

CHAPTER 215. GENERAL PROVISIONS

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.12. Inspections and investigations.

(a) *Maintenance of records.* Licensees and registrants shall maintain records under this article and have these records available for inspection by the Department at permanent sites or facilities of use identified in a license or registration issued under this article.

(b) *Rights of the Department.* The Department and its agents and employees will:

(1) Have access to, and require the production of, books, papers, documents and other records and physical evidence pertinent to a matter under investigation.

(2) Require a registrant or licensee to make reports and furnish information as the Department may prescribe.

(3) Enter the premises of a licensee or registrant for the purpose of making an investigation or inspection of radiation sources and the premises and facilities where radiation sources are used or stored, necessary to ascertain the compliance or noncompliance with the act and this chapter and to protect health, safety and the environment.

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

(c) *Inspections and investigations by the Department.* The Department, its employees and agents may conduct inspections and investigations of the facilities and regulated activities of registrants of radiation-producing machines and licensees of radioactive material necessary to demonstrate compliance with the act or this article.

(d) *Additional inspections and investigations.* The Department, its employees and agents may conduct additional follow-up inspections and investigations if violations of the act or regulations promulgated thereunder were noted at the time of the original inspection, or if a person presents information, or circumstances arise which give the Department reason to believe that the health and safety of a person is threatened or that the act or this article are being violated.

§ 215.14. Availability of records [for public inspection].

The following Department records [**are not available for public inspection**] **may not be disclosed to the public or to any litigant absent a court order**, unless the Department determines that disclosure is in the public interest and is necessary for the Department to carry out its duties under the act:

(1) Trade secrets or secret industrial processes customarily held in confidence.

(2) A report of investigation[, **not pertaining to safety and health in industrial plants,**] which would disclose the institution, progress or results of an investigation undertaken by **or at the direction of** the Department **or other governmental agency**.

(3) Personnel, medical and similar **[files] records**, the disclosure of which would operate to the prejudice or impairment of a person's reputation or personal safety.

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

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

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

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

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.] **No person may operate or maintain within this Commonwealth devices or machines which use X-ray or radiologic technology 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 written information describing the proposed use to the Department for evaluation.

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

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

§ 215.24. Human use.

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(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.]**

[(d) 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).**

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 (relating to X-rays in the healing arts) and comply with §§ 221.71 – 221.76 (relating to therapeutic X-ray systems with energies less than 1 MeV). [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:

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

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

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

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

(5) 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.]X-ray registrants who employ in-house service providers are exempt from this section but are subject to the requirements of 21 CFR 1020.30 (relating to performance standards for ionizing radiation emitting products).**

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

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(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).

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

§ 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 shall be licensed under Chapter 221 (relating to X-rays in the healing arts) and comply with §§ 221.71 – 221.76 (relating to therapeutic X-ray systems with energies less than 1 MeV).

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.

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(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:

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(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. 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*.] [**Reserved**].

[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:

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(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:

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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:

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(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:

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(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:

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(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:

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(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:

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(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).

PAYMENT OF FEES

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

(a) Annual registration fees for radiation-producing machines[, **other than accelerators,**] are the sum of an annual administrative fee and an annual fee for each X-ray tube or radiation generating device **and shall be paid** as follows:

<i>Type Facility</i>	<i>Annual Administrative Fee</i>	<i>Annual Fee per X-ray Tube or Radiation Generating Device</i>
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 **shall be paid as** set forth in Appendix A (relating to fees for radioactive material licenses).

(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.

(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.

(i) Electronic brachytherapy devices are licensed under Chapter 221 (relating to X-rays in the healing arts). The annual fee is \$1,000 for the first unit (controller) at the facility plus \$100 for each additional unit at that facility.

(j) Emerging technology devices require Department safety review and approval prior to use. The registrant shall pay a fee equal to the full cost of staff time for the review and approval process.

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

~~[(i)](l)~~ 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. Special provisions for calculating fees during agreement state transition period.] [Reserved].

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

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

(i) An unintended peak skin dose to the same area in a single procedure greater than 3 Gy (300 rad).

