

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Table with 2 columns: Subch. and Sec. listing sections A through N with their respective titles and section numbers.

Authority

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

Source

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

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 25 Pa. Code § 216.2b (relating to reporting and recordkeeping requirements for registered radiation-producing machine service providers); 25 Pa. Code § 217.1 (relating to purpose and scope); 25 Pa. Code § 217.144 (relating to incidental radioactive material produced by a particle accelerator); 25 Pa. Code § 220.2 (relating to posting of notices to workers); 25 Pa. Code § 224.1 (relating to purpose and scope); 25 Pa. Code § 225.1 (relating to purpose and scope); 25 Pa. Code § 225.74 (relating to training and testing); 25 Pa. Code § 225.84 (relating to operating and emergency procedures); 25 Pa. Code § 225.91 (relating to radiation survey meter requirements); 25 Pa. Code § 226.1 (relating to purpose and scope); 25 Pa. Code § 227a.1 (relating to purpose and scope); 25 Pa. Code § 227a.3 (relating to exemptions); 25 Pa. Code § 228.31a (relating to limitations); 25 Pa. Code § 228.33a (relating to facility and shielding requirements); 25 Pa. Code § 228.38 (relating to radiation safety surveys); 25 Pa. Code § 232.1 (relating to purpose and scope); 25 Pa. Code § 236.15 (relating to protection of individuals during operations); 25 Pa. Code § 236.208 (relating to specific technical information); 25 Pa. Code § 236.209 (relating to technical analyses); 25 Pa. Code § 236.225 (relating to requirements for issuance of license); and 25 Pa. Code § 236.403 (relating to facility operation plan).

Subchapter A. GENERAL PROVISIONS

Table with 2 columns: Sec. and Purpose. listing sections 219.1 through 219.6 with their respective purposes.

- 219.7. Effect of incorporation of 10 CFR 20.1403 “Criteria for license termination under restricted conditions.”
- 219.8. Requirement for a Radiation Safety Committee.
- 219.11—219.15. [Reserved].

### GENERAL PROVISIONS

#### § 219.1. Purpose.

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

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

#### Source

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

#### § 219.2. Scope.

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

#### Source

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

#### § 219.3. Definitions.

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

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

- (i) An unintended peak skin dose to the same area in a single procedure greater than 1500 rad (15 Gy).
- (ii) An unintended dose, other than skin dose, in a single procedure exceeding five times the facility’s established protocol and 50 rad (0.5 Gy) to any organ.
- (iii) A dose to the wrong patient, or wrong site for the entire procedure, and exceeding 50 rad (0.5 Gy) to any organ.

*Medical reportable event for radiation-producing machine therapy*—The administration to a human being, except for an administration resulting from a

direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

- (i) An administration of a therapeutic radiation dose to the wrong individual, wrong treatment site or using a treatment delivery intended for another individual.
- (ii) An administration of a dose for therapy identified in a written directive that differs from the prescribed dose for the treatment site or any other organ from the intended prescribed dose, by one of the following:
  - (A) More than 20% of the total prescribed dose.
  - (B) Exceeds 30% of the weekly prescribed dose.
  - (C) Exceeds 50% of a single fraction dose of a multifraction plan.

**Source**

The provisions of this § 219.3 adopted November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial pages (304456) to (304457).

**Cross References**

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

**§ 219.4. [Reserved].**

**Source**

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

**§ 219.5. Incorporation by reference.**

- (a) Except as provided in this chapter, the requirements of 10 CFR Part 20 (relating to standards for protection against radiation) are incorporated by reference.
- (b) Notwithstanding the requirements incorporated by reference, 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated by reference.

**Source**

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

**Cross References**

This section cited in 25 Pa. Code § 227a.22 (relating to radiation protection responsibility).

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

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

- (1) A reference to “NRC” or “Commission” means Department.

- (2) A reference to “NRC or agreement state” means Department, NRC or agreement state.
- (3) A reference to “licensee” includes registrant.
- (4) A reference to “license” includes registration.
- (5) A reference to “licensed” includes registered.
- (6) A reference to “Department” in 10 CFR means the United States Department of Energy.
- (7) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR (relating to energy) shall be directed to the Department, except as required under 10 CFR 20.2206 (relating to reports of individual monitoring).
- (8) 10 CFR Part 20, notwithstanding, exposures involving the use of X-rays may be weighted, in a manner specified by the Department, so that, with Department approval, the effective dose equivalent may be substituted for the deep dose equivalent in determining compliance with occupational exposure limits for specified groups of individuals.

#### Source

The provisions of this § 219.6 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (304458).

### **§ 219.7. Effect of incorporation of 10 CFR 20.1403 “Criteria for license termination under restricted conditions.”**

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

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

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

**Source**

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

**§ 219.8. Requirement for a Radiation Safety Committee.**

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

**Source**

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

**§§ 219.11—219.15. [Reserved].**

**Source**

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

**Subchapter B. [Reserved]**

**§ 219.21. [Reserved].**

**Source**

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

**§ 219.22. [Reserved].**

**Source**

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

**Subchapter C. [Reserved]****§§ 219.31—219.33. [Reserved].****Source**

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

**§§ 219.34—219.38. [Reserved].****Source**

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

**§§ 219.41—219.49. [Reserved].****Source**

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

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

Sec.

