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this Article V issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P.S. § 1301) (Repealed), unless otherwise noted.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

(394015) No. 530 Jan. 19
CHAPTER 215. GENERAL PROVISIONS

GENERAL PROVISIONS

Sec. 215.1. Purpose and scope.
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EXEMPTIONS

215.32. Exemption qualifications.
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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


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, 37, 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)—(14). 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(b)(6), 30.53, 30.63 and 30.64 are not incorporated. Paragraph 2 of the definition of “commencement of construction” and paragraph 9(ii) of the definition of “construction” in section 30.4 are not incorporated.

(4) Sections 31.4 and 31.14 are not incorporated.

(5) Sections 32.1(c)(1), 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, 32.30, 32.31, 32.32 and 32.40 are not incorporated.

(6) Sections 33.8 and 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. Paragraph 2 of the definition of “commencement of construction” and paragraph 9(ii) of the definition of “construction” in section 36.2 are not incorporated.

(10) Sections 37.3(b)(2), 37.13, 37.73(d) and (e), 37.107 and 37.109 are not incorporated.

(11) Sections 39.5, 39.8, 39.101 and 39.103 are not incorporated. Paragraph 2 of the definition of “commencement of construction” and paragraph 9(ii) of the definition of “construction” in section 40.4 are not incorporated.

(12) Sections 40.6, 40.8, 40.12(b), 40.13(c)(5)(iv), 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), 40.52, 40.53, 40.64, 40.66, 40.67, 40.81, 40.82 and 10 CFR Part 40 Appendix A Criterion 11 A—F and Criterion 12 are not incorporated.

(13) 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, 70.72, 70.74, and 10 CFR Part 70 Appendix A are not incorporated. Paragraph 2 of the definition of “commencement of construction” and paragraph 9(ii) of the definition of “construction” in section 70.4 are not incorporated.

(14) Sections 71.2, 71.6, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, 71.101 (c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125 and 71.126 are not incorporated. The definitions of “certificate holder” and “certificate of compliance (CoC)” in section 71.4 are not incorporated. The term “applicant” when used in 10 CFR Part 71 is not incorporated.
eral 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:


(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, except as noted in 10 CFR 37.27 (relating to requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material) and in 10 CFR 71.17(c)(3) (relating to general license: NRC-approved package).

Authority


Source


(Editor's Note: For a document incorporating subsequent versions of 10 CRF Parts 30—32, 40 and 70, see 42 Pa.B. 6543 (October 13, 2012).)
§ 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.

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, device, equipment, radiation-producing machine 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 $2.58 \times 10^{-4}$ 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.
Authority

Source

Cross References
This section cited in 25 Pa. Code § 221.2 (relating to definitions); 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

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

§ 215.4. [Reserved].

Source

§ 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.”

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(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**

### 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**

#### § 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 for 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.

4. Secure or lock-down a device if a radiation source is abandoned or poses a threat to public health, safety or the environment.
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.

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

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.

The following Department records will not be disclosed to the public or to a litigant absent a court order 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:

1. Trade secrets or secret industrial processes customarily held in confidence.
2. A report of investigation which would disclose the institution, progress or results of an investigation undertaken by or at the direction of the Department or other governmental agency.
PERSONNEL, MEDICAL AND SIMILAR RECORDS, THE DISCLOSURE OF WHICH WOULD BE REASONABLY LIKELY TO RESULT IN A SUBSTANTIAL AND DEMONSTRABLE RISK OF PHYSICAL HARM TO OR THE PERSONAL SECURITY OF AN INDIVIDUAL.

(4) Location, identification, safeguards, security measures or other security-related information relating to a radiation source.

(5) A record designated as classified by a Federal or State authority.

(6) A record exempt from disclosure under any Federal or State law or regulation, or judicial order or decree.

(7) Any other record maintained by the Department, the disclosure of which may endanger or threaten public health, safety or preparedness.

Source

§ 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

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 devices or machines which use X-ray or radiologic technology for human nonmedical use without prior written approval of the Department.
(1) A person requesting the Department to approve the nonmedical human use of radiation shall submit written information describing the proposed use to the Department for evaluation.

(2) The Department will consider efficacy of the device or procedure as a factor when evaluating the proposed nonmedical human use of radiation.

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

Source
The provisions of this § 215.22 amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (333921) to (333922).

§ 215.23. Penalties.

A person who violates this article is subject to the civil and criminal penalties in the act. At a minimum, civil penalties may be assessed in an amount sufficient to recover the costs expended by the Department in the correction of the violation or abatement of the resulting radiological nuisance.

Authority

Source


(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).
(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 or employed by a health care facility 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).

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(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) Subsection (b) 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 subsection (b) to use radiation sources in the healing arts.

Source

§ 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.

Source


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

Source

§ 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

§ 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

EXEMPTIONS

(a) The Department may grant exemptions from this article on its own initiative or upon application from a licensee when the Department determines that the exemptions 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.
(b) The Department will not grant exemptions to the fee requirements in § 218.11 (relating to registration, renewal of registration and license fees).

Source
The provisions of this § 215.31 amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (304413).

§ 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


COMMUNICATIONS

§ 215.41. Contact information.

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; (717) 787-2480; www.dep.pa.gov.

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Source

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