

**CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR
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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.

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 preceding 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 preceding 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.

(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 preceding 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

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 preceding 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.

(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 preceding 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 preceding 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.

(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 preceding 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 preceding 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).

(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 preceding 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 preceding 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 preceding 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 preceding text appears at serial page (282443).

§ 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 preceding 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 preceding 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.

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 preceding 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

<i>Maximum Energy of Electron Beam in MeV</i>	<i>X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose</i>
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.

§ 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).

§ 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.

(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 preceding 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 preceding text appears at serial pages (249370) to (249371).

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 preceding text appears at serial pages (249371) to (249372).

Cross References

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

[Next page is 229-1.]

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