RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 215—221, 223—228, 230 AND 240]

Radiological Health

The Environmental Quality Board (Board) amends Chapters 215—221, 223—228, 230 and 240. The final-form rulemaking is necessary to improve the clarity, coherency and effectiveness of the requirements for the safe use of radiation sources. The final-form rulemaking describes requirements in more detail, provides flexibility for compliance where possible and corrects cross references to other parts of the regulations and the regulations of the United States Nuclear Regulatory Commission (NRC). The final-form rulemaking also addresses equity in the collection of fees to support program activities.

This order was adopted by the Board at its meeting of April 20, 2004.

A. *Effective Date*

The final-form rulemaking is effective upon publication in the *Pennsylvania Bulletin*.

B. *Contact Persons*

For further information, contact Louis Ray Urciuolo, Chief, Division of Radiation Control, P. O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 787-3720; or Scott Perry, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This final-form rulemaking is available on the Department of Environmental Protection's (Department) website: www.dep.state.pa.us.

C. *Statutory Authority*

This final-form rulemaking is being made under the authority of sections 301 and 302 of the Radiation Protection Act (act) (35 P. S. §§ 7110.301 and 7110.302), which directs the Department to develop and conduct comprehensive programs for the registration, licensing, control, management, regulation and inspection of radiation sources and radiation source users, and delegates to the Board the power to adopt the regulations of the Department to implement the act, and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), which authorizes and directs the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background of the Amendments*

In 2001, the Board updated chapters of its radiological health regulations to provide for compatibility with other states and to serve as a basis for the Commonwealth to assume authority from the NRC for radioactive material licensees in this Commonwealth under the Agreement State program. These updates were published at 31 Pa.B. 5239 (September 15, 2001) and 31 Pa.B. 6280 and 6282 (November 17, 2001), and they incorporate by reference certain Nationally recognized radiation safety standards of the NRC. Incorporating by reference results in a single, consistent set of standards applicable to the radiological safety of not only radioactive materials, but radiation-producing machines as well.

As a result of the revisions, many sections in Article V (relating to radiological health) now reference text that no longer exists and appear as "reserved." The final-form rulemaking replaces the orphaned references with the corresponding regulations incorporated by reference and imposes no new requirements. Other amendments address the recent changes to the NRC regulations that are incorporated by reference, most notably the comprehensive revision to 10 CFR Part 35 (relating to the medical use of by-product material). Licensees of this Commonwealth are already subject to these requirements by virtue of their radioactive material licenses and incorporation by reference to 10 CFR (relating to energy). Several amendments clarify the wording of existing regulations and their requirements, in most part involving radiation-producing machines. Section 216.6(c) (relating to transfer and disposal obligations) requires persons involved in certain commercial and service activities involving radiation-producing machines to register their activities with the Department. There is a new § 216.2a (relating to registration of radiation-producing machine service providers), along with the provision for registration fees and reporting requirements in § 216.2b (relating to reporting and recordkeeping requirements for registered radiation-producing machine service providers). In Chapter 218 (relating to fees), a new annual fee of $100 covers the activities and costs regarding §§ 216.2a and 216.2b. The omission of a fixed fee in the previous rulemaking has been corrected to cover the activities and costs related to licenses issued under fee category 3Q in Chapter 218, Appendix A (relating to fees for radioactive material licenses). Overall, the final-form rulemaking improves the clarity and effectiveness of the regulations, corrects cross references and adds flexibility for compliance where possible.

As required by section 301(c)(14) of the act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed and final-form rulemakings and to advise the Department prior to submittal to the Board. On October 24, 2002, and November 20, 2002, the RPAC reviewed the proposed rulemaking and endorsed it at the latter meeting.

The Department also met with staff of the Department of Health (DOH) to discuss their role in assisting the Department in reviewing applications to perform "healing arts screening." Changes were made to § 221.13(b) (relating to information to be submitted by persons requesting approval to conduct healing arts screening) to better define the role of the DOH in providing assistance to the Department.

The proposed rulemaking was adopted by the Board on July 15, 2003, and published with a 30-day public comment period at 33 Pa.B. 4393 (August 30, 2003). A single comment was received from the Independent Regulatory Review Commission (IRRC). This comment has been addressed in the final-form rulemaking and is described in Section E.

On November 13, 2003, the RPAC reviewed the draft final-form rulemaking and the response to IRRC's comment on the proposed rulemaking. The RPAC endorsed the final-form rulemaking for presentation to the Board.

E. *Summary of Changes to the Proposed Rulemaking*

§ 215.24 (relating to human use)

The current reference in subsection (b) to 49 Pa. Code Part I, Subpart A (relating to professional and occupational affairs) spans over 30 chapters, not all of which have requirements that are relevant to radiological health professionals. IRRC requested that the relevant chapters be listed. This was done in the final-form rulemaking.

In light of the change to subsection (b) and at the recommendation of the RPAC, the reference to Departmental approval in subsection (d) of the proposed rulemaking was replaced by reference to Department of State (DOS) accreditation requirements in the final-form rulemaking, since the DOS has accreditation requirements for professional training.

The RPAC also noted that trainees would require authorized supervision. As a result, subsection (d) in the final-form rulemaking also clarifies the requirement for supervision of trainees.

§ 216.4a (relating to expiration and termination of certificates of registration)

A typographical error was corrected in subsection (c)(1) by removing an extra hyphen.

§ 219.228 (relating to reports of medical reportable events for radiation-producing machine therapy)

In subsection (a)(3), a legacy reference to "misadministration" was discovered. This concept no longer exists having been replaced by "medical event." The reference to "misadministration" was deleted in the final-form rulemaking as it had been from the rest of this article.

§ 227.14 (relating to personnel requirements)

In subsection (a)(3), instruction and competence in emergency procedures was added. The preamble to the proposed rulemaking described this amendment, but the wording failed to appear in Annex A of the published text of the proposed rulemaking.

F. *Summary of Comments and Responses on the Proposed Rulemaking*

There was only one comment to the proposed rulemaking. This was from IRRC regarding specification of the applicable chapters of the DOS regulations referenced in § 215.24. The Department implemented that recommendation as discussed in Section E of this preamble.

G. *Benefits, Costs and Compliance*

Benefits

The primary benefit of the final-form rulemaking is to correct cross references that are no longer accurate as a result of changes in previous rulemakings and changes in the regulations of the NRC incorporated by reference. This is part of a comprehensive effort to provide additional clarity to the regulations for radiological health to benefit the regulated community. Existing requirements are clarified in many areas, including: registration, licensing, fee assessment, radiation-producing machine service providers, healing arts screening and human research, determination of competence for auxiliary medical personnel, filtration, radiation safety committees, medical event reporting and radiation therapy simulators. The new requirement for concurrence by the DOH for approval of certain healing arts screening provides additional health protection by bringing in a competent independent third-party regulator. There are also additional benefits to the regulated community in more flexible requirements for personnel exposure to X-rays, quality assurance programs, leak testing of sealed sources, general licenses for sealed source devices, cabinet radiography and shielded room radiography operations. Eligibility for lower fees for general license devices has been extended. In fairness to registrants and the recovery of fees to support this program, the time that an X-ray machine from outside this Commonwealth may be operated before being subjected to registration and payment of associated fees is reduced. Radiation-producing machine service providers are assessed a registration fee to cover the cost of oversight of their activities and a minimum annual fee for accelerators greater than 50 MeV is created.

Compliance Costs

The majority of amendments represent clarifications, as opposed to changes in requirements, so there is no additional cost to comply. Implementing the more flexible requirements for personnel exposure to X-rays, quality assurance programs, leak testing of sealed sources, general licenses for sealed source devices, cabinet radiography and shielded room radiography operations will add no additional costs and generally reduce existing costs. The fixed category 3Q annual general license fee of $315 is identical to what should have been set by formula in footnote 3, Chapter 218, Appendix A, but was omitted from the previous rulemaking that set the current fees in Chapter 218, Appendix A and is less than what the formula based fee will be without this final-form rulemaking. The final-form rulemaking will also permit extension of this fee to certain current category 3P licensees resulting in a fee decrease for about 70 licensees who currently pay $750 annually. There is also a new annual fee of $100 for registration of radiation-producing machine service providers. To the regulated community as a whole, the savings from switching some category 3P licenses to category 3Q is expected to be offset in an equal amount by the new radiation-producing machine service provider registration fee. These fees will cover the cost of administering the program, as required by section 401 of the act (35 P. S. § 7110.401).

Compliance Assistance Plan

The majority of amendments clarifying references and definitions are self-explanatory. They are being made as part of compliance assistance. Guidance is being prepared to explain acceptable alternate methods of determining personnel exposure to X-rays and acceptable X-ray quality assurance programs. Outreach and assistance will be provided by regional inspectors and technical staff of the central office Radiation Control Division.

Paperwork Requirements

Amendments dealing with clarification of existing regulations add no additional paperwork beyond the original requirements. Regulations made more flexible may or may not result in a decrease in recordkeeping requirements depending on what options the registrant or licensee chooses. Persons providing radiation-producing machine services will be required to file a registration of activities form provided by the Department. Paperwork for reporting the details of actual services being provided is already being filed with the Commonwealth through United States Food and Drug Administration Form 2579. The application form for new general license category 3Q replaces the current license application, which requires less supporting documentation than any current category and will constitute a reduction in paperwork over the current alternative licenses.

H. *Sunset Review*

The final-form rulemaking will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 20, 2003, the Department submitted a copy of the notice of proposed rulemaking, published at 33 Pa.B. 4393, to IRRC and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on June 9, 2004, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on June 10, 2004, and approved the final-form rulemaking.

J. *Findings*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and all comments were considered.

(3) These amendments do not enlarge the purpose of the proposal published at 33 Pa.B. 4393.

