the radioactive waste.

Waste—Low-level radioactive waste.

Waste module—A discrete assembly of waste containers within a disposal unit.

Cross References

This section cited in 25 Pa. Code § 236.1 (relating to purpose and scope); 25 Pa. Code § 236.311 (relating to general requirements); and 25 Pa. Code § 237.2 (relating to definitions).

DISPOSAL SITE PERFORMANCE OBJECTIVES

§ 236.11. Scope.

The disposal site performance objectives establish the minimum overall level of safety that the disposal facility is required to meet. Operation within these levels will provide protection of public health, safety and the environment.

§ 236.12. General requirement.

The disposal facility shall be sited, designed, operated, closed and controlled after closure so that reasonable assurance exists that exposures to individuals are within the requirements established in the performance objectives in §§ 236.13—236.16.

§ 236.13. Protection of the general population and environment from releases of radioactivity.

Concentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants or animals may not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid and 25 millirems to any other organ of any

member of the public. Releases of radioactivity in effluents to the general environment shall be as low as reasonably achievable and within the most restrictive Federal and Commonwealth regulations and standards which are applicable.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); 25 Pa. Code § 236.15 (relating to protection of individuals during operations); 25 Pa. Code § 236.225 (relating to requirements for issuance of a license); 25 Pa. Code § 236.314 (relating to enhanced containment); and 25 Pa. Code § 236.603 (relating to assurance for onsite cleanup during operation).

§ 236.14. Protection of individuals from inadvertent intrusion.

Design, operation and closure of the disposal facility shall ensure protection of an individual from inadvertently intruding into the disposal site and occupying the site or contacting the waste after active institutional controls over the disposal site have been removed.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); and 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.15. Protection of individuals during operations.

Operations at the disposal facility shall be conducted in compliance with the standards for radiation protection in Chapter 219 (relating to standards for protection against radiation), except for releases of radioactivity in effluents from the disposal facility, which shall be governed by § 236.13 (relating to protection of the general population and environment from releases of radioactivity). Effort shall be made to maintain radiation exposures as low as is reasonably achievable.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); and 25 Pa. Code § 236.603 (relating to assurance for onsite cleanup during operation).

§ 236.16. Stability of the disposal site.

The disposal facility shall be sited, designed, used, operated and closed to achieve long term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring or minor custodial care are required.

Cross References

This section cited in 25 Pa. Code § 236.12 (relating to general requirement); and 25 Pa. Code § 236.314 (relating to enhanced containment).

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Subchapter B. REQUIREMENTS FOR SITING THE REGIONAL DISPOSAL FACILITY

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Cross References

This subchapter cited in 25 Pa. Code § 236.2 (relating to definitions); 25 Pa. Code § 236.225 (relating to requirements for issuance of a license); 25 Pa. Code § 236.301 (relating to scope and purpose); and 25 Pa. Code § 236.312 (relating to compatibility with site).

GENERAL

§ 236.101. Scope and applicability.

This subchapter contains the requirements for siting a low-level radioactive waste disposal facility in this Commonwealth. The low-level radioactive waste disposal facility shall satisfy other requirements of this chapter. The criteria for siting a low-level radioactive waste disposal facility are divided into two phases, §§ 236.121—236.128 (relating to Phase I screening requirements) and §§ 236.141—236.149 (relating to Phase II site suitability requirements). The proposed site for licensing shall meet the Phase I and Phase II requirements.

§ 236.102. Summary and purpose.

(a) The site selection process for the low-level radioactive waste disposal facility addresses a wide range of public health, safety, environmental, social and economic factors. Considerations such as public health and safety, flooding, tectonics, protection of lands in the public trust, protection and exploitation of natural resources, demographics, transportation, wildlife, air quality, ecology, topography and hydrogeology are addressed in the siting requirements. The primary goal of the siting process is to identify a site that is capable of protecting public health, safety and the environment and to identify a site that is licensable.

(b) Application of the site selection process eliminates land in this Commonwealth that is unsuitable for use as a disposal site. From the remaining land, a site is to be selected by the applicant which will be submitted in the license application for the construction of the low-level radioactive waste disposal facility. At the initiation of the site selection process, all of the land in this Commonwealth is considered suitable for siting the facility. Through application of Phase I screening requirements, the applicant shall evaluate multiple areas and determine whether the areas are qualified or unqualified until the applicant has identified and submitted three sites, of approximately 500 acres each, to the EQB as the preferred potentially suitable sites. Through application of Phase I and Phase II site suitability requirements, the preferred potentially suitable sites will be studied in detail—characterized—and compared to identify the proposed site to be submitted for licensing.

§ 236.103. Siting plan.

(a) The applicant shall submit a siting plan to the Department for approval. The siting plan shall meet the requirements of this subchapter and the act and follow the siting process discussed in the applicant's proposal. A quality assurance/quality control plan, which will be implemented throughout site screening and characterization, shall be submitted as part of the siting plan. Siting activities cannot begin until approval of the siting plan has been granted by the Department.

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(b) The Department will utilize its oversight role to ensure that the applicant is implementing the approved siting plan throughout the site screening and site characterization period.

Cross References

This section cited in 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.206 (relating to program plans).

§ 236.104. Siting process.

(a) The applicant shall screen this Commonwealth for potentially suitable sites using the criteria in §§ 236.121—236.128 (relating to Phase I screening requirements). Screening shall be conducted consistent with the applicant's siting plan under § 236.103 (relating to siting plan), proposal and contract with the Department made under section 306 of the act (35 P. S. § 7130.306). The applicant shall propose three preferred potentially suitable sites and submit those sites to the EQB for approval.

(b) The EQB will hold at least one public information meeting and one public hearing in each proposed potentially suitable area, evaluate the three proposed potentially suitable sites and determine compliance with §§ 236.121—236.128. As part of this determination, the EQB will make a determination that the screening process has identified three of the best potential locations in this Commonwealth, based on the administrative record before the EQB. The administrative record shall consist of the screening report, site justification report, the study of short and long term environmental effects on the potentially suitable sites, the conclusions and siting recommendations of the Department, the testimony presented at the EQB's public hearings and comments received during the comment period.

(c) Upon preliminary approval of the three preferred potentially suitable sites by the EQB, the applicant shall obtain access to the sites and conduct detailed characterization studies under §§ 236.141—236.149 (relating to Phase II site suitability requirements). The studies shall be conducted consistent with the applicant's site characterization plan, proposal and contract with the Department made under section 306 of the act. After concluding the characterization studies, the applicant shall select the site to be considered for licensing.

(d) Detailed site characterization at a site may be discontinued by the applicant if conditions are encountered that would prevent that site from meeting the Phase I site screening evaluation requirements or the Phase II site suitability requirements. If no disqualifying conditions are encountered, the applicant shall continue detailed site characterization.

(e) If disqualifying conditions are encountered at the three sites, the applicant shall submit three other potentially suitable sites under this section prior to reinitiation of Phase II.

Cross References

This section cited in 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.105. Preferred potentially suitable site selection procedure.

(a) The applicant shall propose three preferred potentially suitable sites for preliminary approval for further study and submit those sites to the EQB and the Department.

(b) The proposal shall be accompanied by the following:

(1) A site screening report under § 236.107 (relating to screening report).

(2) A site justification under § 236.108 (relating to site justification).

(3) An environmental impact report under § 236.109 (relating to environmental impact report).

(c) At the same time that the proposal is submitted, the applicant shall submit to the Department a social and economic impact study for each site. Each study shall propose a host municipality and affected municipalities.

(d) The Department will evaluate the proposal and submit its recommendations to the EQB.

(e) The EQB will evaluate the three potentially suitable sites in accordance with section 307(e) of the act (35 P. S. § 7130.307(e)).

§ 236.106. Selection procedure for the proposed site.

(a) Prior to initiating detailed site characterization studies, the applicant shall prepare and submit for the Department's approval a detailed plan for characterizing the three preferred potentially suitable sites.

(b) The site characterization plan shall include:

(1) Detailed plans and procedures, including quality assurance/quality control, for collecting detailed site specific information for compliance with the Phase I and Phase II siting requirements.

(2) The method for determining the proposed site for licensing.

(c) Upon approval of the three preferred potentially suitable sites by the EQB and Department approval of the site characterization plan, the applicant shall obtain access to the sites and commence detailed characterization studies.

(d) Information collected shall be compiled and included as part of the content of the license application as specified in § 236.204 (relating to content of a license application).

§ 236.107. Screening report.

(a) The applicant shall submit a site screening report to the EQB as part of its proposal for approval of three preferred potentially suitable sites. The report shall include the following:

(1) A comprehensive presentation of the information collected.

(2) The analyses conducted.

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(3) The evaluation process that was used in screening this Commonwealth to identify the preferred potentially suitable sites.

(b) The screening report shall identify the stages incorporated in the process to narrow the search from the entire Commonwealth to the level at which the three preferred potentially suitable sites are identified.

(c) The screening report shall include a description of how the Phase I screening requirements were utilized in the process and a description of how meaningful public input was solicited and incorporated in each stage of the process.

(d) The screening report shall include a detailed discussion of how requests for consideration as a potentially suitable site from interested municipalities were considered.

(e) The screening report shall include documentation and references to substantiate the validity of the information presented and the conclusions reached through every stage of analysis. The report shall describe the research and analytical techniques and identify the principal persons responsible for conducting the research and preparing the report. Presentations of information shall be clear, concise and complete to the level that allows for independent evaluation by the EQB.

Cross References

This section cited in 25 Pa. Code § 236.105 (relating to preferred potentially suitable site selection procedure).

§ 236.108. Site justification.

(a) The applicant shall submit site justifications which explain the reasons for the choice of each preferred potentially suitable site.

(b) The applicant shall use the process established in the proposal and the siting plan as approved by the Department, for applying the requirements of §§ 236.121—236.128 (relating to Phase I screening requirements) and show how the process was used to identify each preferred potentially suitable site.

(c) Site justifications shall predict the ability of each preferred site to meet the Phase II site suitability requirements and the performance objectives in Subchapter A (relating to general provisions).

(d) Site justifications shall utilize comparisons of information collected and analyzed during the screening process to defend and justify the choice of a preferred potentially suitable site.

Cross References

This section cited in 25 Pa. Code § 236.105 (relating to preferred potentially suitable site selection procedure).

§ 236.109. Environmental impact report.

An environmental impact report shall be prepared for each of the preferred potentially suitable sites and affected areas. The report shall consider the short and long term effects that a disposal facility would have on public health and safety and the environment at each preferred potentially suitable site and affected areas.

Cross References

This section cited in 25 Pa. Code § 236.105 (relating to preferred potentially suitable site selection procedure).

§ 236.110. Social and economic impact study.

(a) A social and economic impact study shall be prepared for each of the preferred potentially suitable sites. The study shall include information, analyses and discussion to clearly identify social and economic impacts. The level of information that is submitted shall be sufficient to permit the Department to conduct an independent evaluation.

(b) Each social and economic impact study shall:

(1) Propose to the Department a host municipality and affected municipalities.

(2) Evaluate the long and short term potential impacts of the facility on social and economic conditions including the following:

(i) Tax revenue.

(ii) Public and private infrastructure compatibility with regional and local economic goals.

(iii) Emergency management capabilities.

(iv) Loss of resources.

(v) Social service demands.

(c) The Department will use the social and economic impact reports in its consideration for identifying host and affected municipalities.

(d) The Department will identify the host and affected municipalities and incorporate them into the disposal facility license.

§ 236.111. Distances.

The distances from a facility to a feature or structure described in this chapter shall be measured from the boundary of the disposal site.

PHASE I SCREENING REQUIREMENTS

§ 236.121. General requirements.

(a) This section and §§ 236.122—236.128 contain both disqualifying criteria and evaluation requirements.

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(b) Disqualifying criteria denote conditions that are unacceptable for the siting of a low-level radioactive waste disposal facility. Implementation of disqualifying criteria requires that areas be evaluated to determine the existence of disqualifying conditions. Siting a low-level radioactive waste disposal facility in an area containing disqualifying conditions is prohibited. The EQB will deny a proposed site without further review if the proposed site contains disqualifying conditions. The applicant bears the burden of proving that the site contains no disqualifying conditions.

(c) Evaluation requirements denote conditions that require identification, investigation and assessment to determine acceptability. The EQB will not approve a site unless the applicant successfully demonstrates with clear and convincing evidence that the site complies with the evaluation requirements.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.108 (relating to site justification).

§ 236.122. Demography and land use.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located where nearby facilities, activities, population or development will mask monitoring of the disposal site or affect the disposal site's compliance with the performance objectives.

(b) *Evaluation requirements.* Demographic and land use characteristics that could be affected by a potentially suitable site relate to items, such as population distribution and future growth, land use, nearby facilities, safety and support services and economic conditions. Evaluations shall be made to determine the effects a proposed site location could have on existing and projected future conditions.

(1) Conditions of ownership, such as surface ownership, mineral rights, rights-of-way and liens shall be identified and evaluated with respect to site acquisition requirements of section 307 of the act (35 P. S. § 7130.307).

(2) An evaluation of compatibility with adopted county and municipal plans for land use and zoning, population distribution, projected population growth and restrictions shall be on record.

(3) The evaluations shall show potential impacts on facilities and structures, including schools, parks, hospitals, churches, retail centers, nursing homes and business establishments.

(4) An evaluation of support and safety services, including utilities, fire protection, police and medical capabilities shall be currently available upon which the disposal facility would rely. The evaluation shall include an assessment of future service needs necessary to adequately support the disposal facility.

(5) Economic conditions within the affected area of a potentially suitable site shall be described and analyzed. Potential impacts on the existing conditions shall be determined. Sufficient information and analysis shall be provided to allow for assessment of benefits and guarantees under section 318 of the act (35 P. S. § 7130.318).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.123. Evaluation requirements for transportation.

Existing and projected access roads, from potentially suitable sites to points of exit off existing interstate or limited access highways, shall be identified, described and evaluated with respect to:

(1) Their general type, conditions, upgrade or construction needs.

(2) Potential hazards for transportation.

(3) Residential dwellings per road mile.

(4) Facilities such as schools, parks or hospitals, per road mile.

(5) A total travel distance between a potentially suitable site and points of exit from existing interstate or limited access highways.

(6) Past highway safety records.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.124. Evaluation requirements for meteorology and climatology.

Averages and extremes for regional climatic and site-specific meteorology characteristics, such as temperature, precipitation, humidity, freeze-thaw characteristics and historical trends for airflow patterns, pressure systems and frontal movements, shall be described and evaluated to determine potential effects on a potentially suitable site. The potential for severe weather phenomena such as tornadoes and other storm events based on historical data shall be evaluated.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.125. Seismology.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located within 1 mile of an active fault.

(b) *Evaluation requirements.*

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(1) Potentially suitable sites shall be evaluated with respect to regional tectonic history and geologic structure, including stability, faults, folds, joints and fractures.

(2) Capable faults identified in the vicinity of a site shall be evaluated to determine correlation of the fault with recorded or suspect earthquake activity and potential impact on site stability.

(3) Potentially suitable sites shall be evaluated to determine the proximity to known or reported seismic epicenters within 200 miles. The probable seismic risk and impact associated with those epicenters that reported a Mercalli intensity of (IV) or greater shall be evaluated.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.126. Surface geology and hydrology.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located:

(1) Within the limits of the 100-year floodplain of a waterway as defined in the Flood Plain Management Act (32 P. S. §§ 679.101—679.601).

(2) Within the limits of a coastal floodplain as defined in Federal Executive Order 11988, *Flood Plain Management Guidelines* (42 U.S.C.A. § 4321, note).

(3) Within the area below a dam which may be threatened with loss of life or serious damage to property if a failure of the dam occurs.

(4) Where erosional processes or mass movement of landforms, such as mass wasting and landslides, would affect the long term stability and isolation of waste.

(5) Where there are slopes greater than 15% on areas of the disposal site where disposal units may be located, as mapped on USGS 7.5-minute quadrangles utilizing a scale of 1:24,000 with a contour interval of either 10 feet or 20 feet or on county topographic maps that utilize a scale of 1:50,000 and a contour interval of 20 feet.

(b) *Evaluation requirements.* Potentially suitable sites shall be evaluated:

(1) With respect to regional and local geomorphology. Evaluations shall discuss geomorphic features pertinent to site stability and the relationships between regional and local geomorphic features.

(2) With respect to local and site-specific surface hydrology. Characteristics to be evaluated include:

(i) Site drainage conditions.

(ii) Rates of evapotranspiration and infiltration.

(iii) Rates and directions of runoff.

(iv) Fluvial features.

(v) Historical flow conditions.

(vi) Chemical and physical properties of the waters.

(3) To determine the potential for, and the impacts from, major modifications of upstream drainage by others.

(4) With respect to local and site specific erosional processes. Characteristics such as rates, types and directions of erosion shall be described. The potential for mass movement of landforms, including landslides, slumping and mass wasting, shall also be evaluated.

(5) To determine the probable existence and extent of surface water features, including wetlands, springs and ponds that are sustained by groundwater. This evaluation shall also address the potential for future ponding and surface water discharges.

(6) To determine the magnitude, frequency and duration of storm events that would cause inundating floods and probable maximum flood conditions.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.127. Subsurface geology and hydrology.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located in areas where there is limestone or other predominantly carbonate lithologic units which exhibit one of the following characteristics:

(1) Outcrop at the surface.

(2) Occur within 50 feet of the surface and are greater than 5 feet thick.

(3) Have been identified as areas with a potential for subsidence.

(4) Currently exhibit evidence of subsidence at the surface.

(b) *Evaluation requirements.*

(1) The geology at potentially suitable sites shall be evaluated with respect to regional and local stratigraphy, lithologies and potential impact on site stability. Descriptions, illustrations and evaluations shall include characteristics such as local stratigraphic units and their accepted names, relative ages, lithologic descriptions and genetic relationships.

