

## CHAPTER 215. GENERAL PROVISIONS

### GENERAL PROVISIONS

#### § 215.1. Purpose and scope.

- (a) This article establishes requirements for the protection of public health and safety as related to radiation sources and implements the requirements of the act.
- (b) This article, except as otherwise specifically provided in the act, applies to persons who use, manufacture, produce, transport, transfer, receive, acquire, possess, own or dispose of a radiation source.
- (c) A person who, when required, fails to register or obtain a license for radiation sources in the possession or control of the person, shall comply with the act or with this article.
- (d) This article does not apply to the extent the person is subject to regulation by the NRC.
- (e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, ~~37~~, 39, 40, 70, 71 and § § 150.1, 150.2, 150.3, 150.11 and 150.20 of the CFR are incorporated by reference with the exceptions set forth in paragraphs (1)—~~(14~~[13]). Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. § § 7130.101—7130.905).
- (1) Sections 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated.
  - (2) Sections 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated.
  - (3) Sections 30.5, 30.6, 30.8, 30.21(c), 30.34(d) and (e)(1) and (3), 30.41(~~b~~[a])(6), 30.55, 30.63 and 30.64 are not incorporated.
  - (4) Sections 31.4 and 31.14 are not incorporated.
  - (5) Sections 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29 and 32.40 are not incorporated.
  - (6) Sections 33.8, 33.21 and 33.23 are not incorporated.
  - (7) Sections 34.5, 34.8, 34.121 and 34.123 are not incorporated.
  - (8) Sections 35.8, 35.4001 and 35.4002 are not incorporated.
  - (9) Sections 36.5, 36.8, 36.91 and 36.93 are not incorporated.

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

(~~10~~**11**) Sections 39.5, 39.8, 39.101 and 39.103 are not incorporated.

(~~12~~**11** ~~12~~) Sections 40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated.

(~~13~~**12**~~13~~) Sections 70.1(c), (d) and (e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1), (c), (f), (g) and (h), 70.22(b), (c), (f), (g), (h), (i), (j), (k), (l), (m) and (n), 70.23(a)(6), (7), (8), (9), (10), (11) and (12) and (b), 70.23a, 70.24, 70.25(a), 70.31(c), (d) and (e), 70.32(a)(1), (4), (5), (6) and (7), 70.32(b)(1), (3) and (4), (c), (d), (e), (f), (g), (h), (i), (j) and (k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), (d) and (e), 70.52, 70.53, 70.54, 70.55(c)(1), (2) and (3), 70.56(c) and (d), 70.57, 70.58, 70.59, 70.62, 70.71 and 70.72 are not incorporated.

(~~14~~**13**~~14~~) Sections 71.2, 71.6, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, 71.100, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125 are not incorporated.

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

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

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

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

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

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

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

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

(3) The definition of “sealed source” includes NARM.

(4) A reference to “byproduct material” includes NARM.

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

## PROHIBITIONS AND RESTRICTIONS

### § 215.22. Prohibited uses.

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

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

**(c) No person may operate or maintain within this Commonwealth devices or machines which use ~~fluoroscopic~~, X-ray or radiation principles for human non-medical use without prior ~~written~~ approval of the Department.**

**(1) A person requesting the Department to approve the non-medical human use of radiation shall submit in writing information describing the proposed use to the Department for evaluation.**

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

### § 215.24. Human use.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## EXEMPTIONS

### § 215.31. Granting exemptions.

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

**(b) The Department will not grant exemptions to the fee requirements in § 218.11 (relating to registration, renewal of registration and license fees),**

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

### § 216.1. Purpose and scope.

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

(b) A person possessing an accelerator as defined in § 228.2 (relating to definitions) **or a person performing electronic brachytherapy as defined in § 221.2 (relating to definitions)** is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines).

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

**(2) Electronic brachytherapy operations are licensed under Chapter 221 and comply with §§ 221.71 – 221.76 (relating to therapeutic x-ray systems with energies less than 1 MeV). [and license]**

**(c) License** fees are specified in § 218.11(d) (relating to registration, renewal of registration and license fees).

### § 216.2. Registration of radiation-producing machines.

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

**Comment [ccs1]:** The referenced regulations 221.71-221.76 list requirements but do not provide for "licensing"...instead of being "licensed" under these sections should it say: "comply with the requirements in §§ 221.71 – 221.76..."

**Comment [B2R1]:** OK, we'll say are licensed under Chapter 221 and comply with §§ 221.71 – 221.76

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

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

~~(3)~~ (3) Notify the Department in writing within 30 days of a change [of] in name, address, owner or [radiation safety officer] or the individual designated under §216.2(a)(2) to be responsible for radiation protection.[number of machines].

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(4) Maintain a written inventory to include at a minimum the type and location of all radiation-producing devices.

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~~(54) Registrants offering mobile services shall submit. Notify the Department in writing to the Department the date and location where imaging services will be performed before the registrant may provide mobile services. Registrants offering mobile services shall have a current schedule, including the date and location where services are to be performed, available for inspection by the Department.~~

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

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

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

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

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

[After July 17, 2004, a] A person who engages in the business of assembling or installing radiation-producing machines or who offers to assemble or install radiation-producing machines or who is in the business of furnishing or offering to furnish radiation-producing machine servicing or services or who is in the business of selling, leasing or lending radiation-producing machines in this Commonwealth shall apply for registration of the activities with the Department prior to furnishing or offering to furnish those services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The date service was provided.

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

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

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

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

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### **§ 216.3. Exemptions.**

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

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

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

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

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

**(5) Electronic brachytherapy operations are exempt from registration. Electronic brachytherapy shall be licensed under Chapter 221 and comply with §§ 221.71 – 221.76 (relating to therapeutic x-ray systems with energies less than 1 MeV).**

**Comment [ccs3]:** Who is responsible for getting them licensed? Owner's, possessor's?, user's?

**Comment [ccs4]:** The referenced regulations 221.71-221.76 list requirements but do not provide for "licensing"...instead of being "licensed" under these sections should it say: "comply with the requirements in §§ 221.71 – 221.76..."...also, on pg 5 you use "are licensed" here you say "shall be"...

## CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

### Subchapter A. GENERAL

#### § 217.1. Purpose and scope.

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

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

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

## **Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL**

### **§ 217.131. Incorporation by reference.**

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

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

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

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

- (1) A reference to “NRC” or “Commission” means Department.
- (2) A reference to “NRC or agreement state” means Department, NRC or agreement state.
- (3) The definition of “sealed source” includes NARM.
- (4) A reference to “byproduct material” includes NARM.
- (5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department **[and, for NRC licenses, to the NRC until agreement state status is in effect]**.

**§ 217.133. [Reserved].**

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

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

**Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL**

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

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

- (1) A reference to “NRC” or “Commission” means Department.
- (2) A reference to “NRC or agreement state” means Department, NRC or agreement state.
- (3) The definition of “sealed source” includes NARM.
- (4) A reference to “byproduct material” includes NARM.

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

**§ 217.143. Certain measuring, gauging or controlling devices.**

In addition to the parts of 10 CFR 31.5 (relating to certain detecting measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere) incorporated by reference, general licensees subject to registration under 10 CFR 31.5(c)(13)(i) or possessing general licensed devices containing 37 MBq (1 mCi) or more of **cobalt-57**,

**cadmium-109, iron-55 or** accelerator-produced material, as determined on the date of manufacture, or 3.7 MBq (0.1 mCi) or more of radium-226 shall also comply with the following:

\* \* \* \* \*

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

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

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

- (1) A reference to “NRC” or “Commission” means Department.
- (2) A reference to “NRC or agreement state” means Department, NRC or agreement state.
- (3) The definition of “sealed source” includes NARM.
- (4) A reference to byproduct material includes NARM.
- (5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department[ **and, for NRC licenses, to the NRC until agreement state status is in effect**].

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

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

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

- (1) A reference to “NRC” or “Commission” means Department.
- (2) A reference to “NRC or agreement state” means Department, NRC or agreement state.
- (3) The definition of “sealed source” includes NARM.

(4) A reference to byproduct material includes NARM.

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

### **Subchapter G. LICENSING OF SOURCE MATERIAL**

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

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

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

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

(3) The definition of “sealed source” includes NARM.

(4) A reference to “byproduct material” includes NARM.

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

### **Subchapter H. LICENSING OF SPECIAL NUCLEAR MATERIAL**

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

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

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

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

(3) The definition of “sealed source” includes NARM.

(4) A reference to “byproduct material” includes NARM.

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

### **Subchapter J. RECIPROCITY**

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

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

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

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

(3) The definition of “sealed source” includes NARM.

(4) A reference to “byproduct material” includes NARM.

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

## **CHAPTER 218. FEES**

### **GENERAL**

#### **§ 218.1. Purpose and scope.**

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

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

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

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

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

**(4) Is an applicant for or holder of an electronic brachytherapy license issued under Chapter 221 (relating to x-rays in the healing arts).**

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

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

Type Facility	Annual Administrative Fee	Annual Fee per X-ray Tube or Radiation Generating Device
Dentists, podiatrists, veterinarians	\$100	\$50
Hospitals	\$725	\$50
Other Facilities	\$350	\$50

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

(c) Annual license fees for radioactive material **are** shall be paid as set forth in Appendix A (relating to fees for radioactive material licenses).

**Comment [ccs5]:** see the new subsection (h) below

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**Comment [ccs6]:** emerging technology and ele. Brach. are both defined terms and emerging technology is not defined to include ele. Brach....should it say "and Ele Brach" instead of including ele brach...?

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

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

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

(1) Accelerators, below 50 MeV, other than for ion implantation—\$2,100 for the first accelerator at the facility plus \$700 for each additional unit at that facility.

(2) Accelerators used for ion implantation—\$700 plus \$70 for each additional unit at the same facility.

(3) Accelerators 50 MeV and above—full cost of staff time to review license applications and conduct inspections as needed. (Hourly rate is \$150 per hour). For the purpose of anticipating costs and compliance with subsections (e) and (f), a minimum annual fee of \$2,100 for the first accelerator at the facility plus \$700 for each additional unit is established. Additional invoices will be issued by the Department at regular intervals at least quarterly when net costs are incurred above the minimum annual fee.

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

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

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

**(h) The fee schedule in subsection (a) is not applicable to accelerators, emerging technology devices or electronic brachytherapy.**

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~~(h)(i) **Electronic brachytherapy devices are licensed under Chapter 221 (relating to x-rays in the healing arts §§ 221.71—221.76. The annual fee is \$1000 for the first unit (controller) at the facility plus \$100 for each additional unit at that facility.**~~

Comment [ccs7]: Same comment as above

~~(i)(i) **Emerging technology devices shall require Departmental safety review and approval prior to use. The review process registrant shall pay will result in a fee equal to for the full cost of staff time as needed for the review and approval process. (The full cost hourly rate is \$150 per hour).**~~

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[(h)](ki) A radiation-producing machine service provider shall pay an annual registration fee of \$140.

[(i)] (lk) The Department will review the adequacy of the fees established in this section at least once every 3 years and provide a written report to the EQB. The report must identify any disparity between the amount of program income generated by the fees and the costs to administer these programs, and must contain recommendations to increase fees to eliminate the disparity, including recommendations for regulatory amendments to increase program fees.

**§218.11a. [Reserved].**

**[§ 218.11a. Special provisions for calculating fees during agreement state transition period.**

**(a) The fees for the NRC licenses that are transferred to the Commonwealth on the date the Commonwealth becomes an agreement state will be invoiced on the license's next anniversary date.**

**(b) During the first year after the date the Department attains agreement state status, the annual fee for each NRC license transferred to the Commonwealth will include a proportional amount, based on the schedule of fees in Appendix A, for the period from the date agreement state status is attained until the license's next anniversary date, in addition to the amount assessed for the year following the license's anniversary date.**

**(c) In the event that the Commonwealth attains agreement state status prior to January 1, 2009, the provisions of this section and § 218.11 and Appendix A (relating to registration, renewal of registration and fees; and fees for radioactive material licenses) will be applied retroactively to NRC licenses transferred to the Commonwealth.]**

**CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION**

**Subchapter A. GENERAL PROVISIONS**

**§ 219.3. Definitions.**

The following terms, when used in this subchapter, **[has] have** the following meaning, unless the context clearly indicates otherwise:

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**Medical reportable event for radiation-producing diagnostic or interventional machines—  
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 dose to the skin greater than 32 Gy (3200 rads) to the same area for  
a procedure or series.**