(4) These amendments are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

K. *Order*

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapters 215—221, 223—228, 230 and 240, are amended by amending §§ 215.1, 215.2, 215.12, 215.14, 215.24, 215.28, 215.32, 216.1, 216.2, 216.3, 216.4a, 216.6, 216.7, 217.136, 217.141, 217.143, 217.171, 217.201, 217.202, 217.203, 218.1, 218.11, Appendix A, §§ 219.3, 219.6, 219.61, 219.228, 219.229, 220.2, 221.2, 221.11, 221.13, 221.15, 221.25, 221.29, 221.36a, 221.38a, 221.61, 221.73—221.75, 221.202, 221.204, 221.205, Appendix A, §§ 223.21, 223.22, 224.10, 224.22, 224.23, 225.1, 225.4a, 225.71, 225.73, 225.82, 225.83, 225.101—225.103, 226.3a, 227.11a, 227.12a, 227.13a, 227.14, 228.2, 228.11a, 228.12, 228.21a, 228.23a, 228.31a, 228.32a, 228.34a, 228.35, 228.37—228.39, 228.41a, 228.43, 228.44, 228.61, 228.75, 228.76, Appendix A, §§ 230.3 and 240.2; by adding §§ 216.2a, 216.2b and 219.8; and by deleting § 224.21 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson shall submit this order and Annex A to IRRC and the Senate and House Environmental Resource and Energy Committees as required by law.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(e) This order shall take effect immediately upon publication.

KATHLEEN A. MCGINTY,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 34 Pa.B. 3078 (June 12, 2004).)

Fiscal Note: Fiscal Note 7-387 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 215. GENERAL PROVISIONS

§ 215.1. Purpose and scope.

(a) This article establishes requirements for the protection of public health and safety as related to radiation sources and implements the requirements of the act.

(b) This article, except as otherwise specifically provided in the act, applies to persons who use, manufacture, produce, transport, transfer, receive, acquire, possess, own or dispose of a radiation source.

(c) A person who, when required, fails to register or obtain a license for radiation sources in the possession or control of the person, shall comply with the act or with this article.

(d) This article does not apply to the extent the person is subject to regulation by the NRC.

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and §§ 150.1, 150.2, 150.3, 150.11 and 150.20 of the CFR are incorporated by reference with the exceptions set forth in paragraphs (1)—(13). Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

(1) Sections 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated.

(2) Sections 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated.

(3) Sections 30.5, 30.6, 30.8, 30.21(c), 30.34(d) and (e)(1) and (3), 30.41(a)(6), 30.55, 30.63 and 30.64 are not incorporated.

(4) Sections 31.4 and 31.14 are not incorporated.

(5) Sections 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29 and 32.40 are not incorporated.

(6) Sections 33.8, 33.21 and 33.23 are not incorporated.

(7) Sections 34.5, 34.8, 34.121 and 34.123 are not incorporated.

(8) Sections 35.8, 35.4001 and 35.4002 are not incorporated.

(9) Sections 36.5, 36.8, 36.91 and 36.93 are not incorporated.

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

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

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

(13) Sections 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100 are not incorporated.

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

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

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

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

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

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

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

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

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

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

§ 215.2. Definitions.

The definitions in 10 CFR Chapter 1, Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and 150 are incorporated by reference in this article unless indicated otherwise. In addition, the following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

License—Permission issued by the Department in accordance with this article to possess and use radiation sources. Types of licenses are as follows:

* * * * *

(ii) *Specific license*—Written permission to possess and use radioactive material issued by the Department after the Department reviews and approves an application for the possession and use of the radiation sources.

* * * * *

Major X-ray system component—A tube housing assembly, X-ray control, X-ray high voltage generator, X-ray table, cradle, film changer, fixed cassette holder, beam limiting device, fluoroscopic or digital radiographic imaging assembly, spot film device, image intensifier or cephalometric device.

* * * * *

Qualified expert—

(i) For radiation protection, an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs; for example: individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics or those having equivalent qualifications.

(ii) For radiation therapy calibrations, an individual having, in addition to the qualifications in subparagraph (i), training and experience in the clinical applications of radiation physics to radiation therapy.

(iii) For diagnostic X-ray performance evaluations, an individual having, in addition to the qualifications of subparagraph (i), training and experience in the physics of diagnostic radiology.

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Radioactivity—The transformation of unstable atomic nuclei accompanied by the emission of radiation.

Registrant—A person who is legally obligated to register with the Department under this article and the act.

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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.

(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, 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 the Department.

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

PROHIBITIONS AND RESTRICTIONS

§ 215.24. Human use.

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

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

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

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

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

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

(b) Auxiliary personnel employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices 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) notwithstanding, human use of radiation sources is permitted by individuals enrolled in clinical training programs that satisfy the related accreditation requirements of the boards 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) to use radiation sources in the healing arts.

§ 215.28. Improper use of a monitoring device.

The deliberate exposure of, failure to use, or improper use of, an individual monitoring device or area monitoring device by an individual is prohibited.

EXEMPTIONS

§ 215.32. Exemption qualifications.

The following sources, uses and types of users are exempt from Chapters 216—221, 223—228, 230, 232 and 240:

(1) A United States Department of Energy contractor or subcontractor and an NRC contractor or subcontractor of the following categories operating within this Commonwealth to the extent that the contractor or subcontractor under contract receives, possesses, uses, transfers, owns or acquires radiation sources:

(i) Prime contractors performing work for the United States Department of Energy at United States Government-owned or controlled sites, including the transportation of radiation sources to or from the sites and the performance of contract services during temporary interruptions of the transportation.

(ii) Prime contractors of the United States Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, nuclear weapons or components thereof.

(iii) Prime contractors of the United States Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government owned vehicle or vessel.

(iv) Other prime contractors or subcontractors of the United States Department of Energy or of the NRC if the Commonwealth and the NRC jointly determine that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and that the exemption of the contractor or subcontractor is otherwise appropriate.

(2) Federal government agencies.

(3) 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 centimeters from an accessible surface. The equipment is not exempt when operated without adequate shielding during testing and servicing if radiation levels exceed those specified. Electron beam welders and electron microscopes are not exempt.

(4) Radiation-producing machines in transit or in storage incident thereto.

(5) A material, product or use specifically exempted from licensing requirements by the NRC, the Department or an agreement state or authorized for distribution to persons exempt from license requirements.

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) is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines). Accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators) and 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 address, owner or radiation safety officer or number of machines.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The date service was provided.

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

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

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

§ 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).

§ 216.4a. Expiration and termination of certificates of registration.

(a) A certificate of registration expires on the date specified on the certificate of registration. Expiration of the certificate of registration does not relieve the registrant from the requirements of this article.

(b) When a registrant decides to terminate all activities involving radiation-producing machines under the certificate of registration, the registrant shall notify the Department immediately, in writing, and request termination of the certificate of registration. This notification and request for termination of the certificate of registration shall be in accordance with subsection (c).

(c) If a registrant does not submit a renewal for a certificate of registration under § 216.4 (relating to renewal of certificate of registration), the registrant shall, on or before the expiration date specified in the certificate of registration, do the following:

(1) Terminate use of all radiation-producing machines subject to registration under § 216.2 (relating to registration of radiation-producing machines) or cease all radiation-producing machine services subject to registration under § 216.2a (relating to registration of radiation-producing machine service providers).

(2) Transfer or dispose of all radiation-producing machines subject to registration under § 216.2 in accordance with § 216.6 (relating to transfer and disposal obligations).

(3) Remit any outstanding registration or renewal of registration fees owed to the Department under § 218.11 (relating to registration, renewal of registration and license fees).

(4) Request termination of the certificate of registration in writing to the Department.

§ 216.6. Transfer and disposal obligations.

(a) A person, distributor, retailer or other agent who, by selling, leasing, lending or gifting, transfers possession of radiation-producing machines or major X-ray system components in this Commonwealth that are not otherwise reported under § 216.2b (relating to reporting and recordkeeping requirements for registered radiation-producing machine service providers), shall notify the Department within 30 days of the following information:

(1) The name and address of persons who have received the machines or components.

(2) The manufacturer, model and serial number of a machine or component transferred.

(3) The date of transfer of a radiation-producing machine or major X-ray system component.

(b) A person who disposes of a radiation-producing machine shall notify the Department within 15 days of the method of disposal used.

§ 216.7. Out-of-State radiation-producing machines.

(a) If a radiation-producing machine is brought into this Commonwealth for temporary use, the person proposing to do so or an authorized agent shall give written notice to the Department at least 2 working days before the machine enters this Commonwealth. The notice shall include the type of machine, the nature, duration and scope of use and the exact location where the machine is to be used. In addition, the person shall:

(1) Comply with this title.

(2) Supply the Department with other information as the Department may reasonably request.

(3) Not operate within this Commonwealth on a temporary basis in excess of 60 calendar days per year.

(b) If for a specific case, the 2-working-day period would impose an undue hardship, the person, upon application to the Department, may receive a waiver of this requirement.

(c) When a radiation-producing machine is brought into this Commonwealth for temporary use exceeding 60 days per year, a person possessing the machine shall register with the Department under § 216.2 (relating to registration of radiation-producing machines) within 15 days after the 60th day.

CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

§ 217.136. Exempt concentrations.

In addition to the parts of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material) incorporated by reference, the following requirements apply:

(1) Except as provided in paragraph (2), a person may receive, possess, use, transfer, own or acquire products or materials containing radioactive material introduced in concentrations less than those listed in Table 1 without possession of a license under this chapter.

(2) Except under a specific license issued under Subchapter D (relating to specific licenses to manufacture or transfer certain items containing radioactive material), or the general license under Subchapter F (relating to specific domestic licenses of broad scope for radioactive material), a person may not introduce radioactive material into a product or material for distribution to persons exempt under paragraph (1) or equivalent regulations of the NRC, an agreement state or licensing state.

TABLE 1
EXEMPT CONCENTRATIONS

Note: Some of the values in Table A-1 are presented in the computer "E" notation. In this notation, a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600 and 6E+0 represents 6×10^{0} or 6.

Element (atomic number)	*Isotope*	*Column I Gas concentration µCi/ml*	*Column II Liquid and solid concentration µCi/ml*
Actinium (89)	Ac-228		9E-04
Cesium (55)	Cs-129		3E-03
Europium (63)	Eu-154		2E-04
Gallium (31)	Ga-67		2E-03
Germanium (32)	Ge-68		9E-03
Gold (79)	Au-195		1E-02
Indium (49)	In-111		1E-03
Iodine (53)	I-123		3E-04
	I-124		4E-06
	I-125		2E-06
Lead (82)	Pb-212		2E-04
Phosphorus (15)	P-33		3E-04
Potassium (19)	K-43		2E-04
Protactinium (91)	Pa-230		2E-03
Radium (88)	Ra-223		7E-06
	Ra-224		2E-05
	Ra-228		3E-07
Radon (86)	Rn-220	1E-07	
	Rn-222	3E-08	
Sodium (11)	Na-22		4E-04
Technetium (43)	Tc-97m		4E-03
Xenon (54)	Xe-127	4E-06	
Yttrium (39)	Y-88		8E-04

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

§ 217.141. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 31 (relating to general domestic licenses for byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 31.4 and 31.14 (relating to information collection requirements: OMB approval; and criminal penalties) are not incorporated by reference.

§ 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 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:

(1) Conduct a physical inventory every 6 months to account for all sources or devices, or both, received and possessed under this section and do the following:

(i) Maintain the physical inventory records for 3 years from the date of each inventory.

(ii) Furnish a report to the Department annually showing to the extent practicable, the make, model, serial number, isotope, source activity and location of each

device. The report shall list an individual to contact regarding questions about this report.

(2) For portable devices, also comply with the following:

(i) A person who initiates acquisition, transfer or disposal of a portable device shall notify the Department within 15 days of the action. Sending a portable device for calibration, maintenance or source replacement does not constitute transfer.

(ii) Portable devices may only be used by or under the direct supervision of individuals who have been instructed in the operating and emergency procedures necessary to ensure safe use.

(iii) For each individual that the licensee permits to use a portable device, the licensee shall maintain a record showing the type of device use permitted and the basis, such as training certificates, for that authorization. An individual's record shall be kept for at least 3 years after the individual terminates association with the licensee.

(iv) Portable devices shall be secured from access by unauthorized personnel whenever the device is not under the direct surveillance of an individual authorized to use the device.

(v) The licensee shall maintain a current sign out log at the permanent storage location of the portable device. Log entries shall be available for inspection by the Department for 3 years from the date of entry. The following information shall be recorded for each portable device:

(A) The model and serial number of the device.

(B) The name of the assigned user.

(C) The locations and dates of use.

(vi) Emergency instructions shall accompany each portable device taken off the premises of the licensee.

Subchapter G. LICENSING OF SOURCE MATERIAL

§ 217.171. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 40 (relating to domestic licensing of source material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k) and (i), 40.32(d), (e) and (g), 40.33, 40.38, 40.41(d), (e)(1) and (3) and (g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 and 40.82 are not incorporated by reference.

Subchapter J. RECIPROCITY

§ 217.201. Incorporation by reference.

Except as provided in this subchapter, the requirements of 10 CFR 150.1, 150.2, 150.3, 150.11 and 150.20 are incorporated by reference.

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

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

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

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

(3) The definition of "sealed source" includes NARM.

(4) A reference to "byproduct material" includes NARM.

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

§ 217.203. Reciprocity of licenses for byproduct, source, naturally occurring and accelerator-produced radioactive material and special nuclear material in quantities not sufficient to form a critical mass.

(a) Subject to this article, a person who holds a specific license from the NRC or a state where the licensee maintains an office, issued by the agency having jurisdiction to direct the licensed activity and to maintain radiation safety records, is granted a general license to conduct the activities authorized in the licensing document within this Commonwealth, except for areas of exclusive Federal jurisdiction, for a period not in excess of 180 days in a calendar year if:

(1) The licensing document does not limit the activity authorized by the document to specified installation or locations.

(2) The out-of-State licensee notifies the Department in writing at least 3 days prior to engaging in the activity. The notification shall indicate the location, period and type of proposed possession and use within this Commonwealth, and shall be accompanied by a copy of the pertinent licensing document. If for a specific case the 3-day period would impose an undue hardship on the out-of-State licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The Department may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this subsection.

(3) The out-of-State licensee complies with this title and with the terms and conditions of the licensee's document, except terms and conditions which may be inconsistent with this title.

(4) The out-of-State licensee supplies other information as the Department may request.

(5) The out-of-State licensee does not transfer or dispose of radioactive material possessed or used under the general license provided in this subsection except by transfer to a person who is one of the following:

(i) Specifically licensed by the Department, the NRC or by another state to receive the material.

(ii) Exempt from the requirements for a license for the material under Subchapter B (relating to general provisions for radioactive material).

(b) Notwithstanding the provisions of subsection (a), a person who holds a specific license issued by the NRC or a state authorizing the holder to manufacture, transfer, install or service a device described in Subchapter C (relating to general licenses for radioactive material) within areas subject to the jurisdiction of the licensing body is granted a general license to install, transfer, demonstrate or service the device in this Commonwealth subject to the following conditions:

(1) The person files a report with the Department within 30 days after the end of a calendar quarter in which a device is transferred to or installed in this Commonwealth. The report shall identify the general

licensee to whom the device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device.

(2) The device has been manufactured, labeled, installed and serviced in accordance with the specific license issued to the person by the NRC or a state.

(3) The person assures that labels required to be affixed to the device, under regulations of the authority which licensed manufacture of the device, bear a statement that "Removal of this label is prohibited."

(4) The holder of the specific license or his intermediary shall provide a copy of the conditions of general license contained in Subchapter C to the general licensee upon transfer of the radioactive material or installation of a device containing the radioactive material.

(c) The Department may withdraw, limit or qualify its acceptance of a specific license or equivalent licensing document issued by another agency, or product distributed under the licensing document, upon determining that the action is necessary to prevent undue hazard to public health and safety or property.

(d) When a person is granted a general license under subsection (a) and subsequently exceeds the prescribed 180-day period, the person shall file a license application with the Department under Subchapter B within 30 days after the end of the 180-day period.

(e) Implementation of the requirements of this section regarding byproduct, source and special nuclear material is subject to § 217.133 (relating to 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*).

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).

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 as follows:

Type Facility	*Annual Administrative Fee*	*Annual Fee per X-ray Tube or Radiation Generating Device*
Dentists, podiatrists, veterinarians	$ 70	$35
Hospitals	$520	$35
Other Facilities	$250	$35

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

(c) Annual license fees for radioactive material are 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:

(i) Accelerators, below 50 MeV, other than for ion implantation—$1,500 for the first accelerator at the facility plus $500 for each additional unit at that facility.

(ii) Accelerators used for ion implantation—$500 plus $50 for each additional unit at the same facility.

(iii) Accelerators above 50 MeV—full cost of staff time to review license applications and conduct inspections as needed. (Hourly rate is $50 per hour). For the purpose of anticipating costs and compliance with subsections (e) and (f), a minimum annual fee of $1,500 for the first accelerator at the facility plus $500 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 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) A radiation-producing machine service provider shall pay an annual registration fee of $100.

APPENDIX A
Fees for Radioactive Material Licenses

Fee Category[5,6]	*Description*	*Annual Fee ($)*[1,2,3,4,7]
1C	Special Nuclear Material Sealed Source Gauges (X-Ray Fluorescence)	875
1D	Special Nuclear Material—Other	2,475
2B	Source Material as Shielding	450
2C	Source Material—Other (not 11e2)	8,650
3A1	Manufacturing & Distribution Commercial Broad Scope—10 CFR 30, 33	19,875
3A2	Manufacturing & Distribution Commercial Broad Scope—NARM Only	4,000
3B1	Manufacturing & Distribution Commercial Specific License—10 CFR 30	4,650
3B2	Manufacturing & Distribution Commercial Specific License—NARM Only	2,000
3C1	Manufacturing & Distribution Pharmaceuticals—10 CFR 32.72—32.74	11,650
3C2	Manufacturing & Distribution Pharmaceuticals—NARM Only	4,000
3D1	Pharmaceuticals—Distribution Only—10 CFR 32.7x	2,825
3D2	Pharmaceuticals—Distribution Only—NARM Only	2,000
3E	Irradiator—Shielded Source	2,575
3F	Irradiator—Unshielded < 10kCi	4,300
3G	Irradiator—Unshielded >= 10kCi	10,750
3I	Distribution As Exempt—No Review of Device	3,525
3J	Distribution—SSD Devices to Part 31 GLs	1,550
3K	Distribution—No Review-Exempt Sealed Source	1,300
3L1	Research & Development Broad Scope	8,300
3L2	Research & Development Broad Scope—NARM Only	2,000
3M1	Research & Development	3,650
3M2	Research & Development—NARM Only	750
3N	Services other than Leak Testing, Waste Disposal or Calibration	3,875
3O	Radiography	10,850
3P1	Other Byproduct Material	1,900
3P2	NARM Licenses not covered elsewhere	750
3Q	Generally licensed devices under § 217.143 (relating to certain measuring, gauging or controlling devices)	315
4A	Waste Storage, Processing or Disposal	Full Cost *
4B	Waste Packaging or Repackaging	8,175
4C	Waste Receipt of Prepackaged for Disposal	6,125
5A	Well Logging & Non Field Flood Tracers	7,500
5B	Well Logging Field Flood Tracer Studies	Full Cost *
6A	Nuclear Laundry	14,250
7A	Human Use—Teletherapy	11,275
7B1	Human Use—Broad Scope (except Teletherapy)	19,975
7B2	Human Use—Broad Scope (except Teletherapy)—NARM Only	2,000
7C1	Human Use—Specific License (except Teletherapy)	4,300
7C2	Human Use—Specific License (except Teletherapy)—NARM Only	750
8A1	Specifically licensed sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	875
8A2	Specifically licensed NARM sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage	200
14	Decontamination, Decommissioning, Reclamation or Site Restoration	Full Cost *
16A	Reciprocity (180 days/year)	900
16B	Reciprocity—NARM (180 days/year)	300
$SB1_5$	Small Business—Category 1	2,100
$SB2_6$	Small Business—Category 2	400

[1] A license may include as many as four noncontiguous sites at the base fee. Sites that are within 5 miles of the main Radiation Safety Office where the license records are kept will be considered contiguous. An additional fee of 25% of the base fee will be added for each noncontiguous site above four.