(2) Depths to local and regional zones of permanent saturations including seasonal fluctuations, shall be evaluated. The probability and extent of both permanent and seasonal perched water tables potentially affected by a site shall be evaluated.

(3) Local and potentially affected aquifers shall be described, evaluated and illustrated with respect to the following:

(i) Characteristics, such as lateral extent and thickness.

(ii) Rates, directions and volumes of groundwater flow.

(iii) Porosities and permeabilities.

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(iv) Recharge areas and discharge areas.

(v) Reported chemical properties.

(4) Site-specific and local soil conditions shall be evaluated with respect to physical, chemical and mineralogical properties. Characteristics to be evaluated include:

(i) Lateral extent and thickness of soil horizons.

(ii) Classification names.

(iii) Relative ages.

(iv) Genetic relationships.

(v) Porosities and permeabilities.

(vi) Rates, directions and conditions of surface and subsurface flow.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

§ 236.128. Natural resources.

(a) *Disqualifying criteria.* Potentially suitable sites may not be located:

(1) Within 1/2 mile of a well or spring which is used as a public water supply.

(2) Within 1/2 mile of either side of a stream or impoundment for a distance of 5 stream miles upstream of a surface water intake for a public water supply.

(3) Within 1/2 mile of an existing important wetland, as defined in Chapter 105 (relating to dam safety and waterway management).

(4) Within the boundaries of the following:

(i) National Park Systems.

(ii) National Forests.

(iii) Natural Landmarks designated by the National Park Service.

(iv) National Wildlife Refuges.

(v) National Fish Hatcheries.

(vi) National Wild and Scenic River Systems, including study rivers designated under section 5(a) of the Wild and Scenic River Act (15 U.S.C.A. § 1276(a)).

(vii) National System of Trails.

(viii) National Wilderness Preservation Systems.

(ix) Exceptional Value Watersheds.

(x) Historic sites listed on the National Register of Historic Places.

(xi) State, county or municipal park systems.

(xii) Land owned by the Historical and Museum Commission.

(xiii) Lands protected by the Wild and Scenic Rivers Program.

(xiv) Designated natural and wild areas.

(5) Within the boundaries of State Forest and State Game Lands unless the agency administering the lands has been given authority by statute or ordinance to allow the siting and operation of the regional disposal facility.

(6) In areas over active or inactive oil and gas wells or gas storage areas. The phrase "active or inactive oil and gas wells or storage areas" has the same meaning as used in the Oil and Gas Act (58 P. S. §§ 601.101—601.605).

(7) On agricultural land established under the Agricultural Area Security Law (3 P. S. §§ 901—915) or Class I agricultural land as defined by the United States Soil Conservation Service.

(8) In areas over active or inactive mines that are identified and substantiated by public records.

(b) *Evaluation requirements.* Potentially suitable sites shall be evaluated:

(1) With respect to water use characteristics of potentially affected water supplies. Existing private, public and community water supplies located onsite or within 3 miles shall be identified and evaluated. The ability to replace existing water supplies with alternate supplies of like quality and quantity shall be evaluated.

(2) To determine potential impact on designated high quality watersheds that may be affected.

(3) To determine the existence of, and potential impact on, endangered and threated species as defined in the Endangered Species Act of 1973 (16 U.S.C.A. §§ 460K-1, 4601-9, 668aa—668cc-6, 668dd, 715i, 715s, 1362, 1371, 1372, 1402 and 1531—1543).

(4) To determine the existence of, and potential impact on, biologic habitats identified as either endangered, threatened, rare or exemplary; and geologic features identified as outstanding on the Pennsylvania Natural Diversity Inventory.

(5) To determine to what extent previous exploration or exploitation practices have disturbed the natural geologic setting in the area. Evaluations shall identify locations, types and extent of disturbances; and estimate potential impact on site stability.

(6) To determine the types, quantities and physical locations of the natural resources contained therein and shall include an evaluation of the availability of these resources from other areas outside the site. Priority shall be given to avoid areas where natural resources that may be rare or unique to the site exist.

(c) *Wetlands.* The preferred potentially suitable sites submitted to the EQB for approval will be evaluated by the Department to determine the existence of wetlands. The results of this evaluation will be part of the Department's review that will be submitted to the EQB.

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Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); 25 Pa. Code § 236.108 (relating to site justification); and 25 Pa. Code § 236.121 (relating to general requirements).

PHASE II SITE SUITABILITY REQUIREMENTS

§ 236.141. General requirements.

(a) This section and §§ 236.142—236.149 establish and identify the requirements that a site is required to meet to be considered suitable for the proposed low-level radioactive waste disposal facility. Phase II, site-specific characterization of the three preferred potentially suitable sites, begins after approval is granted by the EQB under § 236.104 (relating to siting process) and after the Department approves the site characterization plan. Site characterization will require access to the sites.

(b) Implementation of the site suitability requirements requires the collection, documentation, analysis, discussion and illustration of detailed site-specific data to supplement the data collected during Phase I screening. The Phase II effort will substantiate or disprove the validity of evaluations and projections made for the three preferred potentially suitable sites chosen in Phase I. The applicant shall clearly demonstrate that the preferred site meets the Phase I and Phase II siting requirements and contributes to compliance with the performance objectives of Subchapter A (relating to general provisions). The findings from the detailed site characterization studies shall be presented as part of the license application required in Subchapter C (relating to regional facility license).

(c) For the type of criteria in which the data collected are considered time variant by the Department, there shall be a minimum of 1 year of data acquisition to substantiate the validity of analyses and conclusions.

(d) The issuance of a license by the Secretary constitutes final approval of the site for the disposal facility.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); and 25 Pa. Code § 236.104 (relating to siting process).

§ 236.142. Characterization and modeling.

A disposal site shall be capable of being characterized, modeled, analyzed and monitored. Characterization shall be adequate to define characteristics and conditions, both onsite and offsite, through monitoring, analysis, modeling and demonstration, to substantiate that the site can satisfy site suitability requirements and meet the performance objectives.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.143. Demography and land use.

A disposal site shall be located so that projected population growth and future developments are not likely to affect the ability of the disposal site to meet the performance objectives in Subchapter A (relating to general provisions).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.144. Transportation.

A disposal site shall be located so that the roads connecting the site to an existing or limited access highway allow for safe transportation so that risks to the general population will be as low as reasonably achievable.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.145. Meteorology and climatology.

A disposal site shall be located so that adverse climatic and meteorologic conditions will not affect the ability of the disposal site to meet the performance objectives in Subchapter A (relating to general provisions).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.146. Seismology.

A disposal site shall be tectonically stable to meet the performance objectives in Subchapter A (relating to general provisions). An area shall be avoided where tectonic processes such as faulting, folding or seismic activity may occur with a frequency and to an extent which may affect the isolation of waste and the long term stability of the site.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

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§ 236.147. Surface geology and hydrology.

(a) A disposal site area shall be located where topography and surface geologic processes occur at rates, frequency and extent that they will not affect meeting the performance objectives in Subchapter A (relating to general provisions).

(b) A disposal site shall be generally well drained and free of areas of flooding or frequent ponding. The disposal facility may not be located in a wetland, as defined in Chapter 105 (relating to dam safety and waterway management).

(c) A disposal site shall be located so that upstream drainage areas are minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.148. Subsurface geology and hydrology.

(a) A disposal site may not be located where hydrologic conditions such as hydraulic conductivity or geologic features such as fractured bedrock occur at rates, frequency or extent that could adversely affect the isolation of waste or the ability to meet the performance objectives in Subchapter A (relating to general provisions).

(b) A disposal site shall be located in a hydrogeologic setting that provides sufficient separation from the groundwater, so that water intrusion into disposal units, perennial or otherwise, will not occur.

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

§ 236.149. Natural resources.

(a) A disposal site shall be located so that resources, such as those protected by law, those suitable for human consumption and those culturally or historically unique, can be protected during siting, design, construction, operation, closure, decommissioning and long term care.

(b) A disposal site may not be located where exploration or exploitation of natural resources, such as hydrocarbons, industrial minerals, metallic ores and mineral fuels located on the site or in adjacent areas could affect isolation of waste or, the ability to meet the performance objectives in Subchapter A (relating to general provisions).

Cross References

This section cited in 25 Pa. Code § 236.101 (relating to scope and applicability); 25 Pa. Code § 236.104 (relating to siting process); and 25 Pa. Code § 236.141 (relating to general requirements).

Subchapter C. REGIONAL FACILITY LICENSE

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LICENSE APPLICATION

§ 236.201. Scope.

This subchapter addresses the requirements for licensing the regional disposal facility operator. The requirements included are as follows:

(1) Application for a license.

(2) License application review procedures and standards.

(3) Procedures for requesting changes to the disposal facility.

§ 236.202. License required.

(a) A person may not construct, alter, own or operate a low-level waste disposal facility or may receive, possess or dispose of waste received from other persons at the regional disposal facility unless authorized by a license issued by the Department under this chapter.

(b) A person shall file an application with the Department under § 236.212 (relating to filing and distribution of license application) and obtain a license as provided in this subchapter before commencement of construction of the disposal facility. Failure to comply with this requirement will be grounds for denial of a license.

§ 236.203. License application fee.

The license application fee is $800,000.

§ 236.204. Content of a license application.

In addition to the requirements in § 236.212 (relating to filing and distribution of license application), an application to receive from others, possess and dispose of wastes shall consist of:

(1) General information, program plans, a quality assurance/quality control program, specific technical information, institutional control information and financial information as set forth in §§ 236.205—236.211.

(2) An impact analysis report. The report shall address the impact of licensing the activity and include:

(i) A detailed assessment of the radiological and nonradiological impacts to the public health and the environment.

(ii) A detailed assessment of the impact on the quality and quantity of the surface and groundwater within a 5-mile radius of the site.

(iii) A discussion of the long term public health and environmental impacts, including closure, decommissioning, decontamination and reclamation of the site and facilities associated with the licensed activities and management of radioactive materials which will remain on the site after closure, decommissioning, decontamination and reclamation.

(iv) A discussion of the short and long term social and economic impacts of the regional disposal facility on the host and affected municipali-

ties. These impacts will be used to create a minimum set of items to be considered as part of the host and affected municipality benefit negotiations. At a minimum, the study shall include the impacts on local tax revenues, public and private infrastructures, emergency management capabilities and social service demands.

(v) A preoperational environmental radiation survey and a preoperational health survey of cancer and other disease rates and birth defects within 5 miles of the site.

(vi) Justification for the choice of the proposed site over the other two preferred potentially suitable sites.

Cross References

This section cited in 25 Pa. Code § 236.106 (relating to selection procedure for the proposed site).

§ 236.205. General information.

The license application shall include general information as follows:

(1) The identity of the applicant, including:

(i) The full name, address, telephone number and description of the business or occupation of the applicant.

(ii) The name and address of each partner and the principal location where the partnership does business, if the applicant is a partnership.

(iii) The following, if the applicant is a corporation or an unincorporated association:

(A) The state in which it is incorporated or organized and the principal location at which it does business.

(B) The names and addresses of its directors and principal officers.

(iv) Information required under this section with respect to the other person, if the applicant is acting as an agent or representative of another person in filing the application.

(2) Qualifications of the applicant as follows:

(i) The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority, key positions and assignments of responsibilities, whether in the form of administrative directives, contract provisions or otherwise.

(ii) The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in subparagraph (i) shall be provided.

(iii) A description of the applicant's personnel training program.

(iv) The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling and disposal operations in a safe manner.

(3) A description of:

(i) The location of the proposed disposal site.

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(ii) The general character of the proposed activities.

(iii) The types and quantities of waste to be received, possessed and disposed of.

(iv) The proposed facilities and equipment.

(4) Proposed schedules for construction, receipt of waste and first emplacement of waste at the disposal facility.

(5) A description of the applicant's compliance with State and Federal environmental protection statutes including the Radiation Protection Act and Low-Level Radioactive Waste Disposal Act, the Appalachian States Low-Level Radioactive Waste Compact Act or other state or Federal statute relating to environmental protection or to protect the public health and safety.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.226 (relating to conditions of the license).

§ 236.206. Program plans.

(a) The applicant shall submit the following detailed program plans:

(1) A siting plan under § 236.103 (relating to siting plan).

(2) A quality assurance/quality control plan under § 236.207 (relating to quality assurance/quality control program).

(3) A monitoring plan under § 236.409 (relating to monitoring plan).

(4) A security plan under § 236.403(a)(1) (relating to facility operation plan).

(5) An operations plan under § 236.403.

(6) A contingency plan under § 236.404 (relating to contingency plans).

(7) A radiation control plan under § 236.403(c).

(8) A construction plan under § 236.402 (relating to construction plan).

(9) A site closure and decommissioning plan under § 236.411 (relating to site closure and decommissioning plan).

(b) The plans set forth in subsection (a), and subsequent changes thereto, will be reviewed and approved by the Department. The requirement to implement the approved plans will be incorporated into the facility license.

(c) The plans shall demonstrate that the necessary technical information and analyses can be obtained and used to demonstrate compliance with the performance objectives.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.245 (relating to content of license application for closure).

§ 236.207. Quality assurance/quality control program.

A quality assurance/quality control plan shall be submitted to the Department for approval. The plan shall include a description of the quality assurance/quality

control program for the determination of natural disposal site characteristics and for quality assurance/quality control during the design, construction, operation and closure of the disposal facility and the receipt, handling and emplacement of waste. Audits and managerial controls shall be included.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.206 (relating to program plans).

§ 236.208. Specific technical information.

The specific technical information shall include information needed for demonstrating that the performance objectives and the applicable technical requirements of this chapter will be met. The following shall be included:

(1) A description of the natural and demographic disposal site characteristics as determined by site screening and characterization activities contained in Subchapter B (relating to requirements for siting the regional disposal facility). The description shall include demographic, meteorologic, climatologic, biotic, ecologic, hydrologic, geologic (including geochemical and geotechnical) and natural resource features of the disposal site and vicinity.

(2) A description of the design features of the disposal facility and the disposal units. The description shall include those design features related to the following:

(i) Minimization of water intrusion.

(ii) Integrity of covers for disposal units.

(iii) Structural stability.

(iv) Contact of wastes with standing water.

(v) Disposal site drainage.

(vi) Closure and stabilization.

(vii) Recoverability.

(viii) Elimination to the extent practicable of long term active maintenance.

(ix) Protection from inadvertent intrusion.

(x) Occupational exposures.

(xi) Monitoring.

(xii) Adequacy of the size of the buffer zone for monitoring and potential remedial measures.

(3) A description of the principal design features and their relationship to the performance objectives.

(4) A description of the engineered structures which the applicant has incorporated into the design and which will apply to construction of the disposal facility.

(5) A description of codes and standards which the applicant has applied to the design and which will apply to construction of the disposal facility.

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(6) A description of the construction and operation of the disposal facility. The description shall include at a minimum:

(i) Methods of constructing the disposal units.

(ii) Waste emplacement.

(iii) Procedures for and areas of waste segregation.

(iv) Types of intruder barriers.

(v) Onsite traffic and drainage systems.

(vi) Survey control program.

(vii) Methods and areas of waste storage.

(viii) Methods to control water access to the wastes.

(ix) The methods to be employed in the handling and disposal of wastes containing chelating agents or other nonradiological substances that might affect meeting the performance objectives of Subchapter A (relating to general provisions).

(7) A description of the disposal site closure and decommissioning plan under § 236.411 (relating to site closure and decommissioning plan); specifically those design features which are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance.

(8) An identification of the known natural resources at the disposal site, exploitation of which could result in inadvertent intrusion into the waste after removal of active institutional control.

(9) A description of the various low-level waste streams and the physical and chemical properties, and the volumes and different classes of waste proposed to be received, possessed and disposed of at the disposal facility. The description shall include consideration of projected variations in future waste streams and volumes and their potential affect on the disposal facility.

(10) A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in Subchapter A and occupational radiation exposure to ensure compliance with Chapter 219 (relating to standards for protection against radiation) and to control contamination of personnel, vehicles, equipment, buildings and the disposal site. Both routine operations and accidents shall be addressed. The program description shall include procedures, instrumentation, facilities and equipment. Application of as low as reasonably achievable shall be discussed.

(11) A description of the monitoring program under § 236.409 (relating to monitoring plan) to provide data to evaluate disposal facility performance, potential health and environmental impacts and the plan for taking remedial measures.

(12) A description of the administrative procedures that the applicant will apply to control activities at the disposal facility.

(13) A description of potential operational accidents and the methodology to assure that likely accident scenarios are bounded.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application).

§ 236.209. Technical analyses.

The specific technical information shall also include the following analyses needed to demonstrate that the performance objectives of Subchapter A (relating to general provisions) will be met:

(1) Analyses of the pathways demonstrating protection of the general population from releases of radioactivity. Pathways analyzed shall include air, soil, groundwater, surface water, plant uptake and exhumation by burrowing animals. The analyses shall clearly identify and differentiate between the roles performed by the natural site characteristics and design features in isolating and segregating the wastes. The analyses shall clearly demonstrate that there is assurance that the exposures to humans from the release of radioactivity will not exceed the limits set forth in the performance objectives in Subchapter A.

(2) Analyses of the protection of individuals from inadvertent intrusion. The analyses shall include a demonstration that there is assurance that the waste classification and segregation requirements will be met and that barriers to inadvertent intrusion will be provided.

(3) Analyses of the protection of individuals during operations. The analyses shall include assessments of expected exposures due to routine operations and likely accidents during handling, storage and disposal of waste. The analyses shall provide assurance that exposures will be controlled to meet the requirements of Chapter 219 (relating to standards for protection against radiation).