(ii) **An unintended dose greater than 5 times the facility’s established protocol for a  
procedure and exceeds 0.5 Gy (50 rads) to an organ.**

(iii) **A Dose to the wrong patient or wrong site for the entire diagnostic exam  
(procedure/service) and exceeds 0.5 Gy (50 rads) to an organ.**

~~(iv) **Any equipment failure, personnel error, accident, mishap or other unusual  
occurrence with the administration of ionizing radiation that exceeds 0.05 Gy (5 rads).**~~

**Comment [ccs8]:** Exceeds 0.05 Gy of what?  
Dose to patient, dose to person?

**Comment [B9]:** Patient or person, they’re both  
the same.

*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 **or withusing  
the wrong treatment modality/plan.**

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

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

(iv) **AThe dose delivered to all or part of the intended site that differs byexceeds more  
than 50% from the expected dose for a single fraction of a multi-fraction treatment plan.**

~~(v) **An Unintended overdose to normal organs, tissues or skin.**~~

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

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

- (1) A reference to “NRC” or “Commission” means Department.
- (2) A reference to “NRC or agreement state” means Department, NRC or agreement state.
- (3) A reference to “licensee” includes registrant.
- (4) A reference to “license” includes registration.
- (5) A reference to “licensed” includes registered.
- (6) A reference to “Department” in 10 CFR means the United States Department of Energy.

(7) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department, **except as required in 10 CFR 20.2206, ( relating to Radiation Exposure Information and Reporting System (REIRS)) and 10 CFR 37.27, (relating to requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material)[-and, for NRC licenses, to the NRC until agreement state status is in effect].**

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(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.

### Subchapter M. REPORTS

#### § 219.229. Other medical reports.

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

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**Subchapter M. REPORTS**

**~~§ 219.229. Other medical reports.~~**

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

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

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

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

- (1) A reference to “NRC” or “Commission” means Department.
- (2) A reference to “NRC or agreement state” means Department, NRC or agreement state.
- (3) A reference to “license,” “licenses,” “licensed” and “licensed radioactive material” also include “registration,” “registrant” “registered,” and “registered source of radiation,” respectively.
- (4) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be directed to the Department **[ and, for NRC licenses, to the NRC until agreement state status is in effect ]**.

CHAPTER 221. X-RAYS IN THE HEALING ARTS

GENERAL PROVISIONS

§ 221.1. Purpose and scope.

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

§ 221.2. Definitions.

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

\* \* \* \* \*

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

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

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

\* \* \* \* \*

*Electronic Brachytherapy* – A **modality** of intraoperative radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

**Comment [CCS10]:** Modality is used in other definitions, so my intent is to be consistent...if I am changing the meaning, let me know.

*Emerging technology* – An innovative medical technology that utilizes a radiation source.

\* \* \* \* \*

*Intraoperative radiation therapy (IORT)*— A modality of therapy in which therapeutic levels of ionizing radiation are applied to a target area, such as a cancer tumor, while the area is exposed during surgery.

\* \* \* \* \*

*Unintended dose* – A radiation dose in diagnostic or interventional x-ray resulting from an error in procedure.

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## ADMINISTRATIVE CONTROLS

### § 221.11. Registrant responsibilities.

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

(b) An individual who operates an X-ray system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include items included in Appendix A (relating to determination of competence) and there shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

**(c) The operator of a high-risk procedure, that is, a procedure that could exceed skin doses of 200 rads (2 Gy), shall have additional instruction, including certification in the applicable specialty by a professional organization recognized by the Department.**

**Comment [ccs11]:** In addition to (b)? How often?

**Comment [B12]:** Yes, additional to (b); depending on the specialty.

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

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

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

(3) The type of grid, if any.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**[(m)](n)** Neither the X-ray tube housing nor the collimating device may be hand-held during the exposure.

**[(o) Any functional damage to a patient organ or a physiological system that results from a prescribed causative procedure shall be reported to the Department as outlined in § 219.229 (relating to other medical events).**

## DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

### § 221.25. Beam quality.

(a) Diagnostic X-ray systems shall have filtration that satisfies the requirements of Table I. The requirements of this section shall be considered to have been met if it can be demonstrated that the half value layer of the primary beam is not less than that shown in Table II.

**TABLE I**

**Filtration Required vs. Operating Voltage**

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<u>Operating Voltage (kVp)</u>	<u>Total Filtration (inherent plus added) (millimeters aluminum equivalent)</u>
<u>Below 50...</u>	<u>.5 millimeters</u>
<u>50—70...</u>	<u>1.5 millimeters</u>
<u>Above 70...</u>	<u>2.5 millimeters</u>

**TABLE II**

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<u>Design operating range (Kilovolts peak)</u>	<u>Measured potential (Kilovolts peak)</u>	<u>Minimum half-value layer (millimeters of aluminum)</u>	
		<u>Specified dental systems*</u>	<u>All other X-ray systems</u>
<u>Below 51</u>	<u>30</u>	<u>1.5</u>	<u>0.3</u>
	<u>40</u>	<u>1.5</u>	<u>0.4</u>
	<u>50</u>	<u>1.5</u>	<u>0.5</u>
<u>51 to 70</u>	<u>51</u>	<u>1.5</u>	<u>1.2</u>
	<u>60</u>	<u>1.5</u>	<u>1.3</u>
	<u>70</u>	<u>1.5</u>	<u>1.5</u>
<u>Above 70</u>	<u>71</u>	<u>2.1</u>	<u>2.1</u>

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<u>80</u>	<u>2.3</u>	<u>2.3</u>
<u>90</u>	<u>2.5</u>	<u>2.5</u>
<u>100</u>	<u>2.7</u>	<u>2.7</u>
<u>110</u>	<u>3.0</u>	<u>3.0</u>
<u>120</u>	<u>3.2</u>	<u>3.2</u>
<u>130</u>	<u>3.5</u>	<u>3.5</u>
<u>140</u>	<u>3.8</u>	<u>3.8</u>
<u>150</u>	<u>4.1</u>	<u>4.1</u>