(ii) An unintended dose, other than skin dose, in a single procedure exceeding 5 times the facility's established protocol and 0.5 Gy (50 rad) to any organ.

(iii) A dose to the wrong patient or wrong site for the entire procedure and exceeding 0.5 Gy (50 rad) to any organ.

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

(i) An administration of a therapeutic radiation dose to the wrong individual, **wrong treatment site, or using a treatment delivery intended for another individual.**

(ii) An administration of a dose for therapy [**when the result is an increase in 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. Identified in a written directive that differs from the prescribed dose for the treatment site or any other organ from the intended prescribed dose, by one of the following:**

(A) More than 20% of the total prescribed dose.

(B) Exceeds 30% of the weekly prescribed dose.

(C) Exceeds 50% of a single fraction dose of a multi-fraction plan.

[(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%.]

§ 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:

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(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, for NRC licenses, to the NRC until agreement state status is in effect]

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Subchapter M. REPORTS

§ 219.229. Other medical reports.

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

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

- (1) Notify the Department regarding the medical event within one business day.**
- (2) Provide a written report, including the analysis of the medical event, by the OMP to the Department within 15 business days.**
- (3) Provide a clinical summary to the prescribing physician and patient within 15 business days.**
- (4) Maintain a record of the medical event as part of the patient's permanent medical record.**

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:

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(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:

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Air kerma – Kerma in air (see definition of Kerma).

Air kerma rate – Air kerma per unit time.

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[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).]

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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 to generate a high resolution, 3D image, with high geometric accuracy. Reconstruction algorithms can be used to generate images of any desired plane.

CR - Computed radiography (see also DR) – A digital X-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is

read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.

CT - Computed tomography —The production of a tomogram by the acquisition and computer processing of X-ray transmission data.

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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).

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DDR - Direct digital radiography (see also CR and DR) – An X-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an X-ray image. Some DDR systems use a scintillator to convert X-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert X-rays directly to charge, which is stored on the thin-film transistor.

Direct supervision – A qualified practitioner who exercises general supervision and is present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the licensed practitioner must be present in the room when the procedure is being performed.

DR - Digital radiography – An X-ray imaging method (or radiography) which produces a digital rather than film projection image. Includes both CR and DDR.

DRL - Diagnostic reference level—An investigational level, set as a standard by a recognized body (e.g., ACR, AAPM, NCRP, or similar), used to identify unusually high radiation doses for common diagnostic medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

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Dose length product - The indicator of the integrated radiation dose from a complete CT examination. It addresses the total scan length by the following formula:

$$\underline{DLP (mGy-cm) = CTDI_{vol} (mGy) \times \text{scan length (cm)}}$$

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Electronic brachytherapy – A modality of 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. X-ray devices specifically designed and solely used to treat skin cancer lesions are not considered electronic brachytherapy devices under this definition and shall meet the applicable parts of Title 25 pertaining to registration and use.

Emerging technology – An innovative medical technology that uses an ionizing radiation source.

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FGI - Fluoroscopic-guided interventional procedures – An interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site; to monitor the procedure; and to control and document therapy.

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General supervision – The overall direction and control of a qualified practitioner but who is not required to be physically present during the performance of the procedure.

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Health physics – An application of physics concerned with protection of people and the environment from the biological effects of radiation.

IORT - Intraoperative radiation therapy— 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.

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Image intensifier—[A device]An image receptor with electronic amplification, installed in its housing, which instantaneously converts an X-ray pattern into a corresponding light image of higher energy density.

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Kerma — A measure of energy transferred from radiation to matter and means kinetic energy released per unit mass. It is related to, but not the same as, absorbed dose. Unit of measure is gray.

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Medical physics – An application of physics that addresses the needs of medicine or healthcare. Subfields of medical physics include the following:

- (i) Therapeutic medical physics.**
- (ii) Diagnostic medical physics or imaging.**
- (iii) Nuclear medical diagnostic or molecular imaging and therapy.**
- (iv) Medical health physics or radiation protection.**

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Performance phantom – A device specifically approved by the OMP/QE for evaluation of operational conformance with tolerances established by the OMP/QE or manufacturer.