(4) Analyses of the long term stability of the disposal site to determine the need for ongoing active maintenance after closure. These analyses shall consider active natural processes, including erosion, mass wasting, slope failure, settlement of wastes, infiltration through disposal covers and surface drainage of the disposal site. The analyses shall provide assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application).

§ 236.210. Institutional control information.

The institutional control information submitted by the applicant shall include:

(1) A certification by the Commonwealth that the custodial agency is prepared to accept transfer of the license when § 236.246 (relating to application and transfer of license to the Commonwealth) is met and will assume responsibility for institutional control after site closure and the postclosure observation and maintenance period.

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(2) If the proposed disposal site is on land not owned by the Federal government or the Commonwealth, the applicant shall submit evidence that arrangements have been made for assumption of ownership by the Commonwealth before the Department issues a license.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application); and 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.211. Financial information.

The financial information shall be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet the financial assurance requirements of section 316 of the act (35 P. S. § 7130.316) and Subchapter G (relating to financial assurances and liability). The applicant shall provide documented evidence of the availability of funds. If debt capital will be used, letters of commitment from the financial sources shall be provided.

Cross References

This section cited in 25 Pa. Code § 236.204 (relating to content of a license application).

§ 236.212. Filing and distribution of license application.

(a) An application package to obtain a license under this chapter and the Department licenses and permits necessary to construct and operate the disposal facility shall be filed with the Secretary. The applicant shall submit one signed original and 35 copies to the Secretary.

(b) The application package shall contain a statement, signed by a responsible official of the applicant and attested by a notary public, that certifies that the information contained in the application package is true and correct to the best of the official's information and belief.

(c) The application package shall consist of the following:

(1) The application for a license.

(2) An impact analysis report.

(3) The Department license and permit applications necessary for construction and operation of the disposal facility.

Cross References

This section cited in 25 Pa. Code § 236.202 (relating to license required); 25 Pa. Code § 236.204 (relating to content of a license application); 25 Pa. Code § 236.241 (relating to amendments for closure and transfer); and 25 Pa. Code § 236.247 (relating to termination of license).

§ 236.213. Contact person.

Except as otherwise specified, communications and reports concerning this chapter and applications filed under it shall be addressed to the Secretary, Department of Environmental Resources, Post Office Box 2063, Harrisburg, Pennsylvania 17120.

LICENSE REVIEW PROCEDURES AND STANDARDS

§ 236.221. Verification of receipt of application.

The Department will notify the applicant of its receipt of the license application.

§ 236.222. Public notice.

(a) Upon receipt of the license application, the Department will notify the public of receipt of the application. The notification will include a listing of the locations in which the application can be reviewed by the public. Notification will be provided in the *Pennsylvania Bulletin*, local media, newspapers of wide general circulation and newspapers in the area the regional facility is proposed to be located.

(b) The Department will make the license application available for review in the host municipality.

Cross References

This section cited in 25 Pa. Code § 236.223 (relating to public comment and hearing); 25 Pa. Code § 236.224 (relating to revising the license application); and 25 Pa. Code § 236.241 (relating to amendments for closure and transfer).

§ 236.223. Public comment and hearing.

(a) The Department will hold one public hearing and one public information meeting on the initial license application in the area the regional facility is proposed to be located. The Department will issue a 30-day public notice in the *Pennsylvania Bulletin* and newspapers of general circulation in the area of the proposed host municipality to announce the hearing and meeting dates. There will be a minimum of 30 days time between the public hearing and the public meeting.

(b) Interested persons may submit to the Department written comments regarding the application. Comments shall be submitted within 180 days after notification has been made under § 236.222 (relating to public notice). Interested persons may submit comments at the hearing. A person wishing to examine witnesses shall submit to the Department a numbered list of contentions. The contentions shall be limited to failure of the license application and its contents to conform with the act and this chapter. The applicant shall submit two copies of its testimony 2 weeks before the date the hearing is scheduled. The applicant or

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licensee shall make its staff available to answer questions. The Department may establish the duration for oral testimony and may limit the scope of questioning during the hearing.

(c) Written comments and the transcript of the hearing will be considered in the Secretary's decision on the application and become part of the public record.

(d) The Department will provide a written response to comments or testimony at the time a final action is taken.

Cross References

This section cited in 25 Pa. Code § 236.241 (relating to amendments for closure and transfer).

§ 236.224. Revising the license application.

(a) If the license application is rejected, a revised application may be submitted and may incorporate the portions of the previous application that were not the bases of the rejection.

(b) The Department will notify the public of an application rejection. Notification will be issued under § 236.222 (relating to public notice).

§ 236.225. Requirements for issuance of a license.

A license will not be issued unless the applicant affirmatively demonstrates to the satisfaction of the Department that:

(1) The operation will not endanger public health, safety and welfare or the environment.

(2) The application is accurate and complete and the requirements of the act and this chapter have been satisfied.

(3) The applicant is qualified by reason of training and experience to carry out the disposal operations requested in a manner that protects health and minimizes danger to life or property.

(4) The applicant's proposed disposal site, disposal facility design, disposal facility operations, including equipment, facilities and procedures, disposal site closure and postclosure institutional control are adequate to protect the public health and safety by providing assurance that the general population will be protected from releases of radioactivity as specified in the performance objective in § 236.13 (relating to protection of the general population and environment from releases of radioactivity).

(5) The applicant's proposed disposal site, disposal facility design, disposal facility operations, including equipment, facilities and procedures, disposal site closure and postclosure institutional control are adequate to protect the public health and safety by providing assurance that individual inadvertent intruders are protected in accordance with the performance objective in § 236.14 (relating to protection of individuals from inadvertent intrusion).

(6) The applicant's proposed disposal facility design and disposal facility operations, including equipment, facilities and procedures, are adequate to pro-

tect the public health and safety by providing assurance that the standards for radiation protection in Chapter 219 (relating to standards for protection against radiation) will be met.

(7) The applicant's proposed disposal site, disposal facility design, disposal facility operations, disposal site closure and postclosure institutional control are adequate to protect the public health and safety by providing assurance that long term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance following closure.

(8) The technical requirements of Subchapters B and D—F will be met.

(9) The applicant's proposal for institutional control, as required in § 236.210 (relating to institutional control information), provides assurance that the control will be provided for the long term care period.

(10) The financial or surety arrangements meet the requirements of Subchapter G (relating to financial assurances and liability).

Cross References

This section cited in 25 Pa. Code § 236.241 (relating to amendments for closure and transfer); 25 Pa. Code § 236.242 (relating to other amendments); and 25 Pa. Code § 236.246 (relating to application and transfer of license to the Commonwealth).

§ 236.226. Conditions of the license.

(a) A license issued under this chapter, or a right thereunder, may not be transferred, assigned or disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to another person, unless the Department finds, after securing full information, that the transfer is in accordance with the act and the Department gives its consent in writing in the form of a license amendment.

(b) The licensee shall submit written statements under oath upon request of the Department, before termination of the license, to enable the Department to determine whether the license should be modified, suspended or revoked.

(c) The license will be transferred to the custodial agency on the full implementation of the site closure and decommissioning plan as approved by the Department, including postclosure observation and maintenance.

(d) The licensee shall be subject to the act and to this title and orders of the Department. The terms and conditions of the license are subject to amendment, by reason of amendments to, or by reason of this title and order issued under the act.

(e) The person licensed by the Department under this chapter shall confine possession and use of materials to the locations and purposes authorized in the license.

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(f) The licensee may not dispose of waste until the Department has inspected the disposal facility and has found it to be in conformance with plans described in the application for a license and approved by the Department.

(g) The Department may incorporate in the license at the time of issuance, or thereafter, by appropriate rule, regulation or order, additional requirements and conditions with respect to the licensee's receipt, possession and disposal of waste as the Department deems appropriate or necessary to:

(1) Protect health or minimize danger to life or the environment.

(2) Provide for inspections or activities under the license that may be necessary or appropriate to effectuate the purposes of the act and regulations thereunder.

(3) Require tests, reports and the keeping of records.

(h) The authority to dispose of wastes expires on the date stated in the license. The Department will, on a 5-year basis, review the license and conditions of the license. An expiration date on the license applies only to operational activities and to the authority to dispose of waste. Failure to revise the license does not relieve the licensee of responsibility for implementing site closure and decommissioning, postclosure observation and transfer of the license to the Commonwealth.

(i) The license may be revoked, suspended or modified for a material false statement in the application, or because of conditions revealed by a report, record or inspection or other means which would warrant the Department to refuse to grant a license for the original application.

(j) The licensee shall allow the Department, its agents and employes, and the host municipality and host county inspectors, without advance notice or search warrant, upon presentation of appropriate credentials and without delay, to have access to areas where disposal activities are conducted and to examine the records and books relating thereto.

(k) The licensee shall update on an annual basis the general information required under § 236.205 (relating to general information) and other information the Department may require.

§ 236.227. Effective date of decision.

The initial decision to issue a license under this chapter or an amendment to the license shall become effective immediately upon signed order of the Secretary or a delegated representative.

CHANGES TO THE REGIONAL FACILITY LICENSE

§ 236.241. Amendments for closure and transfer.

An application for a license amendment for site closure or license transfer shall be filed under § 236.212 (relating to filing and distribution of license application) and shall fully describe the changes desired. The application shall be subject to

the notice, comment and hearing requirements of §§ 236.222 and 236.223 (relating to public notice; and public comment and hearing). The application for site closure or transfer will not be approved by the Department unless the applicant has demonstrated to the Department's satisfaction that the standards in § 236.225 (relating to requirements for issuance of a license) have been met.

§ 236.242. Other amendments.

Except for site closure or license transfer, if the operator wishes to amend the license, the licensee shall notify the Department and the host municipality of the proposed amendments. The Department will provide public notice of the application in the *Pennsylvania Bulletin.* The public shall have opportunity to comment on the proposed amendments during a period of 60 days after the notification has been published. The application for license amendment will not be approved by the Department unless the applicant has demonstrated to the Department's satisfaction that the standards in § 236.225 (relating to requirements for issuance of a license) have been met.

§ 236.243. Fees.

The Department will determine license amendment application fees on a case by case basis. The fees will be based on administrative costs incurred by the Department.

§ 236.244. Application for closure.

(a) An application for closure under § 236.245 (relating to content of a license application for closure) shall be filed at least 90 days prior to license expiration.

(b) An application for closure shall be filed under § 236.245. Information contained in previous applications, statements or reports filed with the Department under the license may be incorporated by reference if the references are clear and specific.

§ 236.245. Content of a license application for closure.

(a) Prior to final closure of the disposal site, or as otherwise directed by the Department, the licensee shall submit an application to amend the license for closure. This closure application shall include a final revision and specific details of the disposal site closure and decommissioning plan submitted under § 236.206 (relating to program plans) that includes the following:

(1) Additional geologic, hydrologic or other data pertinent to the long term containment of emplaced wastes obtained during the operational period.

(2) The results of tests, experiments or other analyses relating to the long term containment of emplaced waste within the disposal facility.

(3) Proposed revision of plans for:

(i) Decontamination or dismantlement of facilities, or both.

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(ii) Stabilization of the disposal site for postclosure care.

(4) Significant new information regarding the environmental impact of closure activities and long term performance of the disposal site.

(b) Upon review and consideration of an application to amend the license for closure submitted under this section, the Department will issue an amendment authorizing closure if there is assurance that the long term performance objectives of Subchapter A (relating to general provisions) will be met.

Cross References

This section cited in 25 Pa. Code § 236.244 (relating to application for closure).

§ 236.246. Application and transfer of license to the Commonwealth.

(a) Following closure and the postclosure observation and maintenance period, the licensee may apply for an amendment to transfer the license to the Commonwealth. The license will not be transferred unless the licensee demonstrates to the Department's satisfaction that:

(1) The closure of the disposal site has been made in conformance with the licensee's site closure and decommissioning plan, as approved as part of the license.

(2) The performance objectives of Subchapter A (relating to general provisions) have been met and will continue to be satisfied.

(3) Funds collected for the Account and necessary records for care have been transferred to the Commonwealth.

(4) The monitoring program is operational for implementation by the Commonwealth.

(5) The custodial agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under § 236.225(i) (relating to requirements for issuance of a license) will be met.

(b) Upon demonstration of the requirements of subsection (a), the disposal facility license will be transferred to the Commonwealth and the operator's license will be terminated.

Cross References

This section cited in 25 Pa. Code § 236.210 (relating to institutional control information); 25 Pa. Code § 236.414 (relating to radiation dose rates at the surface); and 25 Pa. Code § 236.415 (relating to postclosure observation and maintenance).

§ 236.247. Termination of license.

(a) At any period of time during the long term care period, the custodial agency—licensee—may apply for an amendment to terminate the license.

(b) The application shall be filed under § 236.212 (relating to filing and distribution of license application) and the requirements of this section.

(c) The licensee shall demonstrate to the satisfaction of the Department that the standards of § 236.508 (relating to determination of hazardous life of the waste) are met.

Subchapter D. DESIGN REQUIREMENTS FOR THE REGIONAL DISPOSAL FACILITY

GENERAL

Sec.
236.301. Scope and purpose.

DESIGN CRITERIA

236.311. General requirements.
236.312. Compatibility with site.
236.313. Acceptance of diverse waste streams.
236.314. Enhanced containment.
236.315. Recoverability.
236.316. Passive isolation.
236.317. Minimization of water intrusion during operations.
236.318. Water management.
236.319. Disposal facility cover system.
236.320. Protection from inadvertent intruders.
236.321. Protection of workers.
236.322. Long term stability of disposal units.
236.323. Disruptive external events.
236.324. Disposal unit monitoring.
236.325. Material performance monitoring.
236.326. Remedial measures.
236.327. Class C waste.
236.328. Mixed waste.
236.329. Nonradiological hazards.
236.330. Performance assessment.

Cross References

This subchapter cited in 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

GENERAL

§ 236.301. Scope and purpose.

(a) This subchapter implements section 305 of the act (35 P. S. § 7130.305). The requirements of this subchapter specify the design criteria for an above-grade low-level radioactive waste disposal facility.

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(b) The selected disposal technology shall meet the design criteria that are established in this subchapter and as a goal, be designed and constructed for zero release of radioactive material. The design requirements for addressing containment of waste and the goal of zero release are specified in § 236.314 (relating to enhanced containment). Furthermore, the site in which the disposal facility is to be located shall independently comply with Subchapter B (relating to requirements for siting the regional disposal facility). Consequently, the design criteria have been established to require the applicant to demonstrate that the disposal technology can complement and augment the site's ability to meet the performance objectives of Subchapter A (relating to general provisions).

DESIGN CRITERIA

§ 236.311. General requirements.

(a) Shallow land burial, as defined in § 236.2 (relating to definitions) is prohibited.

(b) Waste emplaced in the disposal facility shall be above the natural grade of the land which shall be known as above-grade disposal. An above-grade disposal facility shall be used unless the applicant can demonstrate that other designs provide significant improvement for recoverability, monitoring and protection of public health and the environment.

(c) The design and construction methods may not adversely affect the ability of the disposal facility to meet the performance objectives of Subchapter A (relating to general provisions).

§ 236.312. Compatibility with site.

(a) The disposal facility shall be compatible with the natural characteristics of the site, as identified in Subchapter B (relating to requirements for siting the regional disposal facility).

(b) The disposal facility shall complement and augment the natural disposal site's ability to assure that the performance objectives of Subchapter A (relating to general provisions) are met.

§ 236.313. Acceptance of diverse waste streams.

(a) The disposal facility shall be capable of accepting low-level radioactive waste generated within the Appalachian Compact region that is classified as a state responsibility under the Low-Level Radioactive Waste Policy Amendments Act of 1985 (42 U.S.C.A. §§ 2021b—2021j).

(b) The disposal facility shall have sufficient capacity to accommodate at least a 30-year useful facility life, as required by the Appalachian State Low-Level Radioactive Waste Compact. Design consideration for disposal capacity shall be based on reasonable waste projections and be capable of accommodating unanticipated changes in waste streams or volumes.

2(c) The disposal facility shall be capable of accommodating low-level waste streams with different physical and chemical properties.

§ 236.314. Enhanced containment.

(a) The disposal facility shall include engineered structures. The engineered structures shall provide additional measures for isolation of waste from the environment. For the purpose of this section, the container by itself cannot satisfy requirements for enhanced containment.

(b) At a minimum, the engineered structures shall provide:

(1) Leak resistance for a minimum of 100 years, following the postclosure observation and maintenance period.

(2) Structural stability to the disposal units. Design goals for the material integrity and stability of the engineered structure shall be commensurate with the time periods specified in subsection (d).

(c) The disposal facility shall independently comply with performance objectives in §§ 236.13 and 236.16 (relating to protection of the general population and environment from releases of radioactivity; and stability of the disposal site) without consideration of natural site features, through the active institutional control period.

(d) The design goal for the disposal facility to provide containment of the different classes of waste shall be for the following minimum time periods:

(1) Class A radioactive waste—100 years.

(2) Class B radioactive waste—300 years.

(3) Class C radioactive waste—500 years.

(4) Mixed waste—500 years.

Cross References

This section cited in 25 Pa. Code § 236.301 (relating to scope and purpose); 25 Pa. Code § 236.324 (relating to disposal unit monitoring); and 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.315. Recoverability.

(a) The disposal facility design shall allow for recovery of the waste. This section may not compromise or otherwise lessen the ability of the disposal facility to meet the performance objectives of Subchapter A (relating to general provisions) and the stability requirements of § 236.322 (relating to long term stability of disposal units).

(b) Determinations for recovery of the waste shall be based on the analysis of information collected under §§ 236.324, 236.325 and 236.410 (relating to disposal unit monitoring; material performance monitoring; and environmental monitoring).

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Cross References

This section cited in 25 Pa. Code § 236.327 (relating to class C waste); and 25 Pa. Code § 236.328 (relating to mixed waste).