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<u>X-Ray Tube Voltage (kilovolt peak)</u>				
<u>Design Operating Range</u>	<u>Measured Operating Potential</u>	<u>Minimum HVL (mm in Aluminum)</u>		
		<u>Specified Dental Systems \1\</u>	<u>Other X-Ray Systems\2\</u>	<u>Other X-Ray Systems\3\</u>
<u>Below 51</u>	<u>30</u>	<u>1.5</u>	<u>0.3</u>	<u>0.3</u>
	<u>40</u>	<u>1.5</u>	<u>0.4</u>	<u>0.4</u>
	<u>50</u>	<u>1.5</u>	<u>0.5</u>	<u>0.5</u>
<u>51 to 70</u>	<u>51</u>	<u>1.5</u>	<u>1.2</u>	<u>1.3</u>
	<u>60</u>	<u>1.5</u>	<u>1.3</u>	<u>1.5</u>
	<u>70</u>	<u>1.5</u>	<u>1.5</u>	<u>1.8</u>
<u>Above 70</u>	<u>71</u>	<u>2.1</u>	<u>2.1</u>	<u>2.5</u>
	<u>80</u>	<u>2.3</u>	<u>2.3</u>	<u>2.9</u>
	<u>90</u>	<u>2.5</u>	<u>2.5</u>	<u>3.2</u>
	<u>100</u>	<u>2.7</u>	<u>2.7</u>	<u>3.6</u>
	<u>110</u>	<u>3.0</u>	<u>3.0</u>	<u>3.9</u>
	<u>120</u>	<u>3.2</u>	<u>3.2</u>	<u>4.3</u>

	<u>130</u>	<u>3.5</u>	<u>3.5</u>	<u>4.7</u>
	<u>140</u>	<u>3.8</u>	<u>3.8</u>	<u>5.0</u>
	<u>150</u>	<u>4.1</u>	<u>4.1</u>	<u>5.4</u>
<u>\1\ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.</u> <u>\2\ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.</u> <u>\3\ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.</u>				

Note: Half-value layers for kilovoltages not listed in Table II may be determined by interpolation or extrapolation.

**[\* Dental systems manufactured after December 1, 1980, designed for use with intraoral image receptors.]**

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(b) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

(c) For capacitor energy storage equipment, compliance with this section shall be determined with the maximum quantity of charge per exposure.

(d) The required minimal aluminum equivalent filtration shall include the filtration contributed by materials which are always present between the source and the patient.

(e) For X-ray systems having variable filtration in the useful beam, a means shall be provided to prohibit exposure unless the filtration requirements of subsection (a) are met for the kVp selected.

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**§ 221.35a. Fluoroscopic X-ray systems.**

(a) Fluoroscopic X-ray systems shall use an image intensifier or direct-digital receptor and, in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

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(b) Fluoroscopic X-ray systems shall be equipped with a mechanism to monitor and record patient dose during fluoroscopic operations. Systems incapable of monitoring dose shall have guidelines in place addressing operator requirements, such as beam-on time restrictions and awareness of radiation protection procedures.

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Comment [B13]: I'm not sure. My first question is what harm is there in leaving it?

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(c) All available metrics that describe the total radiation dose from interventional procedures shall be reported in the patient's medical record.

(d) Interventional services shall have policies and processes to ensure that when a specific radiation dose threshold is exceeded, appropriate documentation and follow-up are provided.

(a) Fluoroscopic X-ray systems shall use an image intensifier and, in addition to the requirements of §§ 221.1—221.34a, shall meet the requirements of §§ 221.36a—221.38a (relating to limitation of useful beam of fluoroscopic equipment; activation of fluoroscopic tube; and entrance exposure rate).

~~(b) Fluoroscopic X-ray systems shall be equipped with a mechanism to monitor and record patient dose during fluoroscopic operations. Systems incapable of monitoring dose shall have guidelines in place addressing operator requirements, such as beam-on time restrictions and awareness of radiation protection procedures.~~

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**Comment [B14]:** Sections b and c are from NCRPs draft SC 4-6

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#### § 221.38a. Entrance exposure rate.

(a) *Fluoroscopic systems without high level control.* The exposure rate may not exceed 10 roentgens (2.58 mC/kg) per minute except during recording of fluoroscopic images.

(b) *Fluoroscopic systems with high level control.*

(1) When the high level control is activated, the maximum exposure rate shall be 20 roentgens (5.16 mC/kg) per minute.

(2) When the high level control is not activated, the maximum exposure rate shall be 10 roentgens (2.58 mC/kg) per minute.

(3) Special means of activation of high level controls are required. The high level control shall only be operable when continuous manual activation is provided by the operator.

(4) There shall be an indication to the fluoroscopist that the high level control is being used.

(c) *Frequency of output measurements.* Output measurements to show compliance with this section shall be made at least annually and after maintenance that could affect the output of the machine. ~~Devices used to perform procedures that could exceed 200 rads (2 Gy) shall have output measurements recorded quarterly or after any repair or change that which may affect the performance of the device.~~

**Comment [CCS15]:** "Could" is used in 221.11(c) — where high risk procedure is described...should "could" be used here?

(d) *Compliance requirements.* Compliance with subsections (a)—(c) shall be determined as follows:

(1) If the source is below the table, the exposure rate shall be expressed for the center of the useful beam 1 centimeter above the tabletop or cradle with the image intensifier 30 centimeters above the tabletop or cradle.

(2) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(3) In a c-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source at its closest possible position of operation.

(4) The tube potential and current shall be set to give the maximum exposure possible from the X-ray system. For systems with automatic exposure control, at least 3 millimeters of lead shall be placed between the measuring device and image receptor.

(5) The measurement shall be made at the center of the useful beam.

#### § 221.41a. Fluoroscopic timer.

(a) A cumulative timing device activated by the fluoroscope switch shall be provided. It shall indicate the passage of a predetermined period of irradiation either by an audible signal or by temporary or permanent interruption of the irradiation when the increment of exposure time exceeds a predetermined limit not exceeding 5 minutes.

(b) **The cumulative fluoroscopic time shall be recorded on the patient chart.**

(c) **If The estimated dose values if available, are available, the estimated dose values, then estimated dose values, including dose from the record mode, shall be recorded on the patient chart.**

(d) **If estimated dose values are not unavailable, such as on older models, then record settings shall be recorded on the patient chart.**

Comment [ccs16]: If what is available

Comment [ccs17]: What settings?

Comment [B18]: Settings from the technique chart

### OTHER SYSTEMS

#### § 221.63. On-board imaging (OBI) guidance systems.

OBI systems ~~must~~ shall comply with § 221.204(b)(1) and (65) (relating to radiation measurements and performance evaluations).