Personal supervision – A qualified practitioner who exercises general supervision and is present in the room or adjacent control area during the performance of the procedure.

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OMP - Qualified medical physicist – An individual who is competent to independently provide clinical professional services in one or more of the subfields of medical physics or health physics.

(i) A QMP meets the following credentials:

- (A) Is certified in the field of medical physics, radiological physics, medical health physics or health physics by an appropriate national certifying body recognized by the Department.**
- (B) Complies with the certifying body's requirements for continuing education and recertification.**
- (C) Provides clinical professional services and practices only in the subfields of medical physics or health physics, consistent with the individuals training and**

experience, and in accordance with his or her respective certifying body's code of ethics.

(ii) An individual who does not meet the requirements of subparagraph (i) must meet each of the following credentials to qualify as a QMP:

- (A) Has earned a master's and/or doctoral degree in physics, medical physics, biophysics, radiological physics, health physics, or equivalent disciplines from an accredited college or university.
- (B) Has 3 years of documented relevant clinical training and experience in each of the subfields noted in the medical physics definition, under the supervision of a QMP who is qualified to practice in the same subfield(s), for each of the areas in which the individual intends to practice.
- (C) Completes the continuing education requirements of an applicable certifying body of the subfields of medical physics or health physics in which the individual practices.

(iii) An individual who has been practicing as a QMP in one or more of the subfields of medical physics or health physics for at least 5 years prior to (Editor's Note: The blank refers to the date of adoption of this proposal) is exempt from the requirements of subparagraphs (i) and (ii). Documentation of at least 5 years of practicing as a QMP in one or more of the subfields of medical physics or health physics must be maintained for each of the subfields of medical physics or health physics in which the individual practices. As of (Editor's Note: The blank refers to the date of adoption of this proposal), an individual who qualifies as a QMP under this subsection must meet the continuing education requirements in subparagraph (ii)(C).

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SRDL - Substantial radiation dose level – An appropriately selected dose used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically relevant injury in an average patient.

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Unintended dose – A radiation dose in diagnostic or interventional X-ray resulting from an error in procedure or equipment malfunction.

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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.

(1) The operator or the individual who supervises the operation of a high-risk procedure, that is, a procedure that could likely exceed skin doses of 200 rads (2 Gy), shall have additional instruction, including certification or registration in the applicable specialty by a professional organization recognized by the Department. Continuing education for high-risk procedures shall occur, at a minimum, every two years.

(2) Continuing education for all other (low-risk) procedures shall occur, at a minimum, every four years.

(c) **[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:

(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.

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(l) 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; **diagnostic reference levels**; image recording, processing and viewing; **image quality and artifacts**; and maintenance and modifications to the quality assurance program. **For CT, each study shall be checked. If an artifact is present,**

the registrant shall take corrective action as appropriate. Records shall be maintained by the registrant for inspection by the Department for [3]5 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) Neither the X-ray tube housing nor the collimating device may be handheld during the exposure **unless specifically designed to be handheld.**

(n) 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 reports).

(o) The registrant shall maintain records documenting the OMP's qualifications and compliance with continuing education requirements.

§ 221.16 Training, competency and continuing education.

(a) **Training and competency.** The registrant shall ensure that:

(1) **An individual who operates X-ray equipment during diagnostic or interventional procedures or supervises the operation of X-ray equipment during a procedure are trained and competent in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:**

- (i) **Basic properties of radiation.**
- (ii) **Units of measurement.**
- (iii) **Sources of radiation exposure.**
- (iv) **Methods of radiation protection for patients and others.**
- (v) **Biological effects of radiation exposure.**
- (vi) **Facility-specific and modality-specific X-ray equipment.**
- (vii) **Facility-specific and modality-specific image recording and processing.**
- (viii) **Patient exposure and positioning.**
- (ix) **Facility-specific and modality-specific procedures.**
- (x) **Facility-specific and modality-specific quality assurance.**