§ 236.316. Passive isolation.

The disposal facility shall be designed for long term isolation and avoidance of the need for remedial action after site closure.

§ 236.317. Minimization of water intrusion during operations.

(a) The design goal for the disposal facility shall be to prevent the contact of waste and waste containers with water prior to and during disposal.

(b) The disposal facility design shall preclude the contact of waste containers with standing water during emplacement into the disposal units.

§ 236.318. Water management.

(a) The design goal for the disposal facility shall be to prevent infiltration of water and eliminate the accumulation of standing water in the disposal units following waste disposal.

(b) The disposal facility shall be designed to direct surface water drainage away from disposal units at velocities and gradients which would not result in erosion that would require ongoing active maintenance.

§ 236.319. Disposal facility cover system.

The disposal units shall include an engineered cover. The design goal for the cover shall be to prevent water infiltration. The cover shall be designed to:

(1) Provide long term stability without the need for active maintenance. The engineered cover shall perform through the long term care period.

(2) Direct surface runoff away from the disposal unit.

(3) Minimize erosion, differential settlement, ponding, piping, mass wasting and slumping.

§ 236.320. Protection from inadvertent intruders.

(a) The disposal facility shall include intruder barriers for Class B, Class C and mixed wastes. At a minimum, these disposal units shall include an intruder barrier that is an engineered structure, designed to resist inadvertent intrusion for:

(1) Class B waste—300 years.

(2) Class C waste—500 years.

(3) Mixed waste—500 years.

(b) If more than one class of waste is disposed of in the same unit, the more stringent intruder requirement shall be met.

(c) The disposal facility design shall, to the extent practicable, limit radiation exposures to the inadvertent intruder to an annual whole body dose equivalent of 25 millirems.

Cross References

This section cited in 25 Pa. Code § 236.2 (relating to definitions); and 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.321. Protection of workers.

The disposal facility design shall incorporate systems and features which shall maintain exposures to workers which are as low as reasonably achievable.

§ 236.322. Long term stability of disposal units.

(a) The disposal facility shall be designed to provide long term stability to the engineered structures of the disposal units.

(b) At a minimum, the stability requirements for the engineered structures for the different classes of waste shall be:

(1) Class A radioactive waste—100 years.

(2) Class B radioactive waste—300 years.

(3) Class C radioactive waste—500 years.

(4) Mixed waste—500 years.

(c) If more than one class of waste is disposed of in the same disposal unit, the more stringent stability requirement shall be met.

(d) Waste containers or modules shall be emplaced in the disposal unit in a manner that maintains physical integrity.

(e) Waste containers or modules shall be designed and emplaced in the disposal unit in a manner that minimizes void space.

Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); and 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.323. Disruptive external events.

The disposal facility shall be designed to maintain its structural integrity and provide waste containment capability during an external, disruptive, natural or manmade event which may occur in the area.

§ 236.324. Disposal unit monitoring.

(a) The disposal facility design shall include provisions for a continuous monitoring program. The program shall commence upon placement of the waste into the disposal units and continue through the long term care period.

(b) The disposal unit monitoring system that is used to support the continuous monitoring program shall be capable of detecting and identifying the location, within each disposal unit, of leached radioactive materials. The disposal unit monitoring system shall be designed to be compatible with design provisions for waste recovery in § 236.314 (relating to enhanced containment).

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Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); 25 Pa. Code § 236.327 (relating to class C waste); 25 Pa. Code § 236.328 (relating to mixed waste); and 25 Pa. Code § 236.409 (relating to monitoring plan).

§ 236.325. Material performance monitoring.

(a) An analysis of the materials and components of the engineered structures shall be conducted to demonstrate that the disposal facility can perform through the long term care period.

(b) The disposal facility design shall include provisions for a monitoring program which can provide ongoing verification of the performance of the engineered structure. At a minimum, the program shall provide performance verification beginning at initial operation and up to and including the active institutional control period.

Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); 25 Pa. Code § 236.327 (relating to class C waste); 25 Pa. Code § 236.328 (relating to mixed waste); and 25 Pa. Code § 236.409 (relating to monitoring plan).

§ 236.326. Remedial measures.

The disposal facility shall be designed to facilitate remedial action. This criterion may not compromise or otherwise lessen the ability of the disposal facility to meet the performance objectives of Subchapter A (relating to general provisions).

§ 236.327. Class C waste.

(a) Class C waste disposal shall be performed apart from other low-level radioactive waste disposal, and Class C waste shall be placed in individual modules.

(b) A Class C module shall be monitored under §§ 236.324 and 236.325 (relating to disposal unit monitoring; and material performance monitoring) and be recoverable under § 236.315 (relating to recoverability).

Cross References

This section cited in 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.328. Mixed waste.

(a) Mixed waste disposal shall comply with this chapter and Article VII (relating to hazardous waste management).

(b) Mixed waste shall be in a solid and stable form and shall be disposed apart from other low-level radioactive waste disposal.

(c) Mixed waste shall be placed in individual modules. A mixed waste module shall be monitored under §§ 236.324 and 236.325 (relating to disposal unit

monitoring; and material performance monitoring) and be recoverable under § 236.315 (relating to recoverability).

§ 236.329. Nonradiological hazards.

The disposal facility design and operational procedures shall reduce nonradiological hazards to individuals to levels as low as reasonably achievable.

§ 236.330. Performance assessment.

The performance of the disposal facility shall be characterized, analyzed and modeled in order to predict interactions of the disposal units with the environment and compliance with the performance objectives in Subchapter A (relating to general provisions).

Subchapter E. REQUIREMENTS FOR THE CONSTRUCTION, OPERATION AND CLOSURE OF THE REGIONAL DISPOSAL FACILITY

Sec.
236.401. Scope and purpose.
236.402. Construction plan.
236.403. Facility operation plan.
236.404. Contingency plans.
236.405. Receipt and handling of waste.
236.406. Package integrity.
236.407. Minimization of void space.
236.408. Operational activity.
236.409. Monitoring plan.
236.410. Environmental monitoring.
236.411. Site closure and decommissioning plan.
236.412. Boundary locations.
236.413. Buffer zone.
236.414. Radiation dose rates at the surface.
236.415. Postclosure observation and maintenance.
236.416. Institutional control.

Cross References

This subchapter cited in 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.401. Scope and purpose.

(a) Only Classes A, B, C and mixed waste are acceptable for disposal at the regional disposal facility. Waste disposal activities at the regional facility shall meet the construction, operation and closure requirements of this subchapter. The planning and implementation of these activities shall contribute to the goal of zero release of radioactive material.

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(b) A mixed waste is not acceptable for disposal at the regional disposal facility if either the facility operator or the Department has reason to believe that the hazardous waste, as originally generated, was not radioactive.

(c) Waste received at the regional disposal facility may not be intentionally diluted by the licensee to alter its classification as identified on the manifest received under § 236.536 (relating to disposal facility operator requirements).

§ 236.402. Construction plan.

The applicant shall submit a construction plan. The plan shall describe procedures that will be implemented to ensure quality work that will consistently conform to applicable standards and codes.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans).

§ 236.403. Facility operation plan.

(a) The applicant shall submit a facility operation plan for approval by the Department. The plan shall:

(1) Include detailed descriptions of the method of construction of the disposal units, waste emplacement, procedures for and areas of waste segregation, onsite traffic and drainage systems, site security, methods and areas of waste storage, methods to control access of water, mixed wastes or other nonradiological substances or waste that may affect meeting the performance objectives of Subchapter A (relating to general provisions).

(2) Be compatible with other plans required by this chapter.

(b) The plan shall include detailed descriptions of closure and stabilization measures that will be carried out as each disposal unit is filled.

(c) A site health and safety plan which addresses radiological health under Chapter 219 (relating to standards for protection against radiation) and occupational hazards shall be submitted. The plan shall be adequate to protect public health and safety, and the environment and provide reasonable assurance that the standards for radiation protection in Chapter 219 will be met. The plan shall identify measures that are intended to provide assurance that radiation exposures to workers are as low as reasonably achievable.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans).

§ 236.404. Contingency plans.

(a) The applicant shall submit contingency plans for unplanned occurrences, such as fire, industrial accidents, radiological contamination, severe natural events, disposal unit repairs and waste recovery which may adversely affect the health and safety of disposal facility workers or the general public.

(b) The plans shall identify the necessary training, management, procedures, equipment and human resources required to provide emergency response.

(c) The operator shall include one of the following in the license application:

(1) Signed agreements from necessary emergency response units that they will respond to requests from the operator.

(2) Provisions by the operator for adequate emergency response capability as identified in subsections (a) and (b), approved by the Department.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans).

§ 236.405. Receipt and handling of waste.

(a) The applicant shall submit a plan for the receipt, inspection and handling of waste entering the disposal facility. The plan shall include waste acceptance criteria that define specifications for waste acceptable for disposal at the facility and waste containers that are acceptable for disposal.

(b) The plan shall be designed to ensure that:

(1) Waste that arrives at the disposal site complies with Subchapter F (relating to waste classification, waste characteristics, labeling and manifests).

(2) The procedures and equipment for moving, segregating and storing the waste will be carried out in a safe manner and eliminate, to the maximum extent practicable, the contact of the waste with water.

§ 236.406. Package integrity.

Wastes shall be emplaced in a manner that maintains the container integrity and minimizes the void spaces between containers.

§ 236.407. Minimization of void space.

Void spaces between waste containers shall be minimized to reduce the potential for future subsidence.

§ 236.408. Operational activity.

Active waste disposal operations may not have an adverse effect on disposal units for which closure and stabilization measures have been completed.

§ 236.409. Monitoring plan.

(a) The applicant shall submit a monitoring plan. The monitoring plan shall discuss the function and interrelationship of the requirements of §§ 236.324, 236.325 and 236.410 (relating to disposal unit monitoring; material performance monitoring; and environmental monitoring).

(b) The licensee shall have a contingency plan for taking remedial measures including recovery of waste if the disposal unit monitoring system or environmental monitoring system detects radioactive material which would indicate that

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the performance objectives of Subchapter A (relating to general provisions) may not be met. The plan shall identify the necessary training, management procedures and equipment required for corrective action.

(c) The plan shall specifically address monitoring during the preoperational, operational, closure and long term care periods.

(d) An offsite radiation measurement that exceeds the natural background, as established during preoperational environmental monitoring, shall be reported immediately to the Department and host municipality and county. Actions shall be initiated by the licensee to identify and abate the source of the offsite radiation that exceeds the natural background.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans); 25 Pa. Code § 236.208 (relating to specific technical information); and 25 Pa. Code § 236.413 (relating to buffer zone).

§ 236.410. Environmental monitoring.

(a) At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to establish background radiation levels and to provide basic environmental data on the site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry and seismology of the site. For those characteristics that are subject to seasonal variation, data shall cover at least a 12-month period.

(b) During disposal facility construction and operation, the licensee shall maintain an onsite and offsite environmental monitoring program. Measurements and observations shall be made and recorded to provide data to evaluate the potential health and environmental impacts from all significant pathways during the construction and the operation of the facility and to enable the evaluation of long term effects and the need for mitigating measures. The monitoring system shall be capable of providing early warning of releases of waste from the disposal units.

(c) After the disposal site is closed, the custodial agency responsible for postoperational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system shall be capable of providing early warning of releases of waste from the disposal units.

Cross References

This section cited in 25 Pa. Code § 236.315 (relating to recoverability); and 25 Pa. Code § 236.409 (relating to monitoring plan).

§ 236.411. Site closure and decommissioning plan.

(a) The applicant shall submit a plan for closure and decommissioning. The plan shall describe:

(1) Closure, stabilization and monitoring of individual disposal units and their relationship to the final site closure and decommissioning plan.

(2) Methods and procedures that will be implemented to ensure that closed disposal units are not adversely affected by final site closure and decommissioning.

(3) A compatible approach for final closure, decommissioning and stabilization of the regional disposal facility.

(b) The site closure and decommissioning plan will be incorporated into the facility license and will be reviewed every 5 years or at the request of the Department.

Cross References

This section cited in 25 Pa. Code § 236.206 (relating to program plans); and 25 Pa. Code § 236.208 (relating to specific technical information).

§ 236.412. Boundary locations.

The boundaries and locations of each disposal unit shall be accurately located and mapped by means of a land survey. Disposal units shall be marked so that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, shall be established on the site to facilitate surveys. The USGS or NGS control stations shall provide horizontal and vertical controls as checked against USGS or NGS record files.

§ 236.413. Buffer zone.

A buffer zone of land shall be maintained between disposed waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out monitoring activities specified in § 236.409 (relating to monitoring plan) and take remedial measures if needed.

§ 236.414. Radiation dose rates at the surface.

Waste shall be emplaced in a manner that limits the radiation dose rate at the surface of the engineered cover to levels that at a minimum will permit the licensee to comply with this chapter at the time the license is transferred under § 236.246 (relating to application and transfer of license to the Commonwealth).

§ 236.415. Postclosure observation and maintenance.

The licensee shall observe and monitor the disposal site, and carry out necessary maintenance and repairs until the site closure and decommissioning is complete and the license is transferred by the Department under § 236.246 (relating to application and transfer of license to the Commonwealth). Responsibility for postclosure observation and maintenance for the disposal site shall be maintained by the licensee for at least 5 years.

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§ 236.416. Institutional control.

(a) The Commonwealth's custodial agency shall conduct an institutional control program to physically control access to the disposal site following transfer of control from the disposal site operator. During the active institutional control period, the program shall include active methods for access control, surveillance, monitoring, custodial care and administration of funds to cover the costs for these activities.

(b) During the passive institutional control period, the program shall include passive access control, monitoring and administration of funds to cover the costs for these activities.

Subchapter F. WASTE CLASSIFICATION, WASTE CHARACTERISTICS, LABELING AND MANIFESTS

LOW-LEVEL RADIOACTIVE WASTE CLASSIFICATION SYSTEM

Sec.
236.501. Scope and considerations.
236.502. Classes of waste.
236.503. Waste classification.
236.504. Classification by long- and short-lived radionuclides.
236.505. Classification of wastes other than § 236.503.
236.506. Sum of fractions rule.
236.507. Determination of radionuclide concentrations in waste.
236.508. Determination of hazardous life of the waste.

LOW-LEVEL RADIOACTIVE WASTE CHARACTERISTICS

236.521. Minimum requirements for classes of waste.
236.522. Stability requirements for waste form.
236.523. Stabilization of liquid waste.
236.524. Minimization of void spaces within waste packages.

LABELING AND WASTE MANIFESTS

236.531. Labeling.
236.532. Waste manifest.
236.533. Generator requirements.
236.534. Carrier requirements.
236.535. Broker requirements.
236.536. Disposal facility operator requirements.
236.537. Nonacknowledgment.

Cross References

This subchapter cited in 25 Pa. Code § 236.225 (relating to requirements for issuance of a license); and 25 Pa. Code § 236.405 (relating to receipt and handling of waste).

LOW-LEVEL RADIOACTIVE WASTE CLASSIFICATION SYSTEM

§ 236.501. Scope and considerations.

Determination of the classification of waste involves the following considerations:

(1) Consideration shall be given to the concentration of long-lived radionuclides—and their short-lived precursors—whose potential hazard will persist long after precautions such as the active institutional control period and improved waste form have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. The magnitude of the potential dose is limited by the concentration and availability of the radionuclides at the time of exposure.

(2) Consideration shall be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form and disposal methods are effective.

§ 236.502. Classes of waste.

(a) Class A waste is a waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste shall meet the minimum requirements in § 236.521 (relating to minimum requirements for classes of waste). Class A waste shall also be emplaced in a disposal facility that meets the requirements in §§ 236.314 and 236.322 (relating to enhanced containment; and long term stability of disposal units).

(b) Class B waste is waste that meets more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste shall meet both the minimum and stability requirements in §§ 236.521 and 236.522 (relating to stability requirements for waste form). Class B waste shall also be emplaced in a disposal facility that meets the requirements in §§ 236.314 and 236.322. In addition, Class B waste requires protection against inadvertent intrusion, as set forth in § 236.320 (relating to protection from inadvertent intruders).

(c) Class C waste is waste that not only meets more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility including measures to protect against inadvertent intrusion. The physical form and characteristics of Class C waste shall meet both the minimum and stability requirements in §§ 236.521 and 236.522. Class C waste shall also be emplaced in a disposal facility that meets the requirements in §§ 236.314,

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236.320 and 236.322. In addition, Class C waste shall be disposed of in accordance with § 236.327 (relating to Class C waste).

§ 236.503. Waste classification.

(a) *Classification by long-lived radionuclides.* If the waste contains only radionuclides listed in Table 1, classification shall be determined as follows:

(1) If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.

(2) If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.

(3) If the concentration exceeds the value in Table 1, the waste is not generally acceptable for disposal.

(4) For waste containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined under § 236.506 (relating to sum of fractions rule).

Table 1

Radionuclide	Concentration (curies/cubic meter)*
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha-emitting radionuclides with half-life greater than 5 years except Uranium	100**
Pu-241	3,500**
Cm-242	20,000**
Ra-226	100**

*To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabequerels (GBq), multiply by 37.

**Units are nanocuries per gram.

(b) *Classification by short-lived radionuclides.* If the waste does not contain any radionuclide listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. If the waste does not contain a radionuclide listed in Table 1 or Table 2, it is Class A.

(1) If the concentration does not exceed the value in Table 2, Column 1, the waste is Class A.

(2) If the concentration exceeds the value in Table 2, Column 1, but does not exceed the value in Table 2, Column 2, the waste is Class B.

(3) If the concentration exceeds the value in Table 2, Column 2, but does not exceed the value in Table 2, Column 3, the waste is Class C.

(4) If the concentration exceeds the value in Table 2, Column 3, the waste is not generally acceptable for disposal.