219.51. Dose limits for individual members of the public.

219.52. [Reserved].

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

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

**Source**

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

**Cross References**

This section cited in 25 Pa. Code § 223.7 (relating to structural shielding); 25 Pa. Code § 227a.15 (relating to surveys); 25 Pa. Code § 227a.45 (relating to radiation emission limits); and 25 Pa. Code § 227a.50 (relating to handheld radiation-producing devices).

**§ 219.52. [Reserved].****Source**

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

**Subchapter E. TESTING FOR LEAKAGE OR  
CONTAMINATION OF SEALED SOURCES**

Sec.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) Sealed sources containing only hydrogen-3.

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

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

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

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

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

(1) The presence of 185 Bq (0.005  $\mu$ Ci) or more of removable contamination on any test sample.

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

(3) The presence of removable contamination resulting from the decay of 185 Bq (0.005  $\mu$ Ci) or more of radium.

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



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

**Source**

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

**Cross References**

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

**§§ 219.62—219.66. [Reserved].**

**Source**

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

**Subchapter F. [Reserved]**

**§ 219.71. [Reserved].**

**Source**

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

**§ 219.72. [Reserved].**

**Source**

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

**§ 219.73. [Reserved]**

**Source**

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

**§§ 219.74—219.76. [Reserved].****Source**

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

**§ 219.81. [Reserved].****Source**

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

**Subchapter G. [Reserved]****§§ 219.91—219.93. [Reserved].****Source**

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

**Subchapter H. [Reserved]****§§ 219.111—219.113. [Reserved].****Source**

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

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

Sec.

219.131. Security of stored sources of radiation.

219.132. Control of sources of radiation not in storage.

**Source**

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

**§ 219.131. Security of stored sources of radiation.**

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

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

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

**Subchapter J. PRECAUTIONARY PROCEDURES**

Sec.	
219.151—219.158.	[Reserved].
219.159.	Posting of radiation-producing machines.
219.160.	Exceptions to posting requirements.
219.161.	[Reserved].
219.162.	[Reserved].

**Source**

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

**§§ 219.151—219.158. [Reserved].**

**Source**

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

**§ 219.159. Posting of radiation-producing machines.**

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

**“CAUTION—RADIATION  
THIS EQUIPMENT PRODUCES RADIATION  
WHEN ENERGIZED.”**

**Source**

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

**§ 219.160. Exceptions to posting requirements.**

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

**Source**

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

 **§§ 219.161 and 219.162. [Reserved].****Source**

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

**Subchapter K. [Reserved]** **§§ 219.181—219.186. [Reserved].****Source**

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

**Subchapter L. [Reserved]** **§§ 219.201—219.211. [Reserved].****Source**

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

**Subchapter M. REPORTS**

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

- 219.228. Reports of medical reportable events for radiation-producing machine therapy.  
219.229. Diagnostic or interventional procedure medical reports.

**Source**

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

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

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

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

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

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

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

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

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

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

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

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

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

**Source**

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

**Cross References**

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

**§ 219.222. Notification of incidents and reportable events.**

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

**Source**

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

**Cross References**

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

**§§ 219.223—219.226. [Reserved].****Source**

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

**§ 219.227. Reports of leaking or contaminated sealed sources.**

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

**Cross References**

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

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

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

- (1) Notify the Department by telephone within 24 hours after discovery of the event.
- (2) Submit a written report to the Department within 15 days after discovery of the event. The written report shall include the licensee's or registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to

prevent recurrence; actions taken to prevent recurrence; whether the licensee or registrant notified the patient, or the patient's responsible relative or guardian (for notification purposes under this section, this person will be included in subsequent references to "the patient"), and if not, why not; and if the patient was notified, what information was provided to the patient. The report may not include the patient's name or other information that could lead to identification of the patient.

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

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

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

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

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

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

#### Source

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

#### Cross References

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

### **§ 219.229. Diagnostic or interventional procedure medical reports.**

(a) Within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological

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

(b) Upon discovery of a medical reportable event, the registrant or licensee shall:

- (1) Notify the Department regarding the medical reportable event within 1 business day.
- (2) Provide a written report, including the analysis of the medical reportable event, by the qualified medical physicist, as defined in § 221.2 (relating to definitions), to the Department within 15 business days.
- (3) Provide a clinical summary to the prescribing physician and patient within 15 business days.
- (4) Maintain a record of the medical reportable event as part of the patient's permanent medical record.

#### Source

The provisions of this § 219.229 adopted September 14, 2001, effective September 15, 2001, 31 Pa.B. 5239; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3283; amended October 26, 2018, effective January 24, 2019, 48 Pa.B. 6791. Immediately preceding text appears at serial page (304470).

#### Cross References

This section cited in 25 Pa. Code § 221.11 (relating to registrant responsibilities).

### Subchapter N. [Reserved]

## § 219.241. [Reserved].

#### Source

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



**APPENDIX A. [Reserved]****Source**

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

**APPENDIX B. [Reserved]****Source**

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

**APPENDIX C. [Reserved]****Source**

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

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