**§ 221.64. Cone-beam computed tomography (CBCT).**

(a) ~~The following R~~radiation measurements ~~must~~ shall be evaluated annually ~~and~~ as soon as practical after any component repair or change which, in the opinion of the qualified expert, may ~~a~~ffect the performance of the CBCT unit:

(i) ~~HVL (half value layer) determination at the most commonly used kVp.~~

(ii) ~~OutputCTDI~~ as specified in § 221.204(a)(2)~~1~~ (relating to ~~definitions~~radiation measurements and performance evaluations) for commonly used techniques.

(b) CBCT units ~~must~~ shall comply with § 221.204(b)(1) and (65) (relating to radiation measurements and performance evaluations).

**Comment [ccs19]:** It's unclear how i and ii fit under (a)...does "The following..." help?

**THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES  
LESS THAN 1 MEV**

**§ 221.71. Equipment requirements.**

(a) When the tube is operated at its leakage technique factors, the leakage radiation may not exceed:

(1) One hundred milliroentgens (25.8 $\mu$ C/kg) per hour at 5 centimeters from the surface of the tube housing assembly for contact therapy systems.

(2) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured or installed prior to December 19, 1987.

(3) One hundred milliroentgens (25.8 $\mu$ C/kg) per hour at 1 meter from the source for 0-150 kVp systems manufactured on or after December 19, 1987.

(4) One roentgen (.258 mC/kg) per hour at 1 meter from the source for 151 to 500 kVp systems.

(5) One-tenth percent of the exposure rate of the useful beam 1 meter from the source for 501 to 999 kVp systems at 1 meter from the source.

(b) Fixed diaphragms or cones used for limiting the useful beam must provide at least the same protection as required by the tube housing assembly.

(c) Beam limiting devices may, for the portion of the useful beam blocked by these devices, transmit not more than 5% of the original X-ray beam intensity at the maximum voltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

(d) The filter system shall be designed so that:

(1) Filters cannot be accidentally displaced from the useful beam at any possible tube orientation.

(2) The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/kg) per hour under operating conditions.

(3) A filter is marked as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.

(4) On equipment purchased after January 1, 1971, a filter indication system shall be used on therapy machines using changeable filters. The system must indicate from the control panel the presence or absence of a filter and be designed to permit easy recognition of an added filter in place.

(5) An X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

(e) The tube housing assembly shall be immobilized during stationary treatments.

(f) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and the marking shall be readily accessible for use during calibration procedures.

(g) Contact therapy tube housing assemblies shall have a removable shield of at least .5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(h) Systems of greater than 150 kVp manufactured after December 19, 1987, must have a beam monitor system which meets the following requirements:

(1) Not allow irradiation until a preselected value of exposure has been made at the treatment control panel.

(2) Independently terminate irradiation when the preselected exposure has been reached.

(3) Be designed so that, in the event of a system malfunction or electrical power failure or other interruption, the dose administered to a patient prior to the interruption can be accurately determined.

(4) Have a control panel display which maintains the reading until intentionally reset to zero.

(5) Have a control panel display which does not have scale multiplying factors and utilizes a design so that increasing dose is displayed by increasing numbers.

(i) The following apply to timers on the equipment:

(1) A timer shall be provided which has a display at the control panel. The timer must be graduated in minutes and fractions of minutes. The timer must have a preset time selector and an elapsed time indicator.

(2) The timer must be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the timer to zero.

(3) The timer must terminate irradiation when a preselected time has elapsed if a dose monitoring system present has not previously terminated irradiation.

(4) The timer must permit accurate presetting and determination of exposure time as short as 1 second.

(5) The timer may not permit an exposure if set at zero.

(6) The timer may not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

(j) The control panel, in addition to the displays required in this section, must have:

(1) An indication of power status.

(2) An indication of X-ray production.

(3) The means of indicating X-ray tube current and voltage.

(4) The means of terminating an exposure.

(k) When a control panel may energize more than one X-ray tube, the following requirements shall be met:

(1) It must be possible to activate only one X-ray tube at one time.

(2) There must be an indication at the control panel identifying which X-ray tube is energized.

(3) There must be an indication at the tube housing assembly when that tube is energized.

(l) There must be a means of determining the SSD to within 5 millimeters.

(m) Unless it is possible to bring the X-ray output to the prescribed exposure parameters within 5 seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

(1) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

(2) An indication of shutter position must appear at the control panel.

**(n) Electronic brachytherapy devices are exempt from the requirements in subsections (k), (l), and (m).**

## **COMPUTED TOMOGRAPHY X-RAY SYSTEMS**

### **§ 221.201. Definitions.**

\* \* \* \* \*

CTDI—Computed tomography dose index—The integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

$$\overline{\text{CTDI}} = \frac{1}{nT} \int_{-7T}^{+7T} D(z) dz$$

**where:**

**z = position along a line perpendicular to the tomographic plane.**

**D(z) = Dose at position z.**

**T = Nominal tomographic section thickness.**

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

\* \* \* \* \*

CT dosimetry phantom - The phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethyl-methacrylate of density  $1.19 \pm 0.01$  grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. The means used for placement of a dosimeter(s) (i.e., hole size) and the type of dosimeter(s) used is at the discretion of the manufacturer. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

CT Number - The number used to represent the x-ray attenuation associated with each elemental area of the CT image:

$$\overline{\text{CTN}} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Hounsfield scale of CTN is used;

$\mu_x$  = Linear attenuation coefficient of the material of interest;

$\mu_w$  = Linear attenuation coefficient of water.

CBCT - Cone Beam Computed Tomography - A digital volume tomography method used in some imaging applications using two-dimensional digital detector arrays, and a cone-

shaped x-ray beam (instead of fan-shaped) that rotates around the patient to generate a high resolution, 3D image, with high geometric accuracy. Reconstruction algorithms can be used to generate images of any desired plane.

\* \* \* \* \*

Dose profile - The dose as a function of position along a line.

\* \* \* \* \*

Modulation transfer function - The modulus of the Fourier transform of the impulse response of the system.

[MSAD—Multiple scan average dose—The calculated average dose to the tissue within each slice in a series utilizing an ion chamber. The MSAD is calculated using the following equation:

$$\text{MSAD} = (F \times K \times L \times E) / (T \times N)$$

Where

F = Factor to convert exposure in air to absorbed dose in lucite in RADS/mR

K = Calibration factor to account for the ion chamber's response and volume.