(5) For waste containing mixtures of the radionuclides listed in Table 2 the total concentration shall be determined under § 236.506.

Table 2

	Concentration (curies/cubic meter)		
Radionuclide	Col. 1	Col. 2	Col. 3
Total of all radionuclides with less than 5-year half-life	700	**	**
H-3	40	**	**
Co-60	700	**	**
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7,000
Sr-90	0.04	150	7,000
Cs-137	1	44	4,600

To convert nanocuries to becquerels (Bq), multiply by 37. To convert curies to gigabequerels (GBq), multiply by 37.

**There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table 1 determine the waste to be Class C independent of these radionuclides.

Cross References

This section cited in 25 Pa. Code § 236.504 (relating to classification by long- and short-lived radionuclides); 25 Pa. Code § 236.505 (relating to classification of wastes other than § 236.503); and 25 Pa. Code § 236.506 (relating to sum of fractions rule).

§ 236.504. Classification by long- and short-lived radionuclides.

If the waste contains a mixture of radionuclides, some of which are listed in Table 1 of § 236.503 (relating to waste classification) and some of which are listed in Table 2 of § 236.503 classification shall be determined as follows:

(1) If the concentration of a radionuclide listed in Table 1 of § 236.503 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of radionuclides listed in Table 2 of § 236.503.

(2) If the concentration of a radionuclide listed in Table 1 of § 236.503 exceeds 0.1 times the value listed in Table 1, but does not exceed the value in

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Table 1, the waste shall be Class C, if the concentration of radionuclides listed in Table 2 of § 236.503 does not exceed the value shown in Table 2, Column 3.

§ 236.505. Classification of wastes other than § 236.503.

If the waste does not contain a radionuclide listed in either Table 1 or Table 2 of § 236.503 (relating to waste classification), it is Class A waste.

§ 236.506. Sum of fractions rule.

For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits shall be taken from the same column of the same table. The sum of the fractions for the column shall be less than, or equal to, 1 if the waste class is to be determined by that column.

Example: A waste contains Sr-90 in a concentration of 50 Ci/m (1.85 TBq/m) and Cs-137 in a concentration of 22 Ci/m (814 GBq/m). Since the concentrations both exceed the values in Table 2 of § 236.503, Column 1, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = .5; the sum of the fractions = 0.83. Since the sum is less than 1, the waste is Class B.

Cross References

This section cited in 25 Pa. Code § 236.503 (relating to waste classification).

§ 236.507. Determination of radionuclide concentrations in waste.

The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured; or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as nanocuries per gram.

§ 236.508. Determination of hazardous life of the waste.

The hazardous life of the waste is the amount of time that it takes for the disposed low-level radioactive waste to decay to levels so that it can be demonstrated that unrestricted use of the site would result in a dose to a member of the public using the site that is no greater than the dose from natural background radioactivity, in the soil, prior to the site being used for disposal.

Cross References

This section cited in 25 Pa. Code § 236.247 (relating to termination of license).

LOW-LEVEL RADIOACTIVE WASTE CHARACTERISTICS

§ 236.521. Minimum requirements for classes of waste.

The following are minimum requirements for classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site. The requirements are as follows:

(1) Waste shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. If the conditions of the site license are more restrictive than this chapter, the site license conditions shall govern.

(2) Waste may not be packaged for disposal in cardboard, wooden or fiberboard boxes.

(3) Liquid waste shall be solidified.

(4) Waste that has been dewatered shall contain as little free-standing liquid as is reasonably achievable, but the liquid may not exceed 1% of the volume.

(5) Waste may not be capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(6) Waste may not contain, or be capable of generating, quantities of toxic gases, vapors or fumes harmful to persons transporting, handling or disposing of the waste. This restriction does not apply to radioactive gaseous waste packaged under paragraph (8).

(7) Waste may not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared and packaged to be nonflammable.

(8) The Department will review on a case-by-case basis, requests for disposal of gaseous waste. Gaseous waste disposal is required to receive Department approval prior to disposal. Waste in gaseous form shall be packaged at a gauge pressure that does not exceed 1.5 atmospheres at 20°C. Total activity may not exceed 100 curies—3.7 TBq—per container.

(9) Waste containing hazardous, biological, pathogenic or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the nonradiological materials.

Cross References

This section cited in 25 Pa. Code § 236.502 (relating to classes of waste); 25 Pa. Code § 236.523 (relating to stabilization of liquid waste); and 25 Pa. Code § 271.1 (relating to definitions).

§ 236.522. Stability requirements for waste form.

(a) The requirements of this section and §§ 236.523 and 236.524 (relating to stabilization of liquid waste; and minimization of void spaces within waste packages) are minimum requirements that are intended to provide stability of the

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waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse or other failure of the disposal unit. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(b) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture and microbial activity, and internal factors, such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form or placing the waste in a disposal container or structure that provides stability after disposal.

Cross References

This section cited in 25 Pa. Code § 236.502 (relating to classes of waste).

§ 236.523. Stabilization of liquid waste.

Notwithstanding § 236.521(3) and (4) (relating to minimum requirements for classes of waste), liquid waste or waste containing liquid, shall be converted into a form that contains as little freestanding liquid as is reasonably achievable. The liquid may not exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or .5% of the volume of the waste for waste processed to a stable form.

Cross References

This section cited in 25 Pa. Code § 236.522 (relating to stability requirements for waste form).

§ 236.524. Minimization of void spaces within waste packages.

Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

Cross References

This section cited in 25 Pa. Code § 236.522 (relating to stability requirements for waste form).

LABELING AND WASTE MANIFESTS

§ 236.531. Labeling.

A container of waste shall be clearly labeled to identify whether it is Class A, Class B or Class C Waste or mixed waste, under this subchapter.

§ 236.532. Waste manifest.

(a) A shipment of waste shall be accompanied by a shipment manifest that contains the name, address, telephone number and Department permit identifica-

tion number of the generator, the carrier who is to transport the waste and the broker who will manage the waste. The manifest may also designate alternate carriers or brokers.

(b) The manifest shall contain a physical description of the waste, the waste volume, radionuclide identity and quantity, the total radioactivity, the principal chemical form and the waste classification—for example, Class A, Class B, Class C or mixed waste in accordance with this chapter. Waste containing more than .1% chelating agents by weight shall be identified and the weight percentage of the chelating agent shall be identified. The manifest shall show the total quantity of the radionuclides H-3, C-14, Tc-99 and I-129.

(c) The manifest shall have a manifest identification number, and if the shipment contains hazardous waste, an EPA hazardous waste identification number.

(d) The waste manifest shall be on a form prepared by the Department. The information provided shall be sufficient to develop a waste data base and conduct performance assessment analyses.

(e) The manifest shall include a certification by the waste generator that the transported materials are properly classified, described, packaged, marked and labeled and are in proper condition for transportation according to 49 CFR Parts 170—179, 10 CFR Part 71 (relating to packaging and transportation of radioactive material) and this title. The certification shall acknowledge that the signer is subject to penalties for violation of the law. The manifest shall be signed and dated by an authorized representative of the generator.

Cross References

This section cited in 25 Pa. Code § 236.534 (relating to carrier requirements).

§ 236.533. Generator requirements.

A generator who transfers waste to the disposal facility or a broker shall:

(1) Prepare waste so that the waste is classified and characterized under this chapter.

(2) Conduct a quality assurance/quality control program approved by the Department to assure compliance with this subchapter. The program shall include management evaluation of audits.

(3) Prepare a complete manifest. The manifest shall contain the number of copies which will provide the generator, carriers, brokers and the disposal facility with one copy for their records and copies to be returned to the generator and to be forwarded to the disposal facility and the Department.

(4) Obtain the handwritten signature of the initial carrier and date of acceptance on the manifest.

(5) Retain a copy of the manifest with documentation of acknowledgment of receipt as the record of transfer.

(6) Forward a copy of the manifest to the disposal facility and another copy to the Department.

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(7) Give the carrier the remaining copies of the manifest.

(8) Conduct an investigation under § 236.537 (relating to nonacknowledgment), for a shipment or part of a shipment for which acknowledgment of receipt has not been received within the time set forth in § 236.537.

Cross References

This section cited in 25 Pa. Code § 236.535 (relating to broker requirements).

§ 236.534. Carrier requirements.

(a) No carrier may accept waste from a generator or broker unless it is accompanied by and conforms with a complete and valid manifest under § 236.532 (relating to waste manifest).

(b) Before transporting waste, a carrier shall sign and date the manifest acknowledging acceptance of the waste from the generator or broker before leaving the generator's or broker's property.

(c) The carrier shall ensure that the manifest accompanies the waste, and shall deliver it to the carrier, broker or regional facility, as designated on the manifest. The carrier shall contact the generator or broker who delivered the waste to him for further instructions, and shall revise the manifest in accordance with instructions written and signed by the generator or broker. Upon making the designated delivery, the carrier shall:

(1) Obtain a date of delivery and handwritten signature of the carrier, broker or regional facility operator.

(2) Retain a copy of the manifest.

(3) Forward a copy of the manifest to the Department.

(4) Give the remaining copies of the manifest to the regional facility operator or the broker.

(5) Retain the copies of the manifest signed by the person who delivered the waste to him, by himself and by the person receiving the waste from him for a period of 3 years.

(d) The carrier shall certify that nothing has been done to the waste which would invalidate the generator's or broker's certification.

§ 236.535. Broker requirements.

(a) No broker may receive waste from a generator, carrier or broker unless that waste is accompanied by a complete and valid manifest.

(b) The broker receiving waste shall:

(1) Sign and date each copy of the manifest to certify that the waste was received.

(2) Note in the manifest discrepancies between materials listed on the manifest and materials received. The broker shall also attempt to resolve discrepancies with the generator, carrier or broker. If the broker is unable to

resolve the discrepancies within 15 days of receiving the waste, he shall notify the Department in writing, and include a copy of the manifest with the letter.

(3) Give the carrier delivering the waste a copy of the signed manifest.

(4) Notify the generator that the waste has been received.

(5) Obtain the handwritten signature of the next carrier as designated on the manifest and date of acceptance.

(6) Retain a copy of the manifest with documentation of acknowledgment of receipt as a record of transfer for a period of 3 years.

(7) Forward a copy of the manifest to the disposal facility and another copy to the Department.

(8) Give the carrier the remaining copies of the manifest.

(9) Retain the copies of the manifest signed by the person receiving the waste from him for a period of 3 years.

(10) Conduct an investigation under § 236.537 (relating to non-acknowledgment), for a shipment or part of a shipment for which acknowledgment of receipt has not been received within the time set forth in § 236.537.

(c) If the broker repackages, processes, incinerates, solidifies, treats, evaporates or performs another process which results in the generation of a new waste or waste form, the broker shall comply with the generator requirements of § 236.533 (relating to generator requirements), including preparation and implementation of a quality assurance/quality control program, waste preparation and preparation of a new manifest. If the broker consolidates prepackaged waste into one shipment but does not generate a new waste or waste form, he may prepare a new manifest under § 236.533, or he may combine the several manifests of the consolidated shipments.

§ 236.536. Disposal facility operator requirements.

(a) The disposal facility operator may not receive waste from a generator, broker or carrier unless it is accompanied by a complete and valid manifest.

(b) The disposal facility operator shall:

(1) Sign and date the manifest to certify that the waste was received.

(2) Note in the manifest discrepancies between materials listed on the manifest and materials received. The operator shall also attempt to resolve any discrepancies with the operator generator, carrier or broker. If the disposal operator is unable to find an explanation for the discrepancies within 15 days of receiving the waste, the operator shall notify the Department in writing, explaining the discrepancies and attempts to resolve them, and include a copy of the manifest with the letter.

(3) Give the carrier delivering the waste a copy of the signed manifest.

(4) Notify the generator and broker within 15 days of its receipt.

(5) Retain the copies of completed manifests until the license is transferred to the custodial agency. During license transfer, the disposal facility operator

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shall transfer the manifests to the custodial agency. The custodial agency shall maintain copies of the manifest until the license is terminated.

Cross References

This section cited in 25 Pa. Code § 236.401 (relating to scope and purpose).

§ 236.537. Nonacknowledgment.

A generator or broker who has not received acknowledgment of receipt of the waste shipment from the next broker or the regional facility operator within 15 days of delivery shall immediately investigate why the shipment has not been received by the person so designated on the manifest. If the generator or broker is unable to locate the shipment, he shall prepare a report on the investigation conducted and shall file the report with the Department within 2 weeks after completion of the investigation.

Cross References

This section cited in 25 Pa. Code § 236.533 (relating to generator requirements); and 25 Pa. Code § 236.535 (relating to broker requirements).

Subchapter G. FINANCIAL ASSURANCES AND LIABILITY

Sec.
236.601. Scope.
236.602. Applicant qualifications and assurance.
236.603. Assurance for onsite cleanup during operation.
236.604. Assurance for liability during operation.
236.605. Funding for site closure and decommissioning.
236.606. Assurance for long term care.
236.607. Assurance for liability following site closure.

Cross References

This subchapter cited in 25 Pa. Code § 236.211 (relating to financial information); and 25 Pa. Code § 236.225 (relating to requirements for issuance of a license).

§ 236.601. Scope.

The applicant is required to demonstrate, prior to receipt of a license, that funds are available to cover costs for all phases of the facility life. The applicant is provided with several examples of financial or surety arrangements that are acceptable for demonstrating that the necessary funds are available.

§ 236.602. Applicant qualifications and assurance.

Prior to the issuance of a license the applicant shall show to the satisfaction of the Department that the applicant has or can reasonably expect to have necessary

funds to cover the estimated costs of conducting licensed activities over the planned operating life of the project, including costs for construction, operation, closure, postclosure monitoring and emergencies related to the disposal facility.

§ 236.603. Assurance for onsite cleanup during operation.

(a) Prior to receipt of a license, and annually thereafter, the applicant shall provide assurances to the satisfaction of the Department that sufficient funds are available to cover emergency actions necessary to prevent the unpermitted release of radioactive material to the general environment. See §§ 236.13 and 236.15 (relating to protection of the general population and environment from releases of radioactivity; and protection of individuals during operations). In determining the cost of taking emergency actions, the applicant shall provide to the Department any information requested by the Department related to the management, transportation and disposal of low-level radioactivity waste.

(b) The Department will consider factors that may affect the cost of taking emergency actions. The factors include site and waste characteristics, facility design and operating procedures. Based on consideration of the factors, the Department will determine an amount necessary for compliance with the financial assurance requirements of this section. Its determination will include consideration of costs incurred if an independent contractor were hired to perform the work.

(c) Compliance with the financial assurance requirements of this section does not affect the licensee's duty to take emergency actions or have available funds that may be necessary to enable the licensee to take required emergency actions.

(d) Subject to the approval of the Department, the applicant may use financial assurance, insurance or surety arrangements or a combination of arrangements to meet the financial assurance requirements of this section.

§ 236.604. Assurance for liability during operation.

(a) Prior to accepting waste, the licensee shall have in effect insurance or other financial assurance approved by the Department to compensate persons for bodily injury or property damage from sudden or nonsudden incidents arising from the operation of the facility.

(b) In approving the licensee's insurance or other financial assurance, the Department will consider factors that may affect the licensee's potential exposure to liability. The factors include site and waste characteristics, facility design, operating procedures, population within 3 miles of the facility and industrial, commercial or other economic activity within 3 miles of the site.

(c) In approving the licensee's insurance or other financial assurance the Department will consider the licensee's potential exposure to liability as a result of claims for bodily injury or property damage brought against the licensee; and the licensee's duty to defend and indemnify the Commonwealth, the host munici-

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pality, the host county and their agents and employes against claims, actions, demands, liabilities and losses at law and equity.

(d) Based on consideration of the factors described in subsections (b) and (c), the Department will determine an amount initially sufficient for providing liability coverage in compliance with this section. The amount determined may not be less than the capital cost of bidding for, siting, acquiring, licensing, planning, developing and constructing the facility.

(e) After commencement of operation, the licensee shall annually provide to the Department information the Department deems necessary for its consideration in determining additional amounts of liability coverage necessary to meet the requirements of the act and this chapter. In determining the additional amounts of liability coverage required, the Department will consider the factors identified in subsections (b) and (c).

(f) The determination and approval by the Department of amounts or types of financial assurance under this section does not affect the licensee's liability or the duty of the licensee to have available funds that may be necessary to satisfy the liability.

(g) Subject to the approval of the Department, the licensee may use an insurance, financial or surety arrangement or combination of arrangements to provide the assurances required by this section. The licensee may provide evidence of commercial insurance, alone or in combination with other acceptable financial or surety arrangements, to satisfy the requirements of this section.

(h) Evidence of commercial insurance shall include the insurer's policy, including endorsements thereto, evidencing the liability insurance coverage it intends to issue covering the facility for third party claims for bodily injury and property damage caused by sudden incidents or nonsudden incidents arising from the operation of the facility.

(i) A commercial insurance policy offered to comply with the requirement for compensation of third parties for bodily injury and property damage caused by sudden or nonsudden incidents arising from the operation of the facility shall contain the following provisions:

(1) Bankruptcy or insolvency of the insured does not relieve the insurer of its obligations under the policy.

(2) The insurer is liable for the payment of any amount within a deductible which may apply to the policy, with a right of reimbursement by the insured or, in the alternative, the insurer includes, within the policy, a provision to pay on behalf of the insured a deductible amount.

(3) The beginning and ending dates, including tail periods, for the policy.

(4) The insurer will give at least 90 days notice to the Department and the insured before cancellation, termination or expiration of the policy, if upon expiration, the policy will not be renewed.

(5) The policy may not be cancelled by anyone before the expiration of the 90-day notice period.