- (xi) Facility-specific and modality-specific dose reduction, monitoring, and recording procedures.
 - (xii) Units of measurement and dose, including DAP (dose-area product) values and air kerma.
 - (xiii) Factors affecting fluoroscopic outputs.
 - (xiv) High-level control options.
 - (xv) Dose management including dose reduction techniques, monitoring, and recording.
 - (xvi) Principles and operation of the specific fluoroscopic X-ray system(s) to be used.
 - (xvii) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically.
 - (xviii) Applicable State and Federal regulations.
- (2) All individuals who operate X-ray equipment during potentially high-dose diagnostic or interventional procedures or supervise the operation of X-ray equipment during these procedures are registered or credentialed and privileged in the applicable specialty by a professional organization recognized by the Department.
- (3) Documentation demonstrating compliance with this section is maintained for inspection by the Department.
- (b) Continuing education.
- (1) The registrant shall ensure that all individuals who operate X-ray equipment during diagnostic or interventional procedures or supervise the operation of X-ray equipment during a procedure complete continuing education in biological effects of radiation, quality assurance and quality control, and radiation safety, including concepts for minimizing patient and occupational dose and emerging technologies.
 - (i) An individual who does not perform potentially high-dose procedures shall complete continuing education every 4 years.
 - (ii) An individual who performs potentially high-dose procedures shall complete continuing education every 2 years. In addition to the topics outlined above, the continuing education shall include facility and X-ray unit-specific methods to manage patient dose.

- (2) Documentation of continuing education shall be maintained for inspection by the Department for 5 years.

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.21. Diagnostic equipment requirements.

(a) Diagnostic systems incorporating one or more certified components shall comply with 21 CFR 1020.30—1020.33.

(b) New equipment must comply with 21 CFR § 1010.2 (relating to certification).

§ 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

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

TABLE II

<i>[Design operating range (Kilovolts peak)</i>	<i>Measured potential (Kilovolts peak)</i>	<i>Minimum half-value layer (millimeters of aluminum)</i>	
		<i>Specified dental systems*</i>	<i>All other X-ray systems</i>
Below 51	30	1.5	0.3
	40	1.5	0.4

	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1]

<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.]

(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.

§ 221.35a. Fluoroscopic X-ray systems.

(a) General requirements. 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) Operator qualifications. **In addition to the applicable sections of these regulations, the operation of a fluoroscopic X-ray system for clinical purposes shall be limited to:**

(1) A licensed practitioner working within his or her scope of practice.

(2) A Department-recognized radiologist assistant (RA) working within his or her scope of practice and under the direct supervision of a licensed practitioner working within his or her scope of practice.

(3) An individual who passed the American Registry of Radiologic Technologists (ARRT) exam or equivalent, holds a valid certification and is under the personal supervision of a licensed practitioner working within his or her scope of practice.

(4) A medical resident, radiologist assistant or radiologic technology student, in training who is under the personal supervision of a licensed practitioner working within his or her scope of practice.

(c) OMP evaluations. Fluoroscopic equipment shall be evaluated by or under the direction of a QMP within 30 days after installation and after any maintenance of the system that may affect the exposure rate. Thereafter, the evaluations shall be made at intervals not to exceed 14 months from the date of the prior evaluation by or under the direction of a QMP. At a minimum these evaluations shall include:

(1) A measurement of entrance exposure rates over a representative range of attenuating materials, including those that are expected to drive the system to maximum output in all modes clinically used, including fluoroscopy, high-level control, acquisition, digital subtraction and cineradiography (CINE), when available. Measurements shall be performed with a calibrated dosimetry system per manufacturer recommendations not to exceed 2 years and records maintained for 5 years for inspection by the Department. These measurements shall be made as follows:

(i) For systems without automatic exposure control, by utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system.

(ii) For systems with automatic exposure control, by utilizing sufficient attenuating material in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system.

(2) A measurement and verification of compliance of maximum air kerma rate for fluoroscopy and high-level control, if available.

(3) An evaluation of high-contrast resolution and low-contrast resolution in both fluoroscopic and spot-film modes.

(4) An evaluation of the operation of the 5-minute timer, warning lights, interlocks and collision sensors.

(5) An evaluation of the beam quality and collimation in the fluoroscopy and spot-film modes.