L = Effective length of ion chamber in millimeters (mm)

E = Exposure reading in milliroentgen (mR)

T = Nominal slice thickness in millimeters (mm) and

N = Number of slices per scan]

\* \* \* \* \*

§ 221.202. Equipment requirements.

(a) Accreditation. All diagnostic CT x-ray systems shall be accredited by an accrediting organization recognized by the Department.

**(b) Technical and Safety Information. The technical and safety information relating to the conditions of operation, dose information and imaging performance provided by the CT manufacturer shall be maintained by the facility.**

([a]c) Termination of exposure. The operator shall be able to terminate the X-ray exposure at any time during a scan, or series of scans under X-ray system control, of greater than 0.5 second duration. Termination of the X-ray exposure shall necessitate resetting of the conditions of operation prior to initiation of another scan.

([b]d) Tomographic plane indication and alignment.

(1) For any single tomogram system, a means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, a means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic plane.

([c]e) Status indicators and control switches.

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed.

(2) The emergency buttons or switches shall be clearly labeled as to their function.

(3) Each individual scan or series of scans shall require initiation by the operator.

**([d]f) Indication of CT conditions of operation. The CT X-ray system shall be designed so that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.**

**([e]g) Leakage radiation. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 milliroentgens (25.8  $\mu$ C/kg) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.**

**([f]h) Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.**

(1) The total error in the indicated location of the tomographic plane or reference plane by the light field or laser indicator may not exceed 5 millimeters.

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(2) If the X-ray production period is less than 0.5 second, the indication of X-ray production shall be actuated for at least 0.5 second. Beam-on and shutter status indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(3) The CT X-ray system shall be normalized to water.

(4) The CT number for water for a region of interest, not exceeding 100 square millimeters, shall be  $0 \pm 10.0$  CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the qualified **[expert] medical physicist**, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the qualified **[expert] medical physicist** may establish and maintain an equivalent value.

(5) With the performance phantom, the mean CT number of water of one group of pixels may not differ from the mean CT number of water of a second group of pixels equal size within the same image by more than the manufacturer's published specifications.

(6) The noise, utilizing the facility's performance phantom, may not exceed the manufacturer's published specifications.

(7) The total error between the indicated and actual slice thickness may not exceed 2.0 millimeters.

(8) A distance of at least 100 millimeters measured in a CT image shall agree with the actual distance to within  $\pm 5\%$ .

(9) Premature termination of the X-ray exposure by the operator shall necessitate resetting the CT conditions of operation prior to the initiation of another scan.

### **§ 221.203. Facility design requirements.**

(a) Oral communication. Provision shall be made for oral communication between the patient and the operator at the control panel.

(b) Viewing systems.

(1) A means shall be provided to permit continuous observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

(2) If the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

#### **§ 221.204. Radiation measurements and performance evaluations.**

##### (a) Radiation measurements.

(1) The CTDI [or MSAD] along the two axes specified in paragraph (2)(i) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry at the point of maximum surface exposure identified. The CT conditions of operation shall be reproducible and correspond to typical values used by the registrant. If the point of maximum surface exposure constantly changes due to system design, then measurements shall be taken at four different locations—top left, top right, bottom left, bottom right—1 centimeter from the outer surface of the phantom.

(2) CT dosimetry phantoms shall be used in determining the radiation output of a CT X-ray system. The phantoms shall meet the definition for a CT dosimetry phantom under 21 CFR 1020.33(b)(6) (relating to computed tomography (CT) equipment).

(i) The phantoms shall be specifically designed for CT dosimetry and deemed appropriate by the facility's qualified [expert] **medical physicist** and the Department.

(ii) CT dosimetry phantoms shall provide a means for the placement of dosimeters along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. The means for the placement of dosimeters or alignment devices at other locations may be provided.

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(iv) Dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

(3) In addition to the items in subsection (b), the following items shall be evaluated annually [or]and after any component repair or change which in the opinion of the qualified [expert] **medical physicist** may effect the performance of the CT unit:

(i) HVL (half value layer) determination at the most commonly used kVp or 120 kVp.

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(ii) CTDI [or MSAD] as specified in § 221.201 (relating to definitions) for commonly used techniques.

(iii) Tomographic plane indication (light/laser alignment).

(iv) Slice thickness as specified in § 221.202(g)(7) (relating to equipment requirements).

(v) Distance readout calibration.

(4) The measurement of the radiation output of a CT X-ray system shall be performed with a dosimetry system that has calibration traceable to National Institute of Standards and Technology. The calibration of the system shall be in accordance with an established calibration protocol. The calibration protocol published by the AAPM is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent.

(5) An mR/mAs value shall be determined at least annually for the head and body.

(6) Procedures and results shall be maintained for 5 years and be available for review by the Department.

(b) Performance evaluations.

(1) Written performance evaluation procedures (**spot checks**) shall be developed by a qualified **[expert] medical physicist**. These procedures shall be available for review by the Department.

(2) The performance evaluation procedures shall include at least the following using the facility's performance phantom:

(i) Noise.

(ii) Contrast scale.

(iii) Spatial resolution (low and high contrast).

(iv) Mean CT number for water.

(v) Acceptable tolerances.

(3) The performance evaluation shall be performed at intervals not to exceed 3 months by the qualified **[expert] medical physicist** or an individual designated by the qualified **[expert] medical physicist**.

(4) The qualified **[expert] medical physicist** need not be present during the performance evaluation, but shall be informed within 48 hours of any problems or unacceptable deviations.

(5) Performance evaluations shall include acquisition of images obtained with the performance phantom using the same processing mode and CT conditions of operation as are used to perform the measurements required by subsection (a).

(6) Review existing CT protocols along with the evaluation and implementation of new and innovative technologies that can improve image quality and/or lower patient dose in comparison with the older protocol.

(7) Review the capabilities of the individual CT scanner to ensure maximum performance is achieved.

(8) Determine and review the protocols used frequently to ensure over doses do not result. This review shall include acquisition and reconstruction parameters, image quality, and radiation dose. At a minimum, the facility shall review the following clinical protocols, if performed, at intervals not to exceed 14 months:

(i) Pediatric Head (1 year old)

(ii) Pediatric Abdomen (5 year old; 40-50 lb. (about 20 kg)

(iii) Adult Head

(iv) Adult Abdomen (70 kg)

(v) High Resolution Chest

(vi) Brain Perfusion

([6]9) Records of the performance evaluations shall be maintained for inspection by the Department for at least 4 years.