(j) The insurance policy shall be issued by a primary insurer or coinsurers licensed or authorized to do business in this Commonwealth or designated by the Insurance Commissioner as an eligible surplus lines insurer. The primary insurer may reinsure the insurance policy with secondary insurers—reinsurers—who are licensed or authorized to do business in Canada, West Germany, Switzerland, France, or a state of the United States.

(k) The primary insurer may be a commercial insurer, a captive insurer—subject to subsection (j)—or a risk retention group as defined in the Product Liability Risk Retention Act of 1981 (15 U.S.C.A. §§ 3901—3906) as amended by the Liability Risk Retention Act of 1986 (15 U.S.C.A. §§ 3901—3903).

(l) The policy shall provide that the insurer will adhere to the insurance law of the Commonwealth regarding settlement of claims and will be bound by the Unfair Insurance Practices Act (40 P. S. §§ 1171.1—1171.15).

(m) The insurance policy shall follow the comprehensive general liability policy forms approved by the Insurance Department and shall include coverage for environmental impairment liability.

§ 236.605. Funding for site closure and decommissioning.

(a) The applicant shall provide assurances prior to the receipt of a license that sufficient funds are available to carry out disposal site closure and decommissioning, including decontamination or dismantlement of structures. The applicant shall also provide assurances regarding closure and stabilization of the disposal site so that following transfer of the disposal site to this Commonwealth, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance and monitoring are required. These assurances shall be based on cost estimates submitted by the applicant and which reflect the Department approved plan for disposal site closure and decommissioning. The applicant's cost estimates shall take into account the total costs that would be incurred if an independent contractor were hired to perform the closure and decommissioning work.

(b) The licensee's financial or surety arrangement shall be submitted as part of the application, and annually thereafter, for review by the Department to assure that sufficient funds will be available for completion of the closure and decommissioning plan.

(c) The amount of the licensee's financial or surety arrangement shall change in accordance with changes in the predicted costs of closure and decommissioning. Factors affecting closure and decommissioning cost estimates include inflation, increases in the amount of disturbed land, changes in engineering plans, closure and stabilization that has already been accomplished, and other conditions affecting costs. The financial or surety arrangement shall be sufficient to cover the costs of closure and decommissioning of the disposal units that are expected to be used before the next 5 year review period.

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(d) The surety arrangement shall be written for a specified period of time, shall name the Department as the obligee and shall be automatically renewable unless the surety notifies the Department, and the principal—the licensee—at least 90 days prior to the renewal date, of its intention not to renew. In this situation, the licensee shall submit a replacement surety within 30 days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Department within 30 days before the cancellation becomes effective, the failure constitutes grounds for forfeiture of the surety.

(e) Surety bonds will only be acceptable if issued by a surety authorized to do business in this Commonwealth. If the principal place of business of a surety is outside of this Commonwealth the surety bond shall be signed by an authorized Commonwealth resident agent of the surety.

(f) Proof of the licensee's failure to replace the surety is not necessary for the Department to exercise its right of default. The right of the Department to declare a default because of the licensee's failure to replace the surety shall be a condition of the obligation.

(g) Financial or surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposit, government securities rated at least BBB by Standard and Poor or Baa by Moody's Investor Services, trust accounts, irrevocable stand-by letters of credit, trust funds and combinations thereof or other types of arrangements that may be approved by the Department. Self-insurance, or an arrangement which essentially constitutes self-insurance, does not satisfy the financial or surety requirements as they apply to private-sector applicants.

(h) The licensee's financial or surety arrangement shall remain in effect until the closure and decommissioning program has been completed and approved by the Department, and the license has been transferred to the Commonwealth Custodial Agency.

§ 236.606. Assurance for long term care.

Prior to the issuance of the license, the applicant shall provide for the approval of the Department, an agreement between the applicant and the Commonwealth that binds the applicant to ensuring that funds will be collected by the applicant and transferred to the Commonwealth for the purpose of covering the costs of monitoring and required remedial action during the long term care period. The Department will review on an annual basis, funds collected by the operator and paid to the Commonwealth to ensure sufficient funds will be available to provide for long term care.

§ 236.607. Assurance for liability following site closure.

(a) Upon receipt of a license the operator shall collect and transfer to the Commonwealth, at least monthly, funds for paying liability claims against the site operator, Commonwealth, host municipality and host county.

(b) The Department will assure that surcharges levied for deposit into the Protection Fund are adequate to establish a fund of at least $100 million indexed to increase with cost of living adjustments, upon the date of termination of the operator's license.

(c) The Protection Fund shall be used to pay liability claims, including personal injury or property damage, as follows:

(1) Against the Commonwealth, host municipality and host county arising from their responsibilities under the act.

(2) Against the regional facility licensee after the termination of the license and which arose from the operation of the regional facility during the term of the license.

(d) The Department will review the Protection Fund annually to ensure sufficient funds will be available to meet the requirements of subsection (a).

Subchapter H. INSPECTIONS, TESTS AND RECORDS

Sec.
236.701. Inspection of the regional disposal facility.
236.702. Inspection of records.
236.703. Penalties.
236.704. Enforcement and abatement.
236.705. Tests of the regional disposal facility.
236.706. Maintenance of records.
236.707. Recording receipt of waste shipments.
236.708. Submittal of reports to the Department.
236.709. Transfer of records.
236.710. Submittal of reports by generators and brokers.

§ 236.701. Inspection of the regional disposal facility.

The licensee shall provide the Department, its agents and employes, and the host municipality and host county inspectors, with immediate access to inspect the following for the purpose of determining compliance with the license conditions and applicable regulations and laws:

(1) Waste not yet disposed.

(2) Premises, equipment, operations and facilities in which wastes are received, possessed, handled, treated, stored or disposed.

§ 236.702. Inspection of records.

The licensee shall make available for inspection to the Department, its agents and employes, and the host municipality and host county inspectors records kept by it under this chapter. Authorized representatives of the Department, the host municipality or host county inspectors may copy and use any record required to be kept under this chapter.

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§ 236.703. Penalties.

(a) A person who violates the act, this chapter or an order promulgated or issued under the act commits a summary offense and will, upon conviction, be sentenced to pay a fine of at least $100 but not more than $1,000 for each offense. Default of the fine payment will result in a prison term of a maximum of 90 days.

(b) A person who violates the act, this chapter, a license condition or an order promulgated or issued under the act, within 2 years of having been convicted of a summary offense under the act, commits a misdemeanor of the third degree and will, upon conviction, be sentenced to pay a fine of at least $1,000 but not more than $25,000 for each offense or a maximum prison term of 1 year, or both.

(c) A person who intentionally violates the act or this chapter, an order, permit condition or license condition of the Department under the act and whose action causes the possibility of a public nuisance or bodily harm to a person commits a felony of the second degree and shall, upon conviction, be sentenced to pay a fine of at least $2,500 but not more than $100,000 for each offense per day for each violation or be subject to a prison term of at least 1 year but not more than 10 years, or both.

(d) Each day of continued violation of the act or this chapter, an order, permit condition or license condition of the Department issued under the act shall constitute a separate offense.

(e) In addition to subsections (a)—(d) or in equity for a violation of the act or this chapter, an order, permit condition or license condition of the Department issued under the act, the Department may assess a civil penalty. The civil penalty will not exceed $25,000 for each violation.

(f) Civil payments shall be paid under section 504(e) of the act (35 P. S. § 7130.504(e)).

§ 236.704. Enforcement and abatement.

(a) A violation of section 505 of the act (35 P. S. § 7130.505) or this chapter, an order, permit condition or license condition of the Department issued under the act constitutes a public nuisance. A person committing the violation shall be liable for the costs of abatement of the nuisance. The Environmental Hearing Board has jurisdiction over actions to recover costs of the abatement and civil penalties.

(b) The Department may issue orders, injunctions, declarations of emergency or take other actions as specified in section 505 of the act to abate a public nuisance or protect public health and safety and the environment.

§ 236.705. Tests of the regional disposal facility.

The licensee shall perform or permit the Department, its agents and employes, and the host municipality and host county inspectors to perform tests it deems appropriate or necessary for the administration of this chapter, including, but not limited to, tests of:

(1) Waste.

(2) Facilities used for the receipt, storage, treatment, handling or disposal of waste.

(3) Radiation detection and monitoring instruments.

(4) Other equipment and devices used in connection with the receipt, possession, handling, treatment, storage or disposal of waste.

§ 236.706. Maintenance of records.

(a) The licensee shall maintain records and make reports in connection with the licensed activities as may be required by the conditions of the license or by this chapter and orders of the Department.

(b) Records which are required by this chapter or by license conditions shall be maintained for a period specified by this chapter or by license condition. If a retention period is not otherwise specified, the records shall be maintained and transferred to the officials specified in § 236.709 (relating to transfer of records) as a condition of license transfer unless the Department otherwise authorizes their disposition.

(c) Records which shall be maintained under this subchapter may be the original or a reproduced copy of microfilm if the reproduced copy of microfilm is capable of producing a copy that is clear and legible at the end of the required retention period.

Cross References

This section cited in 25 Pa. Code § 236.709 (relating to transfer of records).

§ 236.707. Recording receipt of waste shipments.

Following receipt and acceptance of a shipment of waste, the licensee shall record the date of disposal of the waste, the location in the disposal unit, the condition of the waste packages as received, discrepancies between materials listed on the manifest and those received and evidence of leaking or damaged packages or radiation or contamination levels in excess of limits specified by United States Department of Transportation and this title. The licensee shall briefly describe repackaging operations of the waste packages included in the shipment, plus other information required by the Department as a license condition.

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§ 236.708. Submittal of reports to the Department.

(a) *Annual reports.* The licensed disposal facility operator shall file a copy of its financial report or a certified financial statement annually with the Department in order to update the information base for determining financial qualifications.

(b) *Quarterly reports.*

(1) The licensed disposal facility operator shall submit its quarterly report to the Department, host municipality, host county, Low-Level Waste Advisory Committee and the public. The report shall include:

(i) Specification of the quantity of principal contaminants released to unrestricted areas in liquid and in airborne effluents during the preceding quarter.

(ii) The results of the monitoring program.

(iii) A summary of licensee disposal unit survey and maintenance activities.

(iv) A summary, by waste class, of activities and quantities of radionuclides disposed of.

(v) Instances in which observed site characteristics were significantly different from those described in the application for a license.

(vi) Other information the Department may require.

(2) If the quantities of waste released during the reporting period, monitoring results or maintenance performed are significantly different from those predicted, the report shall cover this specifically.

§ 236.709. Transfer of records.

Notwithstanding § 236.706 (relating to maintenance of records), copies of records of the location and the quantity of wastes contained at the disposal site shall be provided, upon license transfer to the Commonwealth Custodial Agency, to:

(1) The chief executive of the host municipality.

(2) The chief executive of the host county.

(3) The host county zoning board or land development and planning agency.

(4) The Governor.

(5) Other State, local and Federal government agencies as designated by the Department at the time of license transfer.

Cross References

This section cited in 25 Pa. Code § 236.706 (relating to maintenance of records).

§ 236.710. Submittal of reports by generators and brokers.

Generators and brokers shall submit, on a quarterly basis, reports to the Department. The reports shall include a listing of the quantities, types and classes of low-level radioactive waste generated during the previous quarter.

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CHAPTER 237. REBUTTABLE PRESUMPTION OF LIABILITY OF THE OPERATOR OF THE REGIONAL LOW-LEVEL WASTE FACILITY

Subch.		Sec.
A.	GENERAL PROVISIONS	237.1
B.	LIABILITY OF THE OPERATOR	237.101

Authority

The provisions of this Chapter 237 issued under the Low-Level Radioactive Waste Disposal Regional Facility Act (35 P. S. §§ 7130.101—7130.703); the Radiation Protection Act (35 P. S. §§ 7110.101—7110.504); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 237 adopted October 15, 1993, effective October 16, 1993, 23 Pa.B. 4885, unless otherwise noted.

Subchapter A. GENERAL PROVISIONS

Sec.
237.1. Scope.
237.2. Definitions.

GENERAL

§ 237.1. Scope.

(a) This chapter addresses the rebuttable presumption of liability of the operator of a regional low-level radioactive waste disposal facility for all damages and radioactive contamination within 3 miles of the regional facility boundary. This chapter establishes terms, conditions and criteria for the implementation of section 319 of the act (35 P. S. § 7130.319).

(b) The presumption of liability of the regional facility operator applies only to civil and administrative proceedings initiated under the act to the extent the actions provide for recovery for damages, the abatement of radioactive contamination or the replacement of a contaminated water supply. The presumption of liability may be invoked by the Department, county and municipal officials and by private citizens instituting the legal actions under the act.

(c) The regional facility operator may not engage in an activity, operation or process prohibited by the act.

§ 237.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Act—The Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

Contributes to the damage—A causal connection between the damage to a person or property and regional facility operations.

Damages—A pecuniary compensation or indemnity which may be recovered under the act in a court of competent jurisdiction by a person who has actually sustained a loss, detriment or injury, whether to one's person or property, real or personal, associated with exposure to radioactive material.

Operator—A person who operates a regional facility.

Person—An individual, corporation, partnership, association, public or private institution, cooperative enterprise, municipal authority, public utility, trust, estate, group, Federal Government or agency, State institution or agency or another legal entity which is recognized by law as the subject of rights and duties. The term also includes officers and directors of a corporation or another legal entity having officers and directors.

Preoperational survey—The results of sampling, monitoring and data analysis to assess the presence of radioactive material in air, soil, surface water, groundwater, drinking water supply, buildings or other structures, performed by the operator-licensee designate prior to the acceptance of waste at the regional facility. The term also includes other appropriate measures performed by the operator of the regional facility to assess environmental radiation, birth defects, cancer and other disease rates within 5 miles of the regional facility prior to the acceptance of waste.

Radioactive contamination—The deposition of radioactive material into the air, soil, surface water, groundwater, drinking water supply, equipment, buildings or other structures, or on a person in concentrations or mixtures, or both, that exceed background radiation measurements established during preoperational environmental or health surveys.

Radioactive material—A material which spontaneously emits alpha, beta or gamma radiation, X-rays, neutrons, protons, high energy electrons or other atomic particles.

Rebuttable presumption—A presumption that can be overcome upon an affirmative showing of clear and convincing evidence.

Regional facility—A facility which has been approved by the Appalachian States Low-Level Radioactive Waste Commission and licensed under the act. The term includes "disposal facility" and "facility site" as defined in § 236.2 (relating to definitions).

Regional facility boundary—The outer limits of the licensed disposal site established by land survey.

Regional facility operations—Activities, operations or processes conducted within the regional facility boundary which are attributable to the receipt, handling, management, storage or disposal of low-level radioactive waste.

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Subchapter B. LIABILITY OF THE OPERATOR

Sec.
237.101. Presumption of liability.
237.102. Defenses to overcome the presumption.

§ 237.101. Presumption of liability.

It is a rebuttable presumption of law that the regional facility operator is liable and responsible for all damages and radioactive contamination within 3 miles of the regional facility boundary without proof of fault, negligence or causation.

§ 237.102. Defenses to overcome the presumption.

(a) *Damages.* To rebut the presumption of liability for damages, the regional facility operator shall affirmatively prove, by clear and convincing evidence, that the operator did not contribute to the damage.

(b) *Radioactive contamination.* To rebut the presumption of liability for radioactive contamination within 3 miles of the boundary of the regional facility, the regional facility operator shall prove, by clear and convincing evidence, one of the following three defenses:

(1) The radioactive contamination existed prior to disposal operations on the site of the regional facility as determined by a preoperational survey.

(2) The landowner has refused to allow the regional facility operator access to the landowner's property to conduct a preoperational survey.

(3) The radioactive contamination occurred as a result of some cause other than regional facility operations.

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CHAPTER 240. RADON CERTIFICATION

Subchap.		Sec.
A.	GENERAL PROVISIONS	240.1
B.	CERTIFICATION	240.101
C.	CERTIFICATION REVIEW PROCEDURES AND STANDARDS	240.201
D.	OPERATION REQUIREMENTS	240.301
E.	ENFORCEMENT AND DECERTIFICATION	240.401
F.	INTERIM CERTIFICATION	240.501

Authority

The provisions of this Chapter 240 issued under sections 12 and 13 of the Radon Certification Act (63 P. S. §§ 2012 and 2013); section 302 of the Radiation Protection Act (35 P. S. § 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 240 adopted January 18, 1991, effective January 19, 1991, 21 Pa.B. 317, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications).

Subchapter A. GENERAL PROVISIONS

GENERAL

Sec.
240.1. Description of regulatory structure.
240.2. Scope.
240.3. Definitions.

GENERAL

§ 240.1. Description of regulatory structure.

(a) The act directs the Department to establish a Radon Certification Program. This chapter specifies the requirements to certify a person to test for and mitigate radon contamination of occupied buildings and to analyze radon samples. Persons exempt from certification are specified in § 240.2 (relating to scope).

(b) Subchapter B (relating to certification) specifies the requirement that a person shall be certified to conduct radon testing, and the requirements for obtaining certification. Subchapter B also contains the requirements for certification in mitigation and laboratory analysis.

(c) Subchapter C (relating to certification review procedures and standards) provides the standards and procedures for review of applications, renewal and modification of certification.

(d) Subchapter D (relating to operation requirements) contains operation requirements for certified persons who conduct radon-related activities. Subchap-

ter D includes the requirements concerning advertising, notice to clients and disclosure of radon information to the Department. These operation requirements are in addition to specific requirements contained in a certification.

(e) Subchapter E (relating to enforcement and decertification) contains the enforcement provisions, including inspection, decertification and assessment of civil penalties. Other enforcement actions are available under sections 308 and 309 of the Radiation Protection Act (35 P. S. §§ 7110.308 and 7110.309) and section 14 of the act (63 P. S. § 2014).

(f) Subchapter F (relating to interim certification) specifies the requirements for persons certified under the Department's Interim Certification Program.