[2] All fees for NARM licenses will be effective upon publication of the final rules in the *Pennsylvania Bulletin*. The fees for NRC licenses that are transferred to the Commonwealth will be effective on the next license anniversary date. NARM licenses will be changed to the corresponding category of byproduct material license on the next license anniversary date

after achievement of Agreement State status and fees adjusted at that time. The NARM license categories will cease to exist one year after Agreement State status is achieved.

[3] Annual fees for categories of NRC licenses that are not included in this table will be calculated as follows: PA Fee = 0.7 (NRC Annual Fee + 0.10 NRC Application or Renewal fee).

[4] Annual fees charged to holders of transferred NRC licenses with multiple sites will not exceed the fees charged by the NRC for the same licenses in the year of transfer, provided the number of noncontiguous sites remains constant.

[5] Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of more than $350,000 and less than $5 million; Manufacturing Entities that have an average of 35—500 employees with Gross Annual Receipts of more than $350,000 and less than $5 million; Small Government Jurisdictions (including publicly supported, nonmedical educational institutions) with a population between 20,000 and 50,000; and nonmedical Educational Institutions that are not state or publicly supported and have 35—500 employees.

[6] Small Businesses Not Engaged in Manufacturing, and Small Not-For-Profit Organizations with Gross Annual Receipts of less than $350,000; Manufacturing Entities that have an average of less than 35 employees and less than $350,000 in Gross Annual Receipts; Small Government Jurisdictions (including publicly supported nonmedical educational institutions) with a population less than 20,000; and nonmedical Educational Institutions that are not state or publicly supported and have less than 35 employees.

[7] Full cost recovery licensees and licensees required to provide financial assurance for decommissioning are not eligible for reduced fees under category SB1 or SB2.

* Full cost recovery consists of a professional fee, to cover the activities and support of Department personnel, and any other additional incidental charges incurred, such as related contracted services or laboratory costs. The professional fee component (Hourly Rate) is $50 per hour. Other costs are recovered at 100% of actual cost. Invoices shall be issued by the Department at regular intervals but at least quarterly when net costs are incurred.

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

GENERAL PROVISIONS

§ 219.3. Definitions.

The following term, when used in this subchapter, has the following meaning, unless the context clearly indicates otherwise:

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.

(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.

(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:

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

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

(3) A reference to "licensee" includes registrant.

(4) A reference to "license" includes registration.

(5) A reference to "licensed" includes registered.

(6) A reference to "Department" in 10 CFR means the United States Department of Energy.

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

(8) 10 CFR Part 20, notwithstanding, exposures involving the use of X-rays may be weighted, in a manner specified by the Department, so that, with Department approval, the effective dose equivalent may be substituted for the deep dose equivalent in determining compliance with occupational exposure limits for specified groups of individuals.

§ 219.8. Requirement for a Radiation Safety Committee.

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

Subchapter E. TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) Sealed sources containing only hydrogen-3.

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

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

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

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

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

(1) The presence of 185 Bq (0.005 µCi) or more of removable contamination on any test sample.

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

(3) The presence of removable contamination resulting from the decay of 185 Bq (0.005 µCi) or more of radium.

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

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

Subchapter M. REPORTS

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

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

(1) Notify the Department by telephone within 24 hours after discovery of the event.

(2) Submit a written report to the Department within 15 days after discovery of the event. The written report shall include the licensee's or registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee or registrant notified the patient, or the patient's responsible relative or guardian (for notification purposes under this section, this person will be included in subsequent references to "the patient"), and if not, why not; and if the patient was notified, what information was provided to the patient. The report may not include the patient's name or other information that could lead to identification of the patient.

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

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

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

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

(b) The licensee or registrant shall retain a record of each medical reportable event for radiation-producing machine therapy for 5 years. The record shall contain the names of the individuals involved (including the prescrib-

ing physician, allied health personnel, the patient and the patient's referring physician), the patient's Social Security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence and the actions taken to prevent recurrence.

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

§ 219.229. Other medical reports.

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

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

§ 220.2. Posting of notices to workers.

(a) A licensee or registrant shall post current copies of the following documents:

(1) This chapter and Chapter 219 (relating to standards for protection against radiation).

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto.

(3) The operating procedures applicable to activities under the license or registration.

(4) A notice of violation involving radiological working conditions, proposed imposition of civil penalty or order issued under Chapter 215 (relating to general provisions) and response from the licensee or registrant.

(b) If posting of a document specified in subsection (a)(1), (2) or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Department Form 2900-FM-RP0003, "Notice to Employees," shall be posted by a licensee or registrant as required by this article.

(d) Department documents posted under subsection (a)(4) shall be posted within 2 working days after receipt of the documents from the Department; the licensee's or registrant's response shall be posted within 2 working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

(e) Documents, notices or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from the particular work location to which the document applies. The documents, notices or forms shall be conspicuous and shall be replaced if defaced or altered.

CHAPTER 221. X-RAYS IN THE HEALING ARTS

GENERAL PROVISIONS

§ 221.2. Definitions.

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

* * * * *

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and preferentially absorb selected radiation.

Filtration—The amount of material placed in the useful beam to modify the radiation's characteristics, typically expressed in terms of millimeters of aluminum or copper equivalent.

* * * * *

Half-value layer (HVL)—

(i) The thickness of specified material which attenuates the exposure rate by 1/2 when introduced into the path of a given beam of radiation. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(ii) The term is used to describe the penetrating ability of the radiation.

Healing arts screening—The testing of human beings using X-ray machines for the detection or evaluation of health indications when the tests are not specifically and individually ordered for the purpose of diagnosis or treatment by a licensed practitioner of the healing arts legally authorized to prescribe the X-ray tests.

* * * * *

Protective glove—A glove incorporating radiation absorbing materials.

Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

* * * * *

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

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

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

(c) A chart, 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 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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; image recording, processing and viewing; and maintenance and modifications to the quality assurance program. Records shall be maintained by the registrant for inspection by the Department for 3 years. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

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

§ 221.13. Information to be submitted by persons requesting approval to conduct healing arts screening.

(a) The Department will consider efficacy as a factor in evaluating healing arts screening procedures. In its review, the Department will consider National medical organization consensus statements as well as peer reviewed scientific and medical literature that addresses the efficacy of the proposed screening procedures. The review may also consider relevant information from appropriate Federal agencies. For procedures that result in an individual organ dose or deep dose equivalent greater than 1 mSv (100 mrem) to a screened individual the Department will consult with the Department of Health (DOH) for assistance in reviewing the efficacy of the proposed procedures but the final decision will remain that of the Department. The DOH will have access to all relevant materials when rendering its review.

(b) A person requesting that the Department approve a healing arts screening program shall submit in writing the following information for evaluation by the Department. If information submitted to the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) The diseases or conditions for which the X-ray examinations are to be used.

(3) The description in detail of the X-ray examinations proposed in the screening program.

(4) A description of the population to be examined in the screening program—age, sex, physical condition and other appropriate information.

(5) An evaluation of all known alternate methods that could achieve the goals of the screening program and why these methods are not used in preference to the proposed X-ray examinations.

(6) An evaluation by a qualified expert of the X-ray systems to be used in the screening program. The evaluation shall show that the systems satisfy the requirements of this article. The evaluation shall include a measurement of patient entrance exposures and calculation of the maximum shallow dose, deep dose equivalent and organ dose from the X-ray examinations to be performed.

(7) A description of the diagnostic X-ray quality control program.

(8) A copy of the technique chart for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(9) The qualifications of all individuals who will be operating the X-ray systems.

(10) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(11) The name, address and qualifications of the individual who will interpret the screening procedure results.

(12) A description of the information and procedure for advising the individuals screened of the potential for false positive or negative results and the implications for the patient; the procedure for recording informed consent for the procedure following disclosure of this information; and the procedure for advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and further medical needs indicated.

(13) A description of the procedures for the retention or disposition of the diagnostic images, data and other records pertaining to the X-ray examination.

(14) Mammography facilities shall comply with 21 CFR Part 900 (relating to mammography).

(15) An approximation of the frequency of screening activities and duration of the entire screening program.

§ 221.15. Use of X-rays in research on humans.

(a) Registrants conducting research using X-rays involving human subjects are exempted from the requirements of this section if the research is conducted, funded, regulated or supported by a Federal agency which has implemented the Federal policy for the protection of human subjects or if the research is carried out in an institution which conducts other Federally funded or supported human research and follows all Federal requirements for protocol review and research subject protection.

(b) If not exempted under subsection (a), a person shall submit, in writing, the following information and evaluation to the Department and receive approval by the Department before conducting the research. If the information submitted to the Department becomes invalid or outdated, the person shall immediately, in writing, notify the Department.

(1) The name and address of the applicant and, if applicable, the names and addresses of agents within this Commonwealth.

(2) A description of the population to be examined in the research program, age, sex, physical condition and other appropriate information.

(3) An evaluation of all known alternate methods that could achieve the goals of the research program and why these methods are not used in preference to the X-ray examinations.

(4) An evaluation by a qualified expert of the X-ray system to be used in the research program. This evaluation shall show that the system satisfies the requirements of this article. The evaluation shall include a projected measurement of individual and cumulative patient exposures from the X-ray examinations to be performed.

(5) A description of the diagnostic X-ray quality control program.

(6) A copy of the technique chart which specifies the information for the X-ray examination procedures to be used if exposure parameters are set manually or a description of how exposure parameters are determined.

(7) The qualifications of all individuals who will be operating the X-ray system.

(8) The qualifications of the physician who will be supervising the operators of the X-ray systems. The extent of supervision and the method of work performance evaluation shall be specified.

(9) The name, address and qualifications of the individual who will interpret the data.

(10) A copy of the research protocol authorized by a committee consisting of at least three qualified persons. At least one of the committee members shall be knowledgeable in radiation effects on humans.

(11) The provisions for independent institutional review.

(c) Proposed subjects or their legal representative shall sign a statement acknowledging that they have been informed of their anticipated radiation exposure and possible consequences arising from this exposure.

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.25. Beam quality.

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

TABLE I

Filtration Required vs. Operating Voltage

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

TABLE II

Design operating range (Kilovolts peak)	*Measured potential (Kilovolts peak)*	*Minimum half-value layer (millimeters of aluminum)*	
		*Specified dental systems**	*All other X-ray systems*
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

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.

§ 221.29. Kilovoltage (kV) accuracy.

(a) For variable kV units, the kV output may not vary from the set-indicated value by more than 10% over the range of technique factors normally used. Discrepancies of more than 10% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

(b) For fixed kV units, the kV output may not vary from the set-indicated value by more than 20% over the range of technique factors normally used. Discrepancies of more than 20% between set-indicated and measured kV values shall be investigated by a qualified expert or service agent and appropriate action taken.

§ 221.36a. Limitation of useful beam of fluoroscopic equipment.

(a) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-to-image receptor distance.

(b) The X-ray tube used for fluoroscopy may not produce X-rays unless a barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(c) A means shall be provided for stepless (continuous) adjustment of the field size.

(d) The minimum field size at the greatest source to image receptor distance shall be containable in a square of 5 centimeters by 5 centimeters unless otherwise provided in 21 CFR 1020.32(b) (relating to fluoroscopic equipment).

(e) Equipment may not be operated at a source to skin distance less than 30 centimeters or as required under 21 CFR 1020.32(g).

(f) The width of the X-ray field in the plane of the image receptor may not exceed that of the visible area of the image receptor by more than 3% of the source to image receptor distance. The sum of the excess length and the excess width may not be greater than 4% of the source to image receptor distance.

(g) For rectangular X-ray fields used with a circular image receptor, the error in alignment shall be determined along the length and width dimensions of the X-ray field which passes through the center of the visible area of the image receptor.

(h) Compliance with subsections (a)—(g) shall be determined with the beam axis perpendicular to the plane of the image receptor.

(i) Spot-film devices shall meet the following additional requirements:

(1) A means shall be provided between the source and the patient for adjustment of the X-ray field size to the size of the portion of film which has been selected on the spot-film selector.

(2) The adjustments shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the film.

(3) The total misalignment of the edges of the X-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the X-ray field in the plane of the image receptor may not exceed 3% of the source-to image receptor when adjusted for full coverage of the selected portion of the image receptor.

(4) The sum, without regard to sign, of the misalignment along any two orthogonal dimensions, may not exceed 4% of the source to image receptor distance.

(5) The center of the X-ray field in the plane of the film shall be aligned with the center of the film within 2% of the source to image receptor distance.

§ 221.38a. Entrance exposure rate.

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

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

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

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

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

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

(c) *Frequency of output measurements.* Output measurements to show compliance with this section shall be made at least annually and after maintenance that could affect the output of the machine.

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

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

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

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

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

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

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

(a) Fluoroscopic systems used solely for radiation therapy simulations shall comply with §§ 221.35a, 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)(1), (7) and (8) and 221.203 (relating to equipment requirements; and facility design requirements).

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.73. Surveys.

(a) A facility shall have a survey made by, or under the direction of, a qualified expert. The survey shall also be done after a change in the facility or equipment which might cause a change in radiation levels.

(b) The qualified expert or radiological physicist shall report the survey results in writing to the individual in charge of the facility and a copy of the report shall be maintained by the registrant for inspection by the Department. The facility shall be operated in compliance with limitations indicated by the survey.

§ 221.74. Calibration.

(a) The calibration of an X-ray system shall be performed at intervals not to exceed 1 year and after a change of replacement of components which could cause a change in the radiation output.

(b) The calibration of the radiation output of the X-ray system shall be performed by or under the direction of a qualified expert for radiation therapy calibration who is physically present at the facility during the calibration.

(c) The calibration of the radiation output of an X-ray system shall be performed with a calibrated instrument. The calibration of the instrument shall be traceable to a National standard. The instrument shall have been calibrated within the preceding 2 years.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

(e) The calibration of the X-ray system shall include, but is not limited to, the following determinations:

(1) The exposure rates for each combination of field size, technique factors, filter and treatment distance used.

(2) The degree of congruence between the radiation field and the field indicated by the localizing device if a device is present.

(3) An evaluation of the uniformity of the largest radiation field used.

(f) Records of calibration performed under this section shall be maintained by the registrant for at least 5 years after completion of the calibration.

(g) A copy of the most recent X-ray system calibration shall be available at the control panel.

§ 221.75. Spot checks.

Spot checks shall be performed on X-ray systems capable of operation at greater than 150 kVp. The spot checks shall meet the following requirements:

(1) The procedures shall be in writing and shall have been developed by a qualified expert for radiation therapy calibration.

(2) If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a radiological physicist within 15 days.

(3) The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the X-ray system.

(4) The spot-check procedure shall specify the frequency at which tests or measurements are to be per-

formed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in § 221.74 (relating to calibration).

(5) The procedure shall also note conditions which require that the system be recalibrated under § 221.74.

(6) Records of spot-check measurements performed under this section shall be maintained by the registrant for 5 years following the measurement.

(7) Spot check measurements shall be performed using a dosimetry system that has been calibrated under § 221.74(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated under § 221.74(c). The alternative calibration method shall have been performed within the previous year and after each servicing that may have affected the system calibration.

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.202. Equipment requirements.

(a) *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) *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) *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) *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) *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 μC/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) *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 ± 10.0 CT number units. The facility's performance phantom shall be utilized, with the technique factors specified by the qualified expert, to confirm compliance. In instances when a CTN of 0 for water is inappropriate, as in 3D treatment planning, the qualified expert may establish and maintain an equivalent value.

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

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

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

(8) A distance of at least 100 millimeters measured in a CT image shall agree with the actual distance to within ± 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 performance evaluations.

(a) *Radiation measurements.*

(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 effect 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.

(b) *Performance evaluations.*

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

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

(i) Noise.

(ii) Contrast scale.

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

(iv) Mean CT number for water.

(v) Acceptable tolerances.

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

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

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

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

§ 221.205. Operating procedures.

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

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

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

(3) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

(b) If the radiation measurements and performance evaluation of the CT X-ray system indicates that a system operating parameter has exceeded a tolerance established by the qualified expert, 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.

APPENDIX A
DETERMINATION OF COMPETENCE

The registrant shall ensure that individuals who operate diagnostic X-ray equipment have received training on the subjects listed in this appendix. The individual shall be trained and competent in the general operation of the X-ray equipment, and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

(1) Basic properties of radiation.

(2) Units of measurement.

(3) Sources of radiation exposure.

(4) Methods of radiation protection.

(5) Biological effects of radiation exposure.

(6) X-ray equipment.

(7) Image recording and processing.

(8) Patient exposure and positioning.

(9) Procedures.

(10) Quality assurance.

(11) Regulations.

CHAPTER 223. VETERINARY MEDICINE

RADIOACTIVE MATERIAL

§ 223.21. In vitro testing.

A veterinarian who uses radioactive material for in vitro testing shall comply with 10 CFR 31.11 (relating to general license for use of by-product material for certain in vitro clinical or laboratory testing) but is exempt from 10 CFR Part 20 Subpart K (relating to waste disposal).

§ 223.22. Sealed sources.

A veterinarian who uses sealed 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.

CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 224.10. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 35 (relating to medical use of byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 35.8, 35.4001 and 35.4002 (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

Subchapter B. OTHER REQUIREMENTS

§ 224.21. (Reserved).

§ 224.22. Authorization for calibration, transmission and reference sources.

Notwithstanding the incorporation by reference of 10 CFR 35.65 (relating to authorization for calibration, transmission, and reference sources), a licensee authorized for medical use radioactive materials may not receive, possess or use radium in total quantity of 3.7 MBq (100 µci) or more for check, calibration, transmission and reference use except as specifically authorized by the Department.

§ 224.23. Decay-in-storage.

Notwithstanding the incorporation by reference of 10 CFR Part 35 (relating to medical use of byproduct material), a licensee may hold sealed sources of radioactive material with a physical half-life of up to 300 days for decay-in-storage before disposal in ordinary trash.

CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subchapter A. GENERAL PROVISIONS

§ 225.1. Purpose and scope.

(a) This chapter establishes radiation safety requirements for persons utilizing radiation sources for industrial radiography. Licensees and registrants who use radiation sources for industrial radiography shall comply with this chapter. The requirements of this chapter are in addition to and not in substitution for other applicable requirements in this article, in particular, the requirements and provisions of Chapters 215, 217—220, 228 and 230.

(b) Persons using only radiation-producing machines for industrial radiographic operations need not comply with § 225.2a (relating to incorporation by reference) unless otherwise specified in Subchapter B (relating to radiation-producing machines).

(c) This chapter does not apply to the use of radiation sources for medical diagnosis or therapy.

§ 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, 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 ADMINISTRATIVE REQUIREMENTS

§ 225.71. Definitions.

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

Cabinet radiography—Industrial radiography conducted in an enclosure or cabinet (not a room) so shielded that doses to individual members of the public at every location on the exterior meet the limitations specified in 10 CFR 20.1301 (relating to dose limits for individual members of the public).

Cabinet X-ray system—An X-ray system with the X-ray tube installed in an interlocked enclosure or cabinet, designed to exclude personnel from its interior during operation.

(i) Included are all X-ray systems designed primarily for the inspection of baggage or packages.

(ii) An X-ray tube used within a shielded part of a building or X-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet X-ray system.

Certified cabinet X-ray system—An X-ray system which has been certified under 21 CFR 1010.2 (relating to certification) as being manufactured and assembled under 21 CFR 1020.40 (relating to cabinet x-ray systems).

DRD—Direct reading dosimeter—

(i) As used in this subchapter, means an "individual monitoring device" (see 10 CFR 20.1003 (relating to definitions)) that does not require additional processing to measure an individual's dose.

(ii) The term also includes the direct reading personnel (individual) monitoring devices known as pocket dosimeter, pocket ionization chamber and electronic personal dosimeter (EPD).

Field radiography—A location where radiographic operations are conducted (onsite or offsite) other than those designated as a permanent radiographic facility.

Industrial radiography—An examination of the structure of materials by nondestructive methods, including fluoroscopy, which utilizes radiation producing machines to make radiographic images.

NVLAP—National Voluntary Laboratory Accreditation Program.

Permanent radiographic installation—A shielded installation or structure designed or intended for radiography in which radiography is regularly performed.

Personal supervision—The provision of guidance and instruction to a radiographer's assistant given by a radiographer who is:

(i) Physically present at the site.

(ii) In visual contact with the radiographer's assistant while the assistant is using radiation sources.

(iii) In proximity so that immediate assistance can be given if required.

Personnel dosimeter—As used in this subchapter, means any of the "individual monitoring devices" (see 10 CFR 20.1003) that shall be processed and evaluated to generate a permanent record of an individual's dose, for example, a film badge, thermoluminescent dosimeter (TLD) or optically stimulated luminescent dosimeter (OSLD).

RSO—radiation safety officer—An individual who ensures that, in the daily operation of the registrant's or licensee's radiation safety program, activities are being performed in accordance with approved procedures and are in compliance with Department requirements.

Radiographer—An individual who performs radiographic operations or an individual in attendance at a site where radiation producing machines are being used who personally supervises industrial radiographic operations.

Radiographer's assistant—An individual who, under the personal supervision of a radiographer, uses radiation producing machines or radiation survey instrumentation.

Radiographer trainee—An individual who is in the process of becoming a radiographer's assistant or a radiographer.

Radiographic operations—The activities associated with a radiation producing machine during use of the machine, to include surveys to confirm adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

Safety device—As applied to radiation-producing machines in this subchapter, a device or component that causes the unit to de-energize or interrupt the beam.

Shielded room radiography—Industrial radiography that is conducted in an enclosed room, the interior of which is not occupied during radiographic operations.

§ 225.73. Training of personnel.

(a) A registrant may not allow an individual to act as a radiographer or radiographer's assistant unless that individual meets the requirements of § 225.74 (relating to training and testing).

(b) Persons performing field radiography shall comply with the training requirements in Appendix A (relating to subjects to be covered during the instruction of radiographers).

GENERAL TECHNICAL REQUIREMENTS

§ 225.82. Operating requirements.

(a) When radiographic operations are performed at a location other than a permanent radiographic installation, a minimum of two radiographic personnel shall be present to operate the X-ray device. At least one of the radiographic personnel shall be qualified as a radiographer. The other individual may be either a radiographer, a radiographer's assistant or a radiographer trainee.

(b) Other than a radiographer, or a radiographer's assistant who is under the personal supervision of a radiographer, an individual may not manipulate the controls or operate the equipment used in industrial radiographic operations.

(c) At each job site, the following shall be supplied by the registrant or licensee:

(1) The appropriate barrier ropes and warning signs.

(2) At least one operable, calibrated radiation survey instrument.

(3) For each worker requiring monitoring, an individual personnel dosimeter that is processed and evaluated by an NVLAP processor.

(4) An operable, calibrated direct reading dosimeter with a range of zero to 51.6 μC/kg (200 milliroentgen) for each worker requiring monitoring.

(d) An industrial radiographic operation may not be performed if any of the items in subsection (c) is not available at the job site or is inoperable.

§ 225.83. Records required at field radiography sites.

Each registrant or licensee conducting radiographic operations at a field radiography site shall maintain and have available for inspection by the Department at that job site, the following records or documents:

(1) The certificate of registration, license or equivalent document which authorizes radiographic operations, and radiographic personnel certifications.

(2) Operating and emergency procedures.

(3) Relevant regulations of the Department.

(4) Survey records required under this chapter for the period of operation at the site.

(5) Daily direct reading dosimeter records for the period of operation at the site.

(6) The current radiation survey meter calibration records for meters in use at the site. Acceptable records include tags or labels that are affixed to the survey meter.

RADIATION-PRODUCING MACHINE REQUIREMENTS

§ 225.101. Cabinet X-ray systems and baggage/package X-ray systems.

(a) Cabinet and baggage/package X-ray systems that are certified under 21 CFR Chapter I, Subchapter J (relating to radiological health) shall also meet the requirement of 21 CFR 1020.40 (relating to cabinet X-ray systems).

(b) A cabinet X-ray system may not be energized unless all openings are securely closed and exposure to radiation from the system does not exceed the limits in 10 CFR 20.1301 (relating to dose limits for individual members of the public). Each access door to the cabinet shall have an interlock that terminates the exposure whenever the door is opened. The enclosure shall be shielded so that every location on the exterior meets the conditions for an unrestricted area.

(c) A registrant may not permit an individual to operate a cabinet X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the X-ray system and has demonstrated competency in the use of the cabinet X-ray system and an understanding of the operating procedures.

(d) The registrant shall perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 and maintain records of these surveys for inspection by the Department for 3 years:

(1) Upon installation of the equipment.

(2) Following a change in the initial arrangement, relocation of the unit, or following any maintenance requiring the disassembly or removal of any shielding component.

(3) When a visual inspection reveals an abnormal condition.

(e) The registrant shall test on-off switches, interlocks and safety devices at intervals not exceeding 1 year, and make repairs as necessary to maintain all safety features including warning labels. Records of these tests shall be maintained for inspection by the Department for 3 years.

(f) Cabinet X-ray systems and baggage/package X-ray systems are exempt from all other provisions of this chapter.

§ 225.102. Shielded room X-ray radiography.

(a) A room used for shielded room X-ray radiography shall be shielded so that every location on the exterior meets conditions for an unrestricted area and the only access to the room is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

(b) The operator shall conduct a physical radiation survey to determine that the radiation source is deenergized prior to each entry into the radiographic exposure area.

(c) As an alternative to subsection (b), the registrant may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels.

(d) With the exception of the provisions of §§ 225.4a and 225.84 (relating to radiation safety program; and operating and emergency procedures), shielded room radiography is exempt from all other provisions of this chapter.

§ 225.103. Field site radiography.

(a) The operator shall conduct a physical radiation survey to determine that the radiation source is deenergized prior to each entry into the radiographic exposure area. Survey results and records of the boundary location shall be maintained and kept available for inspection by the Department for 3 years.

(b) Mobile or portable radiation producing machines shall be physically secured to prevent tampering or removal by unauthorized personnel.

CHAPTER 226. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

GENERAL

§ 226.3a. Abandonment of a sealed source.

In addition to incorporation by reference of 10 CFR 39.15 and 39.77 (relating to agreement with well owner or operator; and notification of incidents and lost sources; abandonment procedures for irretrievable sources), the requirements of § 78.111 (relating to abandonment) shall also be met.

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

ANALYTICAL X-RAY EQUIPMENT

§ 227.11a. Equipment requirements.

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

(1) A description of the various safety devices that have been evaluated.

(2) The reason each of these safety devices cannot be used.

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Radiation surveys using appropriate radiation survey equipment shall be performed on the analytical X-ray

unit upon installation, after moving the unit to a new location, and after maintenance or repair requiring the disassembly or removal of a local component or radiation shielding.

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

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

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

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

§ 227.12a. Area requirements.

(a) The source housing construction shall be of a type that when all the shutters are closed and the source is in any possible operating mode, the leakage radiation will not be in excess of 2.5 milliroentgens (.645 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(b) The X-ray generator shall have a protective cabinet constructed so that the leakage radiation will not be in excess of 0.5 milliroentgen (.129 μC/kg) per hour at a distance of 5 centimeters from the housing surface.

(c) The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in 10 CFR 20.1301 (relating to dose limits for individual members of the public). For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.

(d) To show compliance with subsections (a)—(c), the registrant shall perform radiation surveys:

(1) Upon installation of the equipment and at least every 12 months thereafter.

(2) Following a change in the initial arrangement, number or type of local components in the system.

(3) Following maintenance requiring the disassembly or removal of a local component in the system.

(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when a local component in the system is disassembled or removed.

(5) When a visual inspection of the local components in the system reveals an abnormal condition.

(6) When personnel monitoring devices show a significant increase in radiation exposure over the previous monitoring period or the readings are approaching the radiation dose limits.

(7) When the machine is operated in a manner other than the routine manner specified in § 227.13a (relating to operating requirements).

(e) The registrant shall test and inspect all safety and warning devices at least annually to insure their proper operation. If a safety or warning device is found to be malfunctioning, the machine shall be removed from service until repairs to the malfunctioning device are completed.

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

(g) The equipment used to conduct the surveys and tests required in this chapter shall be adequate to measure the radiation produced by the radiation source.

§ 227.13a. Operating requirements.

(a) Operating procedures shall be written and available to the analytical X-ray equipment operators. These procedures shall include instructions for sample insertion and manipulation, equipment alignment, routine maintenance and data recording procedures which are related to radiation safety. An individual may not operate analytical X-ray equipment in a manner other than that specified in the operating procedures unless the individual has obtained written approval from the radiation safety officer.

(b) An individual may not bypass or otherwise circumvent a safety device unless the individual has obtained the prior written approval of the radiation safety officer. The radiation safety officer may grant the permission only if the following conditions are met:

(1) The radiation safety officer establishes administrative controls and procedures to assure the radiation safety of individuals working around the system.

(2) The period for the bypass of the safety device is not more than 30 days unless written permission is obtained from the Department for a longer period.

(3) A readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words containing a similar warning, is placed on the radiation source housing.