(6) An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays.

(7) An evaluation of any changes that may impact patient and personnel protection devices.

(d) Additional requirements for facilities performing FGI procedures.

(1) The registrant utilizing FGI studies shall establish and implement written procedures, or procedures documented in an electronic reporting system, that include the following:

(i) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes.

(ii) A method to be used to monitor patient radiation dose during FGI procedures.

(iii) Dose notification levels, as appropriate, at which the physician is notified for actions that may be taken for patient safety.

(iv) SRDL values referencing or consistent with nationally recognized standards.

(v) Actions to be taken for cases when an SRDL is exceeded, which may include patient follow-up.

(vi) A review of the established procedures at an interval not to exceed 12 months.

(2) Records of policies and procedures shall be maintained for inspection by the Department. If the registrant revises a policy or procedure, documentation shall be maintained that includes the justification for the revision.

(3) A record of radiation output information shall be maintained so the radiation dose to the skin may be estimated in accordance with established protocols. The record shall include the following:

(i) Patient identification.

(ii) Type and date of examination.

(iii) Identification of the fluoroscopic system used.

(iv) Peak skin dose, cumulative air kerma or dose area product used if the information is available on the fluoroscopic system.

(4) If the peak skin dose, cumulative air kerma or dose area product are not displayed on the fluoroscopic system, records shall include other information necessary to estimate the radiation dose to the skin in accordance with established protocol or the following, as necessary:

(i) Fluoroscopic mode, such as high-level or pulsed mode of operation.

(ii) Cumulative fluoroscopic exposure time.

(iii) Number of films or recorded exposures.

(5) The registrant shall maintain records for 5 years for inspection by the Department.

§ 221.57 Facilities using CR or DR.

(a) When exposure indicators are available, the facility shall establish, document and post an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented.

(b) Facilities shall establish and follow an image QC program in accordance with the recommendations of a QMP, the system manufacturer, or a nationally recognized organization.

(c) Facilities other than dental, podiatric and veterinary shall complete phantom image evaluation using a phantom approved by a QMP, system manufacturer, or the Department. The evaluation shall be completed on a quarterly basis and include, at a minimum, the following:

(1) Artifacts.

(2) Spatial resolution.

(3) Contrast/noise.

(4) Workstation monitors.

(5) Exposure indicator constancy.

(d) In addition to subsections (a) - (c), CR facilities shall erase all CR cassettes, at a minimum, on a weekly basis.

(e) Dental and podiatric facilities shall maintain and operate photostimulable storage phosphor (PSP) and DDR systems in accordance with manufacturer specifications.

(f) The facility shall maintain records for 5 years for inspection by the Department.

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

(a) Fluoroscopic systems used solely for radiation therapy simulations [**shall**]**must only** comply with § § 221.35a**(a) and (b)**, 221.37a, 221.40a and 221.41a. The requirements in § 221.41a (relating to fluoroscopic timer) may also be satisfied if a means is provided to indicate the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.

(b) CT units used solely for therapy simulations shall comply with § § 221.202(**[f]h**)(1), (7) and (8) and 221.203 (relating to equipment requirements; and facility design requirements).

§ 221.63. Therapy imaging guidance systems.

(a) **The QMP shall develop QC procedures and tolerances following nationally recognized standards or those recommended by the manufacturer.**

(b) **If a system is a CBCT, it should conform to the requirements of § 221.64.**

§ 221.64. CBCT.

(a) **The following radiation measurements must be evaluated annually and as soon as practical after any component repair or change which, in the opinion of the QMP, may affect the performance of the CBCT unit:**

(1)Beam alignment. The X-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than 2 percent of the SID, when the axis of the X-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the X-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID.