(g) This section is for descriptive purposes only. This section does not limit the authority of the Department under the acts or this chapter.

§ 240.2. Scope.

(a) This chapter applies to all persons except a person:

(1) Testing for or mitigating against radon contamination in a building that the person owns or occupies.

(2) Using measures designed to prevent radon contamination in newly constructed buildings. This exemption does not apply to radon testing or installation of radon mitigating devices in these buildings following occupancy.

(3) Performing testing or mitigation in the course of the person's normal duties as an employee or contractor of the Department or the Federal government.

(4) Performing scientific research if the person discloses the information obtained to the Department under § 240.303 (relating to reporting of information) and the person informs the owner or occupant of the affected building of the following:

(i) That the person is not certified by the Department to test for or mitigate against radon contamination.

(ii) That the test results are not certified.

(iii) That the mitigation methods are for experimental purposes and may be unsuccessful.

(5) Purveying, but not placing, or retrieving passive radon testing devices, such as charcoal canisters or track etch monitors supplied by a certified laboratory, if radon concentrations determined by the laboratory are reported directly to the owner or occupier of the building tested.

(b) This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

Authority

The provisions of this § 240.2 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

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Source

The provisions of this § 240.2 amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceeding text appears at serial pages (204016).

Cross References

This section cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.3. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

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Act—The Radon Certification Act (63 P. S. §§ 2001—2014).

Acts—The Radon Certification Act and the Radiation Protection Act (35 P. S. §§ 7110.101—7110.703).

Firm—A person, other than an individual.

Laboratory analysis—The act of determining radon concentrations in air, water, soil or passive radon testing devices.

Mitigate—To repair or alter a building or building design for the purpose in whole or in part of reducing the concentration of radon in the indoor atmosphere.

Person—An individual, corporation, partnership, association, trust, estate, public or private institution, group, agency or political subdivision of this Commonwealth, another state or political subdivision or agency thereof, and a legal successor, representative, agency or agency of the entities listed in this definition.

Picocurie per liter—2.2 disintegrations per minute of radioactive material per liter of air.

Radon—The radioactive noble gas Radon-222 and the short-lived radionuclides which are products of Radon-222 decay, including polonium-218, lead-214, bismuth-214 and polonium-214.

Test—The act of examining a building, soil, air or water for the presence of radon, including taking air, soil or water samples, or the act of diagnosing the cause of radon contamination in a building.

WL—working level—One working level is that amount of potential alpha-particle energy dissipated in air by the short-lived daughters in equilibrium with 100 pCi/1 of Radon-222. One WL is equal to 130,000 Mev of alpha-particle energy deposited per liter of air.

Subchapter B. CERTIFICATION

CERTIFICATION FOR RADON TESTING

Sec.
240.101. Requirement for radon testing certification.
240.102. Prerequisites for radon testing certification.
240.103. Radon testing application contents.
240.104. Application filing deadline.

CERTIFICATION FOR RADON MITIGATION

240.111. Requirement for radon mitigation certification.
240.112. Prerequisites for radon mitigation certification.
240.113. Radon mitigation application contents.

240.114. Application filing deadline.

CERTIFICATION FOR RADON LABORATORY

240.121. Requirement for radon laboratory certification.
240.122. Prerequisites for radon laboratory certification.
240.123. Radon laboratory application contents.
240.124. Application filing deadline.

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

240.131. States with reciprocal agreements with the Commonwealth.
240.132. Limited radon practice in this Commonwealth.
240.133. Certification application contents.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

CERTIFICATION FOR RADON TESTING

§ 240.101. Requirement for radon testing certification.

A person may not test for radon or represent or advertise that he may so test in a building or building lot in this Commonwealth, unless the person has first applied for and obtained certification to test. For a firm to perform radon testing it shall employ at least one person certified to test, and the firm shall submit an application for certification. Not everyone within the firm is required to be certified to test. An individual performing testing and not working for a certified radon testing firm shall obtain radon testing certification prior to performing testing. A person using passive radon monitors, such as charcoal canisters, from a certified radon laboratory does not also have to become certified in radon laboratory analysis.

§ 240.102. Prerequisites for radon testing certification.

(a) *Individual certification for radon testing.* An individual will not be certified to test unless the individual has done the following:

(1) Taken a Department-approved course on radon.

(2) Taken and passed a Department-approved written exam on radon testing. The applicant shall forward an official copy of exam results to the Department.

(3) Had 1 year of professional experience in performing radon measurements.

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(4) Submitted a complete and accurate application to the Department, including applicable fees.

(b) *Firm certification for radon testing.* If the applicant for testing certification is a firm, it shall employ at least one individual who is certified to test and who is in responsible charge of the firm's testing activities. If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.

(c) *Additional requirements.* If the applicant for testing certification is a firm, or an individual performing testing and not working for a certified radon testing firm, the applicant shall also have a quality assurance program, a health and safety program and a continuing education program as required in §§ 240.304—240.307. In addition, the applicant shall be successfully enrolled in the EPA radon measurement proficiency program or equivalent, as required in §§ 240.304—240.307.

Cross References

This section cited in 25 Pa. Code § 240.103 (relating to radon testing application contents).

§ 240.103. Radon testing application contents.

An application for radon testing certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and shall contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.102 (relating to prerequisites for radon testing certification), including the services offered and experience in each. If the applicant is a firm, the application shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of $200 for individuals, $500 for firms.

(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Copies of reporting forms, information distributed to potential clients and recent advertisements.

(6) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon testing.

(7) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief, attested by a notary public or district justice.

§ 240.104. Application filing deadline.

A person who expects to conduct radon testing shall file a complete application for certification a minimum of 30 days prior to the anticipated starting date of testing activity.

CERTIFICATION FOR RADON MITIGATION

§ 240.111. Requirement for radon mitigation certification.

A person may not mitigate radon contamination in a building or represent or advertise that he may so mitigate in a building or building lot in this Commonwealth, unless the person has first applied for and obtained certification to mitigate. For a firm to perform radon mitigation it shall employ at least one person certified to mitigate, and the firm shall submit an application for certification. Not everyone within the firm is required to be certified to mitigate. An individual performing mitigation and not working for a certified radon mitigation firm shall obtain radon mitigation certification prior to performing mitigation of radon contamination.

§ 240.112. Prerequisites for radon mitigation certification.

(a) *Individual certification for radon mitigation.* An individual will not be certified to mitigate unless he has done the following:

(1) Taken a Department-approved course on radon mitigation.

(2) Taken and passed a Department-approved written exam on radon mitigation. The applicant shall forward an official copy of exam results to the Department.

(3) Had 1 year professional experience or supervised experience in radon mitigation system installation or 3 years experience in architecture, engineering, electrical contracting, plumbing, carpentry, masonry or related trades.

(4) Submitted a complete and accurate application to the Department including applicable fees.

(b) *Firm certification for radon mitigation.* If the applicant for mitigation certification is a firm, it shall employ at least one individual who is certified to mitigate and who is in responsible charge of the firm's mitigation activities. If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.

(c) *Additional requirements.* If the applicant for mitigation certification is a firm, or an individual performing mitigation and not working for a certified miti-

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gation firm, he shall also have a health and safety program, and a continuing education program, as required in §§ 240.305 and 240.306 (relating to health and safety program; and continuing education program).

Cross References

This section cited in 25 Pa. Code § 240.113 (relating to radon mitigation application contents).

§ 240.113. Radon mitigation application contents.

An application for mitigation certification, by both individual and firm, shall be submitted to the Department in writing on forms provided by the Department and shall contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.112 (relating to prerequisites for radon mitigation certification), including the services offered and experience in each. If the applicant is a firm, the applicant shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of $200 for individuals, $500 for firms.

(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to radon mitigation.

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief, attested by a notary public or district justice.

§ 240.114. Application filing deadline.

A person who anticipates conducting radon mitigation services shall file a complete application for certification a minimum of 30 days prior to the anticipated starting date of mitigation activities.

CERTIFICATION FOR RADON LABORATORY

§ 240.121. Requirement for radon laboratory certification.

A person may not perform laboratory analysis or represent or advertise that he may perform laboratory analysis of radon testing devices supplied to the public

or of samples or devices received from the public or from other certified persons, unless that person has obtained radon laboratory analysis certification from the Department.

§ 240.122. Prerequisites for radon laboratory certification.

(a) *Individual certification for laboratory analysis.* A person will not be certified to perform radon laboratory analysis unless the person has done the following:

(1) Taken a Department-approved course on radon.

(2) Had 1 year professional experience in performing laboratory analysis of radon measurement devices or samples or is certified in Health Physics by the American Board of Health Physics.

(3) Received a bachelors degree in the physical sciences or engineering or related fields as approved by the Department, or the education or professional work experience equivalent to a degree, as determined by the Department.

(4) Submitted a complete and accurate application to the Department, including applicable fees.

(b) *Firm certification for laboratory analysis.* If the applicant for radon laboratory certification is a firm, it shall employ at least one individual who is certified to perform radon laboratory analysis and who is in responsible charge of the laboratory radon analytical activities. If the firm loses its certified individual, the certification automatically lapses and is void until the firm has notified the Department of employment of another certified individual. Within 5 days the firm shall notify the Department in writing when it loses its certified individual.

(c) *Additional requirements.* If the applicant for radon laboratory certification is a firm, or an individual performing laboratory analysis and not working for a certified laboratory, the applicant shall also have a quality assurance program and a continuing education program as required in §§ 240.304—240.307. In addition, the applicant shall be successfully enrolled in the EPA radon measurement proficiency program or equivalent, as required in §§ 240.304—240.307.

Cross References

This section cited in 25 Pa. Code § 240.123 (relating to radon laboratory application contents).

§ 240.123. Radon laboratory application contents.

An application for radon laboratory certification shall be submitted to the Department in writing on forms provided by the Department and shall contain:

(1) Evidence that the applicant has the certification prerequisites contained in § 240.122 (relating to prerequisites for radon laboratory certification), including the services offered and experience in each. If the applicant is a firm, the applicant shall also include the duties assigned to the certified individual.

(2) A nonrefundable fee of $250 for individuals, $500 for firms.

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(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholder, parent corporation and certified person within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications or technical or administrative information related to laboratory analysis of radon samples.

(6) A verification by a responsible official of the applicant that the information contained in the application is correct to the best of the official's information and belief, attested by a notary public or district justice.

§ 240.124. Application filing deadline.

A person who anticipates performing laboratory analysis of samples to determine radon concentrations shall file a complete application for laboratory analysis certification a minimum of 30 days prior to the anticipated starting date of laboratory analysis.

CERTIFICATION FOR PERSONS CERTIFIED IN ANOTHER STATE

§ 240.131. States with reciprocal agreements with the Commonwealth.

The Department may enter into a reciprocal agreement with another state recognizing each state's radon certification program. The Department will not recognize another state's program unless the program's certification is compatible with the one established under the act and this chapter. The Department will publish a notice in the *Pennsylvania Bulletin* listing the state programs it has recognized.

§ 240.132. Limited radon practice in this Commonwealth.

A person may test, mitigate or perform laboratory analysis without first obtaining certification from the Department if the person does the following:

(1) The person has obtained certification to do so from a state with which the Department has entered into a reciprocal agreement.

(2) The person conducts that activity in this Commonwealth less than 90 days each calendar year.

§ 240.133. Certification application contents.

A person who has a certification from a state with which the Department has entered into a reciprocal agreement, and who intends to conduct the radon-related activity in this Commonwealth for at least 90 days a year, shall obtain certification from the Department. The application shall be in writing and contain:

(1) A copy of the certification from the foreign state.

(2) A nonrefundable fee of $200.

(3) The applicant's name, address and telephone number. It shall also indicate if the applicant is an individual, partnership, limited partnership, corporation or other entity. The application shall include, when appropriate, the name and address of every officer, general and limited partner, director, principal shareholders, parent corporations and certified persons within the applicant's organization.

(4) Compliance information, including descriptions of notices of violation, administrative orders, civil penalty assessments and actions for violations of the act, this chapter or a term or condition of a certification.

(5) Other information the Department may require related to an applicant's qualifications, or technical or administrative information related to radon testing, mitigation of radon contamination or laboratory analysis of radon samples.

(6) A verification by a responsible official of the applicant that the information contained in the application is true and correct to the best of the official's information and belief, attested by a notary public or district justice.

Subchapter C. CERTIFICATION REVIEW PROCEDURES AND STANDARDS

Sec.
240.201. Criteria for certification issuance or denial.
240.202. Terms of certification.
240.203. Conditions of certification.
240.204. Certification renewal.
240.205. Certification modification.
240.206. Notice of certification.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.201. Criteria for certification issuance or denial.

(a) A certification application will not be approved unless the applicant affirmatively demonstrates to the Department's satisfaction that the following conditions are met:

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(1) Neither the applicant nor a person identified in the application is in violation of the act or this chapter or has been decertified under § 240.403 (relating to decertification).

(2) The application is accurate and complete and the applicant is in compliance with the requirements of the act and this chapter.

(3) The applicant has the qualifications required in this chapter and is capable of performing the activities for which he is seeking certification as required by the act and this chapter.

(b) The Department may deny certification to a person who has shown a lack of ability or intention to comply with the acts or this chapter, as indicated by past or continuous conduct. A certification lapse under § 240.203(b) (relating to conditions of certification) may be considered evidence of a lack of ability or intention to comply with the acts or this chapter.

Cross References

This section cited in 25 Pa. Code § 240.204 (relating to certification renewal).

§ 240.202. Terms of certification.

(a) A certification will be valid for 2 years following issuance.

(b) Testing, mitigating or other radon-related activity may not be conducted after the expiration of the term of certification.

§ 240.203. Conditions of certification.

(a) Persons certified under this chapter shall, at a minimum, comply with the following conditions:

(1) The certified person shall conduct his activities as described in the approved application.

(2) The certified person shall allow the Department, its agents and employes, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to the person's facilities, offices and files for inspection and examination of records. The certified person shall also allow the Department, its agents and employes to accompany him while performing radon-related activities for the purpose of inspection of those activities.

(3) The certified person shall remain in compliance with the acts and this chapter.

(4) For certification of a firm, the certified person shall continue to direct the radon-related activities. The certified person shall have his duties listed in the firm's certification application.

(b) The Department may suspend certification if a condition of certification is violated. The Department will publish notice of the suspension in the *Pennsylvania Bulletin.*

Cross References

This section cited in 25 Pa. Code § 240.201 (relating to criteria for certification issuance or denial).

§ 240.204. Certification renewal.

An application for certification renewal shall contain the contents required in an initial certification application, except that the Department may permit an applicant to rely on information previously submitted if the information remains the same. A certification renewal application shall be issued or denied according to the criteria in § 240.201 (relating to criteria for certification issuance or denial).

§ 240.205. Certification modification.

The terms and conditions of a certification are subject to amendment, revision or modification for a violation of the acts, this chapter or a term or condition of the certification, or for a false statement made to the Department by the certified party, or for a change of condition which would warrant the issuance or denial of a certification on the basis of an original application.

§ 240.206. Notice of certification.

The Department will publish as a notice in the *Pennsylvania Bulletin* the name and address of each person certified under this chapter.

Subchapter D. OPERATION REQUIREMENTS

Sec.
240.301. Advertising.
240.302. Notice to clients.
240.303. Reporting of information.
240.304. Quality assurance program.
240.305. Health and safety program.
240.306. Continuing education program.
240.307. EPA Radon Measurement Proficiency Program.
240.308. Testing and mitigation protocols.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.301. Advertising.

A person may not advertise a radon-related service or product with false or misleading statements regarding the offered service or product, or the risks to health or property value. A person required to obtain certification may not advertise a service or product, unless the person has previously obtained a valid certification from the Department to perform that service or provide that product.

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§ 240.302. Notice to clients.

(a) A person may not test, mitigate against radon or provide a radon-related service or product without first offering the potential client a price list of services offered, and providing evidence of certification and a notice that only persons certified under the act and this chapter may provide the services or products. For a person who mitigates against radon, a written estimate for services shall constitute a price list. The notice shall read substantially as follows:

NOTICE

The Radon Certification Act requires that anyone who provides any radon-related service or product to the general public must be certified by the Pennsylvania Department of Environmental Protection. You are entitled to evidence of certification from any person who provides such services or products. You are also entitled to a price list for services or products offered. All radon measurement data will be sent to the Department as required in the Act and will be kept confidential. If you have any questions, comments or complaints concerning persons who provide radon-related services, please contact the Department at the Bureau of Radiation Protection, Department of Environmental Protection, P. O. Box 8469, Harrisburg, Pa. 17105-8469, (717) 783-3594.

(b) For a person performing mitigation, warranty information and information on the proper method of checking and servicing of mitigation equipment to maintain its function shall be provided in writing to the client.

§ 240.303. Reporting of information.

(a) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing the service shall submit to the Department in a format approved by the Department the results of testing, including screening measurements, follow-up measurements, premitigation measurements, postmitigation measurements and the method used to mitigate against radon contamination. At a minimum, these results will be retained for 2 years. The information shall include:

(1) The name of the person providing the service.

(2) The name and address of the owner or occupant of the building involved.

(3) The address and location of the building involved, including street and number, post office, full zip code and county.

(4) The date each measurement was taken, or the mitigation performed.

(5) The type of house or building, the types of measurements, location within the building of specific measurements, and the results in picocuries per liter or in working levels.

(6) The type and price of mitigation system installed.

(b) Within 45 days after testing, mitigation or other radon-related service is provided, the person providing radon-related services shall report in writing to the owner or occupier of the building the results in picocuries per liter and when appropriate in working levels of radon measurements taken in the building. If a person provides the service through a certified intermediary, it is the responsibility of the intermediary to report the results.