(c) Except as specified in subsection (b), an operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops may not be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Emergency procedures shall be written and posted near the equipment and shall list the names and telephone numbers of personnel to contact. The emergency procedures shall also provide information necessary to de-energize the equipment, such as location and operation of the power supply or circuit breakers.

§ 227.14. Personnel requirements.

(a) An individual may not operate or maintain analytical X-ray equipment unless the individual has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment.

(2) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions necessary if the devices are absent or bypassed.

(3) Written operating and emergency procedures for the equipment.

(4) Symptoms of an acute localized radiation exposure.

(5) Procedures for reporting an actual or suspected exposure.

(6) Use of survey and personnel monitoring equipment.

(7) The applicable regulations of this article and those incorporated by reference.

(b) Finger or wrist personnel monitoring devices shall be provided to and shall be used by:

(1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device as described in § 227.12a(c) (relating to area requirements).

(2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when a local component in the analytical X-ray system is disassembled or removed or when safety devices are bypassed.

(c) Reported dose values may not be used for the purpose of determining compliance with 10 CFR 20.1201 (relating to occupational dose limits for adults) unless they are evaluated by a qualified expert.

(d) The registrant or licensee shall notify the Department within 5 days of a suspected radiation overexposure to an individual from analytical X-ray machines. This notification is required even if subsequent investigation reveals no actual over-exposure actually occurred.

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

GENERAL PROVISIONS

§ 228.2. Definitions.

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

Accelerator or *particle accelerator*—A radiation-producing machine that imparts kinetic energies of one of the following:

(i) One-tenth of one MeV or greater to electrons if the electron beam is brought out of the evacuated region of the unit.

(ii) One MeV or greater to electrons if the electrons are utilized for X-ray production.

(iii) One-tenth of one MeV or greater to other particles.

Applicator—A structure which determines the extent of the treatment field at a given distance from the virtual source.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

Beam scattering filter—A filter used to scatter a beam of electrons.

Central axis of the beam—A line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

Dose monitoring system—A system of devices for the detection, measurement and display of quantities of radiation.

Dose monitor unit—A unit response from the dose monitoring system from which the absorbed dose can be calculated.

Existing equipment—Systems manufactured on or before October 3, 1998.

Field flattening filter—A filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

Field size—The configuration of the radiation field along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50% isodose line.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and remove radiation that does not contribute to the efficacy of the useful beam.

Isocenter—A fixed point in space located at the center of the smallest sphere through which the central axes of the beams pass.

Leakage radiation—Radiation emanating from the source assembly except for the following:

(i) The useful beam.

(ii) Radiation produced when the exposure switch or timer is not activated.

Moving beam therapy—Radiation therapy with relative displacement of the useful beam and the patient during irradiation.

New equipment—Systems manufactured after January 1, 1985.

Normal treatment distance—

(i) For isocentric equipment, the isocenter.

(ii) For nonisocentric equipment, the target to patient skin distance along the central axis as specified by the manufacturer.

Particle accelerator—See the definition of "accelerator."

Phantom—A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Primary dose monitoring system—A system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been attained.

Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Radiation head—The structure from which the useful beam emerges.

Secondary dose monitoring system—A system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Shadow tray—A device attached to the radiation head to support auxiliary beam limiting material.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Stationary beam therapy—Radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subsystem—A combination of two or more components of an accelerator.

Target—The part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

Tube housing assembly—The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Virtual source—The nominal location of either the first scattering foil (for equipment providing electrons only) or the photon focal spot (for equipment capable of delivering both photons and electrons).

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.

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.

(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.

§ 228.12. Information and maintenance record and associated information.

The licensee shall maintain records of surveys, calibrations, maintenance, machine malfunctions and modifications performed on the accelerators, including the names of persons who performed the services. The licensee shall keep these records for inspection by the Department for 5 years.

NOTIFICATION AND LICENSING PROCEDURES

§ 228.21a. Notification and license requirements.

(a) A person who intends to purchase, construct or acquire an accelerator shall notify the Department of this intent by filing an application for a specific license within 30 days after the initial order is issued to obtain any or all parts of the accelerator.

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

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

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

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

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

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

(f) The application shall be signed by the applicant or licensee or an individual authorized by the applicant or licensee.

(g) A license issued under this chapter may not be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, to any person except through submission of a written request by the licensee to the Department for approval.

§ 228.23a. Expiration and termination of a license.

(a) Except as provided in § 228.24a (relating to renewal of licenses), and subject to subsection (d)(5)(ii), a specific license expires on the date specified in the license. A license is effective for 5 years.

(b) A licensee shall notify the Department in writing when the licensee decides to permanently discontinue activities involving the accelerator authorized under the license and request termination of the license. The notification and request for termination shall include the reports and information specified in subsection (d)(3)—(5). The licensee is subject to subsections (d) and (e), as applicable, until termination.

(c) At least 30 days before the expiration date specified in a specific license, the licensee shall do one of the following:

(1) Submit an application for license renewal under § 228.24a.

(2) Notify the Department in writing if the licensee decides not to renew the license.

(d) If the licensee does not submit an application for license renewal under § 228.24a on or before the expiration date specified in the license, the licensee shall:

(1) Terminate the use of, and transfer or dispose of the accelerator.

(2) Properly dispose of incidental radioactive material generated by the operation of the accelerator.

(3) Submit a completed Department Form 2900-PM-RP0314, "Certificate of Disposition of Materials," describing the disposition of materials in paragraph (2).

(4) Submit a radiation survey report to confirm the absence of radioactive materials or establish the levels of residual radioactive contamination unless the Department determines a radiation survey report is not necessary. This report shall include:

(i) The levels of beta and gamma radiation (in units of microrems or microsieverts, or in microrads or micrograys per hour) at 1 centimeter and gamma radiation at 1 meter from surfaces, levels of removable and fixed alpha, beta and gamma contamination on surfaces (in becquerels or microcuries per 100 square centimeters), and concentrations of contamination in soils (in units of picocuries or becquerels per gram) or in water (in units of picocuries or becquerels per liter) where soil and water concentrations are reported.

(ii) The survey instrumentation used to perform these surveys.

(5) Proceed with one of the following:

(i) Submit a certification that no detectable radioactive contamination was found if no residual contamination attributable to activities conducted under the license is detected. If the information submitted under this section

is adequate, the Department will notify the licensee in writing that the license is terminated.

(ii) Continue the license in effect beyond the expiration date. If necessary, with respect to possession of residual radioactive material present as contamination if detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall comply with subsection (e), in addition to the information submitted under paragraphs (3) and (4) and this paragraph, the licensee shall submit a plan for decontamination, if necessary.

(e) A licensee who possesses residual radioactive material under subsection (d)(5)(ii) following the expiration date specified in the license, shall:

(1) Limit activities involving radioactive materials to those activities which are solely related to decontamination and other activities related to preparation for release for unrestricted use.

(2) Continue to control entry to restricted areas until the restricted areas are suitable for release for unrestricted use and until the Department notifies the licensee in writing that the license is terminated.

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.31a. Limitations.

(a) The facility shall operate within the terms and conditions of the license issued for the operation of the accelerator.

(b) A licensee may not permit an individual to act as an operator of an accelerator until the individual:

(1) Has been instructed in radiation safety and has demonstrated an understanding thereof.

(2) Has received copies of and instruction in this chapter and Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations), pertinent license conditions and the licensee's operating and emergency procedures and demonstrated understanding thereof.

(3) Has demonstrated competence to use the accelerator, related equipment and survey instruments which will be utilized in that individual's assignment.

(c) The radiation safety officer shall have the authority to restrict or terminate operations at an accelerator facility if the action is necessary to minimize danger to health and safety, property or the environment.

§ 228.32a. Shielding and safety design requirements.

(a) The licensee shall consult a qualified expert for radiation protection concerning the shielding design of an accelerator installation.

(b) An accelerator facility shall have primary and secondary protective barriers that are necessary to assure compliance with 10 CFR Part 20, Subpart D (relating to dose limits for individual members of the public).

§ 228.34a. Accelerator controls and interlock systems.

(a) Instrumentation, readouts and controls on the accelerator control console shall be clearly identified and easily discernible.

(b) Entrances into a target room or high radiation areas shall have interlocks that meet the requirements of 10 CFR Part 20, Subpart G (relating to control of exposure from external sources in restricted areas) and 10 CFR 20.1902 (relating to posting requirements). If the radiation beam is interrupted by a door opening, it shall be possible to reinitiate the radiation exposure only by closing the door first and then by manual action at the control panel.

(c) When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the interlock position, and lastly at the main control console.

(d) Safety interlocks shall be fail-safe, that is, designed so that a defect or component failure in the interlock system prevents operation of the accelerator.

(e) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. The cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

§ 228.35. Operating procedures.

(a) Accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) An interlock may not be used to turn off the accelerator beam except in an emergency or for testing the interlock.

(c) Each safety and warning device, including interlocks, shall be checked at least every 3 months for proper functioning and shall be repaired as necessary. Results of these checks and records of repairs shall be maintained for 4 years at the accelerator facility for inspection by the Department.

(d) In the event of a malfunction of a safety or warning device, the accelerator may not be operated unless appropriate interim precautions are instituted to provide equivalent protection.

(e) If it is necessary to intentionally bypass a safety interlock system or component thereof, the action shall be the following:

(1) Authorized in writing by the radiation safety officer.

(2) Recorded in a permanent log and a notice posted at the accelerator operator's position.

(3) Terminated as soon as possible.

(f) A copy of the current operating and emergency procedures shall be maintained in the accelerator operator area.

(g) For accelerators used in the healing arts, operating procedures shall meet the following requirements:

(1) No individual other than the patient is in the treatment room during treatment of a patient.

(2) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(3) The system may not be used in the administration of radiation therapy unless the requirements of this chapter have been met.

(4) A medical reportable event for radiation-producing machine therapy, as defined in § 219.3 (relating to definitions), shall be reported as required under § 219.228

(relating to reports of medical reportable events for radiation-producing machine therapy).