(c) Surveys.

(1) All CT x-ray systems installed after (Editor's Note: The blank refers to the date of adoption of this proposal) and those systems not previously surveyed shall have a survey performed by or under the direction of a qualified medical physicist. In addition, such surveys shall be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard.

(2) The registrant shall obtain a written report of the survey from the qualified medical physicist, and a copy of the report shall be made available to the Department upon request.

(d) Radiation Calibrations.

(1) The calibration of the CT x-ray system shall be performed by or under the direction of a qualified medical physicist who is physically present at the facility during such calibration.

(2) Calibration standards and tolerances shall be established by a qualified medical physicist and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT x-ray system.

(3) The calibration of a CT x-ray system shall be performed after initial installation and before use on human patients, at intervals not to exceed 14 months, and after any change or replacement of components which, in the opinion of the qualified medical physicist, could cause a change in the radiation output or image quality.

(4) The calibration shall include but not be limited to:

(i) Geometric factors and alignment including alignment light accuracy, alignment of table to gantry, table and gantry tilt, and table incrementation accuracy.

(ii) Slice localization from scanned projection radiograph (localization image).

(iii) Slice thickness.

(iv) Image quality including high-contrast (special) resolution, low-contrast resolution, image uniformity, noise, and artifact evaluation.

(v) CT number accuracy and linearity.

(vi) Image quality for display devices (video and hard copy where applicable).

(vii) A review of the results of the spot checks required under §221.204(b).

(viii) A safety evaluation of audible and visual signals, posting requirements, and scatter radiation.

(ix) Dosimetry.

(5) The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding 2 years.

§ 221.205. Operating procedures.

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(a) The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

(a) Information shall be available at the control panel regarding the operation and performance evaluations of the system. The information shall include the following:

(1) The dates of the latest radiation measurements and performance evaluation and the location within the facility where the results of those tests may be obtained.

(2) Instructions on the use of the CT phantoms including a schedule of performance evaluations appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent performance evaluation conducted on the system.

(3) Current protocol information available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(b) If the radiation measurements and performance evaluation of the CT X-ray system indicates that a system operating parameter has exceeded a tolerance established by the qualified expert medical physicist, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of qualified expert medical physicist.

## CHAPTER 223. VETERINARY MEDICINE

### RADIOACTIVE MATERIAL

#### § 223.22. Sealed and unsealed sources.

A veterinarian who uses sealed or unsealed sources for therapeutic treatment of animals shall comply with 10 CFR Part [35, Subparts F, G, H and K but is exempt from 10 CFR 35.632—35.645 and 35.2632—35.2645]30, “(relating to rRules of gGeneral aApplicability to dDomestic lLicensing of Bbyproduct mMaterial)” and 10 CFR Part 31, ParagraphParagraph Section 31.11, (relating to“gGeneral to general lLicense for uUse of bByproduct mMaterial for cCertain iIn vVitro cClinical or lLaboratory tTesting).”

Comment [ccs20]: Paragraph or section?

### ADMINISTRATIVE CONTROLS

**§ 223.31. Registrant responsibilities.**

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

**Comment [CCS21]:** Do you mean article or something more specific?

**Comment [B22]:** Article V

**(b) A person who operates an X-ray system shall be instructed adequately about the safe X-ray operating procedures and be competent in the safe use of the X-ray equipment. The instructions shall include the items included in Chapter 221 Appendix A (relating to determination of competence) and the person shall receive continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.**

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

**Comment [ccs23]:** Who is responsible for ensuring that b and c are complied with?

**Comment [B24]:** The registrant is responsible.

**(d) Only the staff and ancillary personnel or other persons required for the medical procedure or training may shall be in the room during the radiographic exposure. The following apply to for persons involved with the examination:**

**Comment [ccs25]:** What examination? X-ray examination

**Comment [B26]:** Yes, the x-ray examination

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

**(2) Each person required for the medical procedure shall be protected from the stray radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be so positioned so that the no persons are not is person is in the direct line of the useful beam and the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.**

**(3) No individual may be positioned in the useful beam unless required to conduct the procedure.**

**~~(3) No individual, other than the animal being examined, may be positioned in the useful beam, unless required to conduct the procedure.~~**

**(e) If an animal or image receptor requires auxiliary support during a radiation exposure, the following apply:**

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

**(2) The person holding the animal shall be protected as required in subsection (d).**

(3) A person may not ~~be used routinely to~~ hold image receptors or subjects. Procedures and auxiliary equipment designed to minimize personnel exposure commensurate with the needed diagnostic information shall be ~~utilized~~.

(f) The registrant shall have a quality assurance program. This quality assurance program shall be documented and be in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. At a minimum, the quality assurance program shall address radiation safety to personnel and ~~maintenance and~~ modifications to the quality assurance program.

(g) Neither the X-ray tube housing nor the collimating device may be hand-held during the exposure.

**Comment [CCS27]:** I'm not sure what this means. Does the department plan to approve QA programs?

**Comment [B28]:** An inspector will review and accept a QA program, but not 'formally' approve. "Maintenance" (that is, equipment maintenance) can be deleted.

## CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

### Subchapter A. GENERAL PROVISIONS

#### § 225.3a. Effect of incorporation of 10 CFR Part 34.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 34, the following words and phrases shall be substituted for the language in 10 CFR Part 34 as follows:

- (1) A reference to "NRC" or "Commission" means Department.
- (2) A reference to "NRC or agreement state" means Department, NRC or agreement state.
- (3) The definition of "sealed source" includes NARM.
- (4) The definition of "licensed material" includes NARM.

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

#### § 225.4a. Radiation safety program.

(a) A person who intends to use radiation-producing machines for industrial radiography shall have a program for training personnel, written operating procedures and emergency procedures,

**individual monitoring reports per 10 CFR 20.2206(a)(2) (relating to reports of individual monitoring)**, an internal review system and an organizational structure for radiographic operations which includes specified delegations of authority and responsibility for operation of the program. This program shall be approved by the Department before commencing industrial radiographic operations.

(b) The registrant shall notify the Department of intended changes to the registrant's radiation safety program and obtain Departmental approval.

## **Subchapter B. RADIATION-PRODUCING MACHINES**

### **GENERAL TECHNICAL REQUIREMENTS**

#### **§ 225.81. Permanent radiographic installations.**

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in 10 CFR 20.1601 and 20.1902 (relating to control of access to high radiation areas; and posting requirements) shall also meet the following requirements.

(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the X-ray source is energized. The audible signal shall be actuated when an attempt is made to enter the installation while the X-ray source is energized.

(2) The entrance control device or alarm system shall be tested for proper function prior to beginning operations on each day of use.

(3) The radiographic exposure system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used provided that the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.~~52~~**53** (relating to surveillance; posting), § 225.83 (relating to records required at field radiography sites) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the radiation safety officer or an individual designated by the radiation safety officer shall validate the repair.

(b) Records of the tests performed under subsection (a) shall be maintained for inspection by the Department for 3 years.

**CHAPTER 227. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT, X-RAY GAUGING EQUIPMENT, ELECTRON MICROSCOPES AND X-RAY CALIBRATION SYSTEMS**

**ANALYTICAL X-RAY EQUIPMENT**

**§ 227.11a. Equipment requirements.**

(a) Open-beam configurations shall have a safety device which either prevents the entry of any portion of an individual's body into the primary X-ray beam path, or causes the beam to be terminated or interrupted upon entry into the path. A registrant may apply to the Department for an exemption from the requirement of a safety device. The application for an exemption shall include the following:

- (1) A description of the various safety devices that have been evaluated.
- (2) The reason each of these safety devices cannot be used.

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Open-beam configurations shall be provided with a readily discernible indication of one or both of the following:

- (1) X-ray tube status (on-off) located near the radiation source housing, if the primary beam is controlled in this manner.
- (2) Shutter status (open-closed) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified. In addition, equipment manufactured after December 17, 1987, shall have fail-safe characteristics.

(d) An easily visible warning light located immediately adjacent to the tube head or port and labeled with the words "X-ray on," or words containing a similar warning, shall be provided and shall be illuminated when the X-ray tube is energized.

(e) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(f) Analytical X-ray equipment shall be labeled with a readily discernible sign bearing the radiation symbol and both of the following:

(1) “CAUTION—HIGH INTENSITY X-RAY BEAM” or words having a similar intent on the X-ray source housing.

(2) “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,” or words having a similar intent, near any switch that energizes an X-ray tube.

(g) On equipment with an open-beam configuration manufactured and installed after December 19, 1987, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or coupling has been connected to the port.

(h) Equipment exclusively designed and exclusively used for vacuum spectroscopy where the tube housing and sample chamber is located behind all external surfaces of the unit shall be exempt from the requirements of this section, § § 227.12a and 227.13a (relating to area requirements; and operating requirements), but shall meet the requirements of § 227.14 (relating to personnel procedures) and the following:

(1) The unit shall be designed so that when the unit is operating at the maximum kilovoltage and current ratings, the leakage radiation will not be in excess of 0.5 milliroentgens (.129  $\mu\text{C}/\text{kg}$ ) per hour at a distance of 4 centimeters from any external surface.

(2) Radiation surveys using appropriate radiation survey equipment shall be performed on the analytical X-ray unit upon installation, after moving the unit to a new location, and after maintenance or repair requiring the disassembly or removal of a local component or radiation shielding.

(3) Safety and warning devices shall be tested for proper operation at least annually. If the test reveals that a safety or warning device is not working properly, the unit may not be operated until the warning device is repaired or replaced.

(4) Records of all tests and surveys sufficient to show compliance with subsection (h) shall be maintained and kept available for inspection by the Department for 4 years.

(5) A sign bearing the radiation symbol and the words “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,” or words of similar intent shall be placed next to any switch or device that activates the X-ray tube.

(6) A sign bearing the radiation symbol and the words “CAUTION—RADIATION,” or words of similar intent shall be placed next to the opening of the sample chamber.

**(i) Analytical X-ray equipment operating at less than or equal to 50 kV tube voltage and designed to be held by an operator during use shall be exempt from the requirements of this section and § 227.12a(b) (relating to area requirements), but shall**

meet the requirements of subsection (f)(2) of this section and §§ 227.13a(a) and 227.14(a) (relating to operating requirements; and personnel requirements).

## CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

### ADMINISTRATIVE CONTROLS

#### § 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 **and have additional instruction, including certification in the applicable specialty by a professional organization recognized by the Department.**

(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.

### NOTIFICATION AND LICENSING PROCEDURES

#### § 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)](c)** 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)](d)** The application shall be signed by the applicant or licensee or an individual authorized by the applicant or licensee.

**[(g)](e)** 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.

## **GENERAL RADIATION SAFETY REQUIREMENTS**

### **§ 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)] **(h)** 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) **for medical accelerator operations, as well as basic radiation protection for non-medical accelerator operations**. There shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

**Comment [CCS29]:** Do you want these to follow Appendix A as well?

**Comment [B30]:** Non-medical accelerator operators do not need to address "patient exposure" or "patient positioning"

## RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

### § 228.61. Leakage radiation to the patient area.

(a) **[New equipment]** **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.

**Comment [CCS31]:** Do you want equipment installed prior to July 17, 2004 to also meet these requirements?

**Comment [B32]:** I don't want to designate "new". The last regulation was written to allow existing equipment to be grandfathered from certain licensing requirements.

(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, **manufactured or installed prior to July 17, 2004**, 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.

#### **§ 228.72. Selection of radiation type.**

Equipment capable of **[both]** X-ray therapy **[and], or** electron therapy, **or both**, 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.

**§ 228.73. Selection of stationary beam therapy or moving beam therapy.**

Equipment capable of **[both]** stationary beam therapy **[and], or** moving beam therapy, **or both**, 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.
- ~~(5) —(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).

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**CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL**

**Subchapter B. GENERAL**

**§ 230.15. Transportation of unlicensed material.**

Material not licensed by the Department or under the specific regulatory control of another state or federal agency, but meeting the definition of radioactive material in the United States Department of Transportation regulations in 49 CFR ~~Part 173.403~~, shall conform to the standards and requirements of those regulations.

**Comment [B33]:** Should be 173.403 (no need to add "Part")

**Comment [CCS34]:** Should this refer to a different part of 49 CFR?

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