- (2) A performance evaluation shall be performed by or under the direct supervision of a QMP. The evaluation shall follow nationally recognized standards and tolerances or those recommended by the manufacturer. The evaluation shall be performed within 30 days of initial installation, at intervals not to exceed 14 months, and within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality.**
- (3) The registrant shall document and implement QC guidelines in accordance with nationally recognized guidelines.**
- (4) The registrant shall implement and document a policy addressing deviations from established protocols.**
- (5) In addition to the requirements of § 221.16, the CBCT X-ray system shall only be operated by an individual who has been specifically trained in its operation.**
- (6) The facility shall maintain documentation of the established standards and tolerances and testing results for 5 years for inspection by the Department.**
- (b) The CBCT operator shall have instructions on performing routine QC, including the use of the CBCT phantom(s); a schedule of routine QC appropriate for the system; allowable variations set by the QMP, if required, for the indicated parameters; and the results of at least the most recent routine QC completed on the system.**
- (c) CBCT systems capable of operating at no greater than 100 kV or 20 mA are exempt from an annual QMP performance evaluation.**

§ 221.65. X-ray attenuation systems.

CT systems solely used to calculate attenuation coefficients or for image registration in nuclear medicine studies must meet the requirements in §§ 221.202 – 221.205 unless otherwise exempted below:

- (1) Section 221.202(a) (relating to accreditation) is exempted.**
- (2) Instead of § 221.204(a) (relating to performance evaluations), the registrant shall complete a performance evaluation on the CT system following the recommendations of a QMP, the system manufacturer, or a nationally recognized organization at intervals not to exceed 14 months.**
- (3) Section 221.204(a)(4)(xi) (relating to dosimetry) is exempted.**

(4) Instead of § 221.204(b) (relating to routine QC), checks shall be established and documented by the registrant following nationally recognized guidelines or those recommended by the manufacturer.

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.71. Equipment requirements.

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(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) - (m).

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.201. Definitions.

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Alert value – A dose index value (e.g., CTDI_{vol} (mGy) or of DLP (mGy-cm)) that is set by the registrant/licensee to trigger an alert to the operator prior to scanning within an ongoing examination. The alert value represents a value well above the registrant’s or licensee’s established range for the examination that warrants more stringent review and consideration before proceeding.

* * * * *

CTDI—Computed tomography dose index—

(i) 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.

$$CTDI = \frac{1}{NT} \int_{-\infty}^{\infty} D(z) dz ,$$

where:

z = Position along a line perpendicular to the tomographic plane.

D(z) = Dose at position z.

T = Nominal tomographic section thickness (cm).

N = Number of tomograms produced in a single scan.

(ii) 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.

CTDI_{vol} - Volume Computed Tomography Dose Index— A radiation dose parameter derived from the CTDI_w (weighted or average CTDI given across the field of view), that is:

$$CTDI_{vol} = (N)(T)(CTDI_w)/I, \text{ where}$$

N = number of simultaneous axial scans per X-ray source rotation,

T = thickness of one axial scan (mm), and

I = table increment per axial scan (mm).

Thus,

$$\underline{CTDI_{vol} = (1 / pitch) \times CTDI_w}$$

CTDWw - Weighted Computed Tomography Dose Index– The estimated average CTDI100 across the field of view (FOV). The equation is:

$$\underline{CTDI_w = 1/3 CTDI_{100,center} + 2/3 CTDI_{100,edge}}$$

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 or 32 cm acrylic phantom. CTDI_w uses CTDI₁₀₀ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

CTDI₁₀₀ - The accumulated multiple scan dose at the center of a 100-mm scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The CTDI₁₀₀ requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of CTDI₁₀₀, the integration limits are +50 mm, which corresponds to the 100-mm length of the commercially available “pencil” ionization chamber. CTDI₁₀₀ is acquired using a 100-mm long, 3-cc active volume CT “pencil” ionization chamber and the two standard CTDI acrylic phantoms (16 and 32 cm diameter) and a stationary patient table.

* * * * *

CT dosimetry phantom - The phantom used for determination of the dose delivered by a CT X-ray system.

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

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

where:

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

μ_x = Linear attenuation coefficient of the material of interest.

μ_w = Linear attenuation coefficient of water.

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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]

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Notification value - A dose index value (e.g. CTDI_{vol} (mGy) or DLP (mGy-cm)) that is set by the registrant to trigger a notification to the operator prior to scanning when the dose index exceeds the established range for the examination.

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§ 221.202. Equipment requirements.

(a) Accreditation. All diagnostic CT X-ray systems shall be accredited by an accrediting organization recognized by the Department effective within one year from acquisition of first patient use.

(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 and readily accessible to the operators.

(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 $\mu\text{C}/\text{kg}$) 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.

(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 $0 \pm [10.0]7.0$ CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the **[qualified expert]QMP**, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the **[qualified expert]QMP** 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, **or those established by the QMP.**

(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.

§ 221.204. [Radiation measurements and p]Performance evaluations, routine QC, and surveys.

(a) ***[Radiation measurements]Performance evaluations.***

(1) **[The CTDI or MSAD along the two axes specified in paragraph (2)(ii) 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 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 after any component repair or change which in the opinion of the qualified expert may affect the performance of the CT unit:

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

(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.]

The performance evaluation of the CT X-ray system shall be performed by or under the direction of a QMP.

(2) Evaluation standards and tolerances shall be established by a QMP and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT X-ray system.

(3) The performance evaluation of a CT X-ray system shall be performed after initial installation and before use on human patients. Thereafter, the evaluation shall be made at intervals not to exceed 14 months.

(4) The performance evaluation shall include, but not be limited to, the following:

(i) Geometric factors and alignment, including alignment light accuracy and table incrementation accuracy.

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

(iii) Slice thickness.

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

(v) CT number accuracy.

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

(vii) A review of the results of the routine QC required under subsection (b).

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

(ix) A review of commonly used CT protocols along with the evaluation for appropriateness of dose and image quality, in comparison with the older protocols. The review should be by the QMP along with the radiologist and lead CT technologist.

(x) For dosimetry, a review of the protocols deemed appropriate by the QMP which could result in significant doses. This review shall include acquisition and reconstruction parameters, and radiation dose. At a minimum, the QMP shall review the following clinical protocols, if performed, at intervals not to exceed 14 months:

(A) Pediatric head (1-year-old).

(B) Pediatric abdomen (5-year-old; 40-50 lb. (about 20 kg).

(C) Adult head.

(D) Adult abdomen (70 kg).

(E) Brain perfusion.

(xi) Review DRL, notification values and alert values for the procedures reviewed under subparagraph (x) of this paragraph.

(xii) Review actions to be taken when a dose alert value is exceeded including patient follow-up.

(xiii) Review the process determining who has access and authority to make changes to the protocol management systems, including a policy or procedure to prevent inadvertent or unauthorized modifications to a CT protocol.

(5) A performance evaluation shall be made within 30 days after any change or replacement of components which, in the opinion of the QMP, could cause a change in the radiation output or image quality.

(6) Dose measurements of a CT unit shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system must have been calibrated within the preceding 2 years.

(b) [Performance evaluations]Routine QC.

(1) Written [performance evaluation]routine QC procedures shall be developed by a [qualified expert]QMP. These procedures shall be available for review by the Department.

(2) The [performance evaluation]routine QC procedures shall include[at least], at a minimum, 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.

(iii) Artifact evaluation.

[(v) Acceptable tolerances.]

(3) The [performance evaluation]routine QC shall be performed at intervals not to exceed [3 months]one week [by the qualified expert or an individual designated by the qualified expert].

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

(5) [Performance evaluations]Routine QC 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) Records of the performance evaluations shall be maintained for inspection by the Department for at least 4 years.]

(c) Radiation protection 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 QMP. 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 QMP, and a copy of the report shall be made available to the Department upon request.

(d) Records.

Records of the performance evaluations and surveys shall be maintained for inspection by the Department for at least 5 years. Routine QC records shall be maintained for at least 1 year.

§ 221.205. Operating procedures.

(a) In addition to the training requirements in § 221.16, a CT X-ray system shall be operated only by an individual who has been specifically trained in its operation.

[(a)b] [Information]The following information shall be readily available [at the control panel regarding the operation and performance evaluations of the system. The information shall include the following]to the CT operator:

(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 and a process for reporting deviations in protocols including a schedule of [performance evaluations]routine QC 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.**

(2) **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)c] 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] QMP, the use of the CT X-ray system on patients shall be limited to those uses permitted by established written instructions of the [qualified expert] QMP.

CHAPTER 223. VETERINARY MEDICINE

§ 223.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons utilizing radiation sources in veterinary medicine. Persons who use radiation sources for veterinary medicine, **or research on animals**, shall comply with this chapter. The requirements of this chapter are in addition to and not in substitution for other applicable requirements of this article.

ADMINISTRATIVE CONTROLS

§ 223.10. Registrant responsibilities.

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

(b) A person who operates an X-ray system shall be instructed adequately about safe X-ray operating procedures and be competent in the safe use of X-ray equipment. The instructions shall include the subjects listed in Chapter 221 Appendix A (relating to determination of competence), and the person shall receive continuing education at least every 4 years in radiation safety, biological effects of radiation, species-specific positioning techniques, QA and QC.

(c) Written safety procedures and rules shall be available at the 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.

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

(1) No individual or extremity may be positioned in the useful beam unless required to conduct the procedure.

(2) 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.

(3) Each person shall be protected from stray radiation by protective aprons or whole protective barriers of at least 0.25 millimeter lead equivalent or shall be positioned so that no 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.

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

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

(2) An individual 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 used.

(3) The person who has to hold the animal or image receptor shall be protected as required in subsection (d).

(f) The registrant shall have a QA program. The QA 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 QA program shall address radiation safety to personnel and modifications to the QA program.

(g) Neither the X-ray tube housing nor the collimating device may be handheld during the exposure unless specifically designed and shielded to be handheld.

(h) CT systems used solely for non-human imaging are exempt from §§ 221.202 – 221.205.

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 rules of general applicability to domestic licensing of byproduct material) and 10 CFR Part 31 Section 31.11 (relating to general license for use of byproduct material for certain in vitro clinical or laboratory testing).

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:

* * * * *

(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 required by 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[.]:

* * * * *

(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]5 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.

* * * * *

(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 are 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. **The operator of an accelerator used for healing arts shall 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]90** days after the initial order is issued to obtain any or all parts of the accelerator.

(1) The application shall be filed in duplicate on a form prescribed by the Department and shall be accompanied by the required fee as described in § 218.11(d) (relating to registration, renewal of registration and license fees).

(2) The application shall contain pertinent information to permit the Department to evaluate the accelerator facility for compliance with the act and this article.

(b) In addition to the notification requirement in subsection (a), a person who intends to install an accelerator shall notify the Department within 30 days after the initial construction or installation begins.

(c) **[Except as provided in subsection (d), a person may not operate a particle accelerator after October 3, 1998, without having obtained a license from the Department.]**

(d) **A registrant possessing an accelerator before October 3, 1998, may continue to operate the accelerator provided an application for a license is filed in duplicate with the Department by October 4, 1999.]**

[(e)]The Department may, after the filing of an original application, and before the expiration of the license, require further information to enable the Department to determine whether the application will be granted or denied or whether a license will be modified or revoked.

[(f)](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]except** interlocks, shall be checked at least every 3 months for proper functioning and shall be repaired as necessary. **Interlocks shall be checked at least annually.** Results of these checks and records of repairs shall be maintained for **[4]5** years at the accelerator facility for inspection by the Department.

* * * * *

(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.

§ 228.36. Radiation monitoring requirements.

An independent radiation monitoring system shall be provided so that the individuals entering or present in a potential very high radiation area become aware of the existence of the hazard. Independent radiation monitors shall be tested for response **[at least annually]**daily and after each servicing or repair.

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.

(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.

(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).

§ 228.75. Calibrations.

* * * * *

(e) The calibration of the therapy beam shall include, but is not limited to, the following determinations:

(1) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and beam limiting device (collimator) system.

(2) The absorbed dose rate at various depths (depth dose) and beam profile measured in water and the beam flatness and symmetry for the range of field sizes used, for each beam energy, **and if applicable, for each Flattening Filter Free (FFF) mode.**

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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 Department, but meeting the definition of radioactive material in the United States Department of Transportation regulations in 49 CFR 173.403, shall conform to the standards and requirements of those regulations.