(5) An individual who operates an accelerator system shall be instructed adequately in the safe operating procedures and be competent in the safe use of the equipment. The instructions shall include, but not be limited to, items included in Appendix A (relating to determination of competence). There shall be continuing education in radiation safety, biological effects of radiation, quality assurance and quality control.

§ 228.37. Production of radioactive material.

(a) A licensee who produces radioactive material incidental to the operation of an accelerator shall comply with the general license requirements of § 217.144 (relating to incidental radioactive material produced by a particle accelerator).

(b) A licensee possessing radioactive material intentionally produced by bombarding nonradioactive material with the accelerator beam shall comply with the specific license requirements of Chapter 217 (relating to licensing of radioactive material).

§ 228.38. Radiation safety surveys.

(a) Prior to first use, a facility shall have a survey made by, or under the direction of, a qualified expert for radiation protection. A survey shall also be done after a change in the facility or equipment, including a relocation of the equipment within the irradiation or treatment room.

(b) The qualified expert shall report the survey results in writing to the individual in charge of the facility and a copy of the initial report shall be maintained by the licensee for inspection by the Department for the life of the facility. Other survey reports shall be maintained for inspection by the Department for 4 years. The facility shall be operated in compliance with limitations indicated by the survey.

(c) The report of the survey results shall include:

(1) The date of the measurements.

(2) The reason the survey is required.

(3) The manufacturer's name, model number and serial number of the therapeutic radiation machine accelerator.

(4) The instrument used to measure radiation levels.

(5) A plan of the areas surrounding the treatment room that were surveyed.

(6) The measured dose rate at several points in each area expressed in microsieverts or millirems per hour.

(7) The calculated maximum level of radiation over a period of 1 year for each restricted and unrestricted area.

(8) The signature of the individual who conducted or is responsible for conducting the survey.

(d) If the survey required by subsection (a) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 10 CFR 20.1201 (relating to occupational dose limits for adults) or 10 CFR 20.1301 (relating to dose limits for individual members of the public), the licensee shall do the following:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with Chapter 219 (relating to standards for protection against radiation).

(2) Perform the survey required by subsection (a) again.

(3) Prepare and submit the report required by subsection (a). The report shall also include:

(i) The results of the initial survey.

(ii) A description of the modification made to comply with this section.

(iii) The results of the second survey.

§ 228.39. Records.

In addition to the requirements of 10 CFR Part 20, Subpart L (relating to records), the licensee shall maintain:

(1) Records of the tests and safety and warning devices described in § 228.35 (relating to operating procedures).

(2) The surveys described in §§ 228.32a and 228.38 (relating to shielding and safety design requirements; and radiation safety survey).

(3) The radiation monitoring equipment calibrations and repairs of that equipment under § 228.36 (relating to radiation monitoring requirements).

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL AND RESEARCH ACCELERATORS

§ 228.41a. Warning devices.

(a) A location designated as a high radiation area and an entrance to the location shall be equipped with easily observable warning lights that operate only when radiation is being produced.

(b) A high radiation area shall meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

§ 228.43. Radiation surveys.

(a) Periodic surveys shall be made to determine the amount of airborne radioactivity present in areas of airborne hazards.

(b) Periodic smear surveys shall be made to determine the amount of contamination in target and other pertinent areas.

(c) Area surveys shall be made in accordance with the written procedures established by a qualified expert for radiation protection or the radiation safety officer of the accelerator facility.

(d) Records of surveys shall be kept current and on file at an accelerator facility. Records of surveys shall be maintained as described in 10 CFR Part 20, Subpart L (relating to records).

§ 228.44. Ventilation systems.

(a) A licensee shall control the concentration of radioactive material in air to meet the requirements of 10 CFR 20.1204 (relating to determination of internal exposure).

(b) A licensee may not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which does not meet the requirements of 10 CFR 20.1301 (relating to dose limits for individual members of the public). Every reasonable effort shall be made to maintain releases of radioactive material to uncontrolled areas as far below these limits as practicable. Compliance with this section shall be demonstrated as described in 10 CFR 20.1302 (relating to compliance with dose limits for individual members of the public).

RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

§ 228.61. Leakage radiation to the patient area.

(a) New equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the dose due to leakage radiation, including X-rays, electrons and neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size, may not exceed 0.1% of the maximum dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to, but not exceeding, 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

(2) For each system, the licensee shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records for 5 years on leakage radiation measurements for inspection by the Department.

(b) Existing equipment shall meet the following requirements:

(1) For operating conditions producing maximum leakage radiation, the absorbed dose due to leakage radiation, including neutrons, at any point on a circle of 2 meters radius centered on and perpendicular to the central axis of the beam 1 meter from the virtual source, may not exceed 0.1% of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(2) For each system, the licensee shall have available the leakage radiation data existing at the positions specified in paragraph (1) for the specified operating conditions. The licensee shall maintain records on radiation leakage for 5 years for inspection by the Department.

§ 228.75. Calibrations.

(a) The calibration of systems subject to this subchapter shall be performed in accordance with an established calibration protocol. The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. Other protocols which are equivalent will be accepted, but the user shall submit that protocol to the Department for concurrence that the protocol is equivalent. The calibration shall be performed as follows:

(1) Before the system is first used for irradiation of a patient and, at time intervals which do not exceed 1 year.

(2) After a change which alters the calibration, spatial distribution or other characteristics of the therapy beam.

(b) The calibration shall be performed by, or under the direct supervision of, a qualified expert for radiation therapy calibrations.

(c) Calibration radiation measurements required by subsection (a) shall be performed using a dosimetry system meeting the following specifications:

(1) The system has an exposure calibration factor appropriate to the beam energy measured and traceable to a National standard.

(2) The system has been calibrated within the previous 2 years and after servicing that may have affected its calibration.

(3) The system has been calibrated so that an uncertainty can be stated for the radiation quantities monitored by the system.

(4) The system has had constancy checks performed on the system as specified by a qualified expert for radiation therapy calibrations.

(d) Calibrations made under this section shall be made so that the dose at a reference point in soft tissue may be calculated as accurately as possible but with an uncertainty of no greater than 5%.

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

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

(2) The absorbed dose rate at various depths (depth dose) and beam profile measured in water and the beam flatness and symmetry for the range of field sizes used, for each beam energy.

(3) The uniformity of the radiation field and a dependency upon the direction of the useful beam.

(4) Verification of depth-dose data and isodose curves applicable to the specific machine.

(5) Verification of the applicability of transmission factors of accessories such as wedges, shadow trays, compensators and their effects on electron buildup.

(6) The dose per monitor unit, end effect, linearity and dose rate dependence of the dose monitor systems.

(7) For photon beams, the congruence of the light field and the radiation field.

(8) For electron beams, the validity of commissioning data for virtual source distances or effective source-to-skin distances is to be verified at a single electron energy with a beam restriction device. When the replacement of a beam restriction device occurs, the determination will be required for each electron energy.

(f) Records of calibration measurements under subsection (a) and dosimetry system calibrations under subsection (c) shall be preserved for 5 years.

(g) A copy of the latest calibration performed under subsection (a) shall be available at the facility.

§ 228.76. Spot checks.

Spot checks shall be performed on systems subject to this subchapter during full calibrations and thereafter once in each calendar month. The spot checks shall meet the following requirements:

(1) The procedures shall be in writing and developed by a qualified expert for radiation therapy calibrations.

(2) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a qualified expert within 15 days of the completion of the spot check.

(3) The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation delivered to a patient during a therapy procedure.

(4) The spot-check procedures shall specify the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the full calibration.

(5) If a spot check indicates a change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system shall be recalibrated as required in § 228.75 (relating to calibrations).

(6) Records of spot-check measurements performed under this section shall be maintained by the licensee for 5 years after completion of the spot-check measurements and necessary corrective actions.

(7) Spot check measurements shall be performed using a dosimetry system that has been calibrated in accordance with § 228.75(c). Alternatively, a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with § 228.75(c). This alternative calibration method shall have been performed within the previous year and after a servicing that may have affected the system calibration.

APPENDIX A
DETERMINATION OF COMPETENCE

The licensee shall ensure training on the subjects listed in Appendix A has been conducted. The individual shall be trained and competent in the general operation of the radiation therapy equipment and its functions, and in the following subject areas, as applicable to the procedures performed and the specific equipment utilized:

(1) Basic properties of radiation.

(2) Units of measurement.

(3) Sources of radiation exposure.

(4) Methods of radiation protection.

(5) Biological effects of radiation exposure.

(6) Medical accelerator operation.

(7) Treatment planning and execution.

(8) Patient positioning and protection.

(9) Operating and emergency procedures.

(10) Quality assurance.

(11) Regulations.

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE AND DEFINITIONS

§ 230.3. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.52, 71.53, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99 and 71.100 are not incorporated by reference.

CHAPTER 240. RADON CERTIFICATION

Subchapter A. GENERAL PROVISIONS

GENERAL

§ 240.2. Scope.

(a) This chapter applies to all persons except a person:

(1) Testing for or mitigating against radon contamination in a building that the person owns or occupies.

(2) Using measures designed to prevent radon contamination in newly constructed buildings. This exemption does not apply to radon testing or installation of radon mitigating devices in these buildings following occupancy.

(3) Performing testing or mitigation in the course of the person's normal duties as an employee or contractor of the Department or the Federal government.

(4) Performing scientific research if the person discloses the information obtained to the Department under § 240.303 (relating to reporting of information) and the person informs the owner or occupant of the affected building of the following:

(i) That the person is not certified by the Department to test for or mitigate against radon contamination.

(ii) That the test results are not certified.

(iii) That the mitigation methods are for experimental purposes and may be unsuccessful.

(5) Purveying, but not placing, or retrieving passive radon testing devices, such as charcoal canisters or track etch monitors supplied by a certified laboratory, if radon concentrations determined by the laboratory are reported directly to the owner or occupier of the building tested.

(b) This chapter is in addition to, and not in substitution for, other applicable provisions of this article.

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