(c) For a person performing mitigation, each building shall be tested for radon levels before and after the mitigation is performed. Each test shall be at least 24 hours in duration and follow EPA- or DEP-approved protocols. The postmitigation test shall be conducted no sooner than 48 hours after completion of the mitigation. The results of radon testing shall be reported in accordance with this section.

Cross References

This section cited in 25 Pa. Code § 240.2 (relating to scope).

§ 240.304. Quality assurance program.

A person conducting radon testing or radon laboratory analysis activities shall have a quality assurance program to assure that measurements are accurate and errors are controlled. The program shall insure that testing devices are routinely and properly calibrated. The program shall provide the information related to the following activities:

(1) Organization and responsibilities.
(2) Sampling procedures.
(3) Detector custody.
(4) Analytical procedures.
(5) Data reduction, validation and reporting.
(6) Corrective action.
(7) Quality assurance reports to management.

Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.305. Health and safety program.

A person conducting radon-related activities shall have a radon health and safety program to protect himself and employes from exposure to radon during the course of their employment. The program shall include records of each individual's exposure to radon. Persons conducting radon-related activities shall maintain exposure to radon as low as reasonably achievable.

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Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.112 (relating to prerequisites for radon mitigation certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.306. Continuing education program.

A person conducting radon-related activities shall have a radon education program to assure that the applicant and all employes have a minimum of 4 hours initial training, and the certified person shall participate in a continuing education program consisting of a minimum of 8 hours of Department-approved courses or seminars on radon testing or mitigation each year.

Source

The provisions of this § 240.306 amended March 30, 2001, effective March 31, 2001, 31 Pa.B. 1742. Immediately preceding text appears at serial page (204029).

Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.112 (relating to prerequisites for radon mitigation certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.307. EPA Radon Measurement Proficiency Program.

A person conducting radon testing or radon laboratory activities shall provide written evidence of successful participation in the most recent EPA Radon/Radon Progeny Measurement Proficiency Program or an alternative program approved by the Department for each radon measurement utilized.

Cross References

This section cited in 25 Pa. Code § 240.102 (relating to prerequisites for radon testing certification); 25 Pa. Code § 240.122 (relating to prerequisites for radon laboratory certification).

§ 240.308. Testing and mitigation protocols.

A person conducting radon testing or mitigation for radon contamination shall conduct the testing and mitigation in accordance with EPA- or DEP-approved protocols and shall comply with applicable statutes, regulations, ordinances and building codes. The following protocols, "Interim Protocols for Screening and Follow-up Radon and Radon Decay Product Measurements," "Indoor Radon and Radon Decay Product Measurement Protocols" and "Guidelines for Radon Mitigation of Residential Dwellings" are available upon request from the following sources:

Environmental Protection Agency
Office of Radiation Programs
Washington, D.C. 20460

Department of Environmental Protection
Bureau of Radiation Protection
Rachel Carson State Office Building, 13th Floor
400 Market Street
Post Office Box 8469
Harrisburg, Pennsylvania 17105-8469

Subchapter E. ENFORCEMENT AND DECERTIFICATION

Sec.
240.401. Inspection.
240.402. Civil penalties.
240.403. Decertification.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.401. Inspection.

(a) The Department and its agents and employes will:

(1) At all reasonable times, have access to, and require the production of, books and papers, documents and physical evidence pertinent to a matter under investigation related to radon testing, mitigation of radon contamination or radon laboratory analysis.

(2) At all reasonable times, enter a building, property, premises or place of a person who conducts radon-related activities for the purpose of making an investigation or inspection necessary to ascertain the compliance or noncompliance with the act and this chapter.

(b) The Department, its agents and employes may conduct inspections of a building, property, premises or place of business of a person who conducts radon-related activities if a person presents information to the Department or the Department has access to information which gives it reason to believe that one of the following exists:

(1) A person may have violated the act or this chapter.

(2) A person is not in compliance with the terms or conditions of the person's certification.

(3) A condition or practice exists which may pose a threat to public health, safety, welfare or the environment.

(c) An agent or employe of the Department may not enter a private residence for the purpose of conducting an inspection under this section without a search warrant or without the consent of the occupant.

(d) Inspections made under this section are subject to Chapter 220 (relating to notices, instructions and reports to workers; inspections and investigations).

§ 240.402. Civil penalties.

(a) The Department may assess a civil penalty for a violation of the acts or this chapter.

(b) A civil penalty may be assessed or increased, based upon:

(1) The seriousness of the violation.

(2) The monetary loss of an owner or occupier, including the cost to the owner or occupier to remedy the violation.

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(3) The risks to health and safety.

(4) The cost to the Commonwealth in administration, inspection and enforcement, to remedy the violation.

(5) The costs avoided by the violator by the violation.

(6) The culpability of the violator.

(7) The frequency of the violation.

(c) Each day of a continuing violation is considered a separate violation for purposes of this chapter.

§ 240.403. Decertification.

(a) The Department may decertify a person who has violated the acts, this chapter or a term or condition of certification.

(b) The Department may hold a public hearing or informal conference prior to decertifying a person.

(c) The Department will publish in the *Pennsylvania Bulletin* a notice of decertification.

Cross References

This section cited in 25 Pa. Code § 240.201 (relating to criteria for certification issuance or denial).

Subchapter F. INTERIM CERTIFICATION

Sec.
240.501. Scope.
240.502. Reapplication when this chapter is adopted as final.

Cross References

This subchapter cited in 25 Pa. Code § 240.1 (relating to description of regulatory structure).

§ 240.501. Scope.

This subchapter applies to persons certified in accordance with the Department's interim certification program as required under section 11 of the act (63 P. S. § 2011).

§ 240.502. Reapplication when this chapter is adopted as final.

A person granted interim certification by the Department shall reapply for certification under this chapter. If a person fails to apply for certification within 60 days of Departmental notification, the interim certification automatically lapses and is void.

[Next page is 241-1.]

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Regulations 17 May 2005

http://www.pacode.com/secure/data/025/articleIDV_toc.html

There is no, and never has been a chapter 234, 238, or 239. These are available for use when necessary.

Rachel Carson State Office Building
P.O. Box 8469
Harrisburg, PA 17105-8469

[date become agreement state]

Bureau of Radiation Protection 717-787-4937

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION

CERTIFIED MAIL

In the Matter of	:	
	:	
Licensees Authorized to	:	Order Modifying Licenses
Possess Radioactive Material	:	to Impose Increased Controls
Quantities of Concern	:	

ORDER

The Commonwealth of Pennsylvania, Department of Environmental Protection (Department), has found and determined as follows:

I

1. The Licensees identified in Attachment A to this Order previously held licenses issued in accordance with the Atomic Energy Act of 1954, 42 U.S.C. § 2011 *et seq.* (AEA), by the U.S. Nuclear Regulatory Commission (NRC) authorizing them to possess certain quantities of radioactive material of concern.

2. The Licensees were previously subject, *inter alia*, to NRC regulations set forth in 10 CFR Pt. 20. NRC regulations at 10 CFR § 20.1801 require Licensees to secure, from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. NRC regulations at 10 CFR § 20.1802 require Licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

3. On November 14, 2005, NRC issued an Order Imposing Increased Controls to the Licensees identified in Attachment A to this Order (the NRC Order). The NRC Order took effect immediately and was published in the Federal Register on December 1, 2005. *See* 70 FR 72128 (Dec. 1, 2005). As a result of an NRC staff confirmatory review of licensees potentially subject to the NRC Order, the NRC staff issued the NRC Order to an additional 635 NRC licensees that met the criteria for receiving the NRC Order but were not included in the November 14, 2005 mailing.

4. The NRC explained its action in the NRC Order, in part, as follows:

> Prior to the terrorist attacks of September 11, 2001 (9/11), several national and international efforts were underway to address the potentially significant health and safety hazards posed by uncontrolled sources. These efforts recognized the need for increased control of high-risk radioactive materials to prevent inadvertent and intentional unauthorized access, primarily due to the potential health and safety hazards posed by the uncontrolled material. Following 9/11, it was recognized that these efforts should also include a heightened awareness and focus on the need to prevent intentional unauthorized access due to potential malicious acts. These efforts . . . seek to increase the control over sources to prevent unintended radiation exposure and to prevent malicious acts.
>
> A licensee's loss of control of high-risk radioactive sources, whether it be inadvertent or through a deliberate act, has a potential to result in significant adverse health impacts and could reasonably constitute a threat to the public health and safety. In this regard, the Commission has determined that certain additional controls are required to be implemented by Licensees to supplement existing regulatory requirements in 10 CFR § 20.1801 and 10 CFR § 20.1802, in order to ensure adequate protection of, and minimize danger to, the public health and safety. Therefore, the Commission is imposing the requirements set forth in Attachment B on radioactive materials licensees who possess, or have near term plans to possess, radionuclides of concern at or above threshold limits, identified in Table 1. These requirements . . . will provide the Commission with reasonable assurance that the public health and safety continues to be adequately protected.

70 FR 72128-29.

5. The NRC recognized that Licensees may already have initiated many controls set forth in Attachment B to the NRC Order in response to previously issued advisories or on their own. It was also recognized that some controls may not be possible or necessary at some sites, or may need to be tailored to accommodate the Licensees' specific circumstances to achieve the intended objectives and avoid any unforeseen adverse effect on the safe use and storage of the sealed sources. The NRC stated further that although the additional controls implemented by the Licensees in response to Safeguards and Threat Advisories have been adequate to provide reasonable assurance of adequate protection of public health and safety, the NRC concluded that additional controls must be imposed by an Order, consistent with the established regulatory framework. 70 FR at 72129.

6. Accordingly, to provide assurance that the Licensees are implementing prudent measures to achieve a consistent level of control, the NRC ordered that all Licensees who hold licenses issued by the NRC authorizing possession of radioactive material quantities of concern as listed in Attachment B, Table 1 must implement the requirements identified in Attachment B to the NRC Order. Compliance with these requirements was required by May 13, 2006 for those licensees who received the November 14, 2005 mailing of the NRC Order, by June 2, 2006 for those licensee who received the December 22, 2005 mailing of the NRC Order, or by the first day that radionuclides of concern are possessed at or above threshold limits. Because of the

potentially significant adverse health impacts associated with failure to control high risk radioactive sources, the NRC found that the public health, safety, and interest required that the NRC Order be effective immediately, and that the requirements imposed by the NRC remain in effect until the NRC modifies its regulations to reflect increased controls. 70 FR at 72129.

7. The NRC Order stated that, to effect nationwide implementation, the measures imposed by the NRC Order have been determined by the NRC to be an immediate mandatory Category "B" matter of compatibility for Agreement States. See 62 FR 46517 (Sept. 3, 1997) (Statement of Principles and Policy for the Agreement State Program; Policy Statement on Adequacy and Compatibility of Agreement State Programs). Accordingly, the NRC Order provided that, in parallel with the NRC's issuance of the NRC Order, each Agreement State is required to issue legally binding requirements to put essentially identical measures in place for licensees under their regulatory jurisdiction. 70 FR at 72129.

II

8. On [date] the Commonwealth of Pennsylvania and the NRC entered into an agreement, pursuant to section 274 of the AEA, 42 U.S.C. § 2021, and section 201 of the Pennsylvania Radiation Protection Act (RPA), Act of July 10, 1984, P.L. 688, No. 147, 35 P.S. § 7110.201 (the Agreement).

9. The Agreement provides for discontinuance of the regulatory authority of the NRC within the Commonwealth under Chapters 6, 7, and 8, and Section 161 of the AEA with respect to byproduct materials as defined in Sections 11e.(1), (3) and (4) of the AEA, source materials, and special nuclear materials in quantities not sufficient to form a critical mass, as well as with respect to the regulation of the land disposal of all waste byproduct, source and special nuclear materials covered by the Agreement. Pennsylvania thereby became an Agreement State upon publication of notice of the Agreement in the Federal Register on [date], and the Commonwealth assumed regulatory authority as prescribed by the Agreement.

10. Upon Pennsylvania becoming an Agreement State, the Licensees identified in Attachment A to this Order—which licensees possess a specific license issued by the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass—are deemed to possess a like license issued under the RPA and 25 Pa. Code Chapter 217. *See* 25 Pa. Code § 217.133. Accordingly, the Licensees identified in Attachment A to this Order now hold licenses issued in accordance with the RPA and its implementing regulations.

11. As an Agreement State, in order to comply with the NRC Order Pennsylvania must issue legally binding requirements to put essentially identical measures in place for licensees under its regulatory jurisdiction as those which are set forth in the NRC Order. Consequently, the Department is issuing this Order, which will put essentially identical measures in place for licensees now under its jurisdiction as an Agreement State. The requirements set forth in Attachment B to this Order are essentially identical to those set forth in Attachment B to the NRC Order; in addition, Attachment B, Table 1 is essentially identical in both Orders.

12. The Department is the agency with the duty and authority to administer and

enforce the RPA, section 1917-A of the Administrative Code of 1929, act of April 9, 1929, P. L. 177, No. 175, 71 P.S. § 510-17, and the rules and regulations promulgated thereunder.

13. Pennsylvania regulations incorporate 10 CFR §§ 20.1801 and 1802 by reference, see 25 Pa. Code §§ 215.1 and 219.5. In addition, 25 Pa. Code § 219.131 requires Licensees to secure from unauthorized removal or access radiation sources that are in storage, and § 219.132 requires Licensees to maintain control of radiation producing machines that are not in storage.

III

Accordingly, pursuant to Sections 301(c)(4), 301(c)(15), 303(d) and 304 of the Radiation Protection Act, 35 P.S. §§ 7110.301(c)(4), 7110.301(c)(15), 7110.303(d) and 7110.304, and the Department's regulations in 25 Pa. Code Chapters 217 and 219, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT THE LICENSES OF ALL THE LICENSEES IDENTIFIED IN ATTACHMENT A TO THIS ORDER ARE HEREBY MODIFIED ACCORDING TO THE TERMS OF THIS ORDER AND THAT ALL LICENSEES IDENTIFIED IN ATTACHMENT A TO THIS ORDER SHALL COMPLY WITH THE REQUIREMENTS OF THIS ORDER AS FOLLOWS:

A. The Licensee must comply with the requirements in Attachment B to this Order. Unless properly granted an extension of time to comply or other relief by the NRC, the Licensee shall have completed implementation by no later than June 2, 2006 or the first day that radionuclides of concern at or above threshold limits, as identified in Table 1, were possessed.

B. 1. The Licensee shall in writing, within fifteen (15) days of the date of this Order, notify the Department: (1) that the Licensee is currently in compliance with the requirements described in Attachment B or that the Licensee has been granted an extension of time for compliance by the NRC; (2) that the Licensee recognizes that it is now subject to Pennsylvania jurisdiction with respect to the materials covered by the Agreement; (3) if compliance with any of the requirements is unnecessary in its specific circumstances; or, (4) if implementation of any of the requirements would cause the Licensee to be in violation of the provisions of any Department regulation or its license. The notification shall provide the Licensee's justification for seeking relief from or variation of any specific requirement.

B. 2. If the Licensee considers that implementation of any of the requirements described in Attachment B to this Order would adversely impact safe operation of the facility, the Licensee must notify the Department, in writing, within fifteen (15) days of this Order, of the adverse safety impact, the basis for its determination that the requirement has an adverse safety impact, and either a proposal for achieving the same objectives specified in the Attachment B requirement in question, or a schedule for modifying the facility to address the adverse safety condition. If neither approach is appropriate, the Licensee must supplement its response to Condition B.1 of this Order to identify the condition as a requirement with which it cannot comply, with attendant justifications as required in Condition B.1.

C. 1. The Licensee's notification submitted pursuant to Condition B.1(1) shall include a certification that the Licensee completed each requirement in Attachment B in response to the

NRC Order and currently remains in compliance with the requirements in Attachment B to this Order, or, a schedule for completion of each requirement described in Attachment B.

C. 2. For those Licensees granted an extension of time to comply with the requirements in Attachment B, the Licensee shall report to the Department when they have achieved full compliance with the requirements in Attachment B.

D. Notwithstanding any provisions of the Department regulations to the contrary, all measures implemented or actions taken in response to this Order shall be maintained until the Department modifies its regulations to reflect increased controls.

Licensee responses to Conditions B.1, B.2, C.1, and C.2 above shall be submitted to the Director, Bureau of Radiation Protection, Pennsylvania Department of Environmental Protection, Rachel Carson State Office Building, P.O. Box 8469, Harrisburg, PA 17105-8469. Licensee's responses shall be marked as "Confidential."

The Director of the Bureau of Radiation Protection may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

IV

Any person aggrieved by this action may appeal, pursuant to Section 4 of the Environmental Hearing Board Act, 35 P.S. Section 7514, and the Administrative Agency Law, 2 Pa.C.S. Chapter 5A, to the Environmental Hearing Board, Second Floor, Rachel Carson State Office Building, 400 Market Street, P.O. Box 8457, Harrisburg, PA 17105-8457, 717-787-3483. TDD users may contact the Board through the Pennsylvania Relay Service, 800-654-5984. Appeals must be filed with the Environmental Hearing Board within 30 days of receipt of written notice of this action unless the appropriate statute provides a different time period. Copies of the appeal form and the Board's rules of practice and procedure may be obtained from the Board. The appeal form and the Board's rules of practice and procedure are also available in braille or on audiotape from the Board Secretary at 717-787-3483. This paragraph does not, in and of itself, create any right of appeal beyond that permitted by applicable statutes and decisional law.

If you want to challenge this action, your appeal must reach the Board within 30 days. You do not need a lawyer to file an appeal with the Board. Important legal rights are at stake, however, so you should show this document to a lawyer at once. If you cannot afford a lawyer, you may qualify for free pro bono representation. Call the Board Secretary (717-787-3483) for more information.

FOR THE DEPARTMENT

_____

David Allard, Director
Bureau of Radiation Protection

Dated: