

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

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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); 25 Pa. Code § 220.1 (relating to purpose and scope); and 25 Pa. Code § 227a.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) or a person performing electronic brachytherapy as defined in § 221.2 (relating to definitions) is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines).

(1) Accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators).

(2) Electronic brachytherapy operations are licensed under Chapter 221 (relating to X-rays in the healing arts) and must comply with §§ 221.71—221.76 (relating to therapeutic X-ray systems with energies less than 1 MeV).

(c) 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; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (304417) to (304418).

§ 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 in name, address, owner or the individual designated under paragraph (2) to be responsible for radiation protection.
 - (4) Maintain a written inventory to include, at a minimum, the type and location of all radiation-producing devices.
 - (5) For registrants offering mobile services, have a current schedule, including the date and location where services are to be performed, available for inspection by the Department.
- (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; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (304418).

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.

A person who engages in the business of assembling or installing radiation-producing machines or who offers to assemble or install 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(k) (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(k) has been paid.

(4) X-ray registrants who employ in-house service providers are exempt from this section but are subject to the requirements of 21 CFR 1020.30 (relating to diagnostic X-ray systems and their major components).

Authority

The provisions of this § 216.2a 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 § 216.2a adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (304418) to (304419).

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 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.
- (e) A radiation-producing machine service provider shall comply with the requirements of Chapter 219 (relating to standards for protection against radiation).

Authority

The provisions of this § 216.2b 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 § 216.2b adopted July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (304419) to (304421).

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 0.5 mrem (0.005 mSv) per hour at 5 centimeters 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, which are 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).
- (5) Electronic brachytherapy operations, which are licensed under Chapter 221 (relating to X-rays in the healing arts) and comply with §§ 221.71—221.76 (relating to therapeutic X-ray systems with energies less than 1 MeV).

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; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (304421).

§ 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.

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 preceding 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 preceding 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 preceding text appears at serial page (282341).

Cross References

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

[Next page is 217-1.]