RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 215, 217, 219, 220, 224—226, 230 AND 232]

Radiological Health

The Environmental Quality Board (Board) by this order amends Chapters 215, 217, 219, 220, 224—226 and 230, and adds new Chapter 232. The amendments update the standards for protection against radiation to meet compatibility requirements for the Commonwealth to become an agreement state with the United States Nuclear Regulatory Commission (NRC). This order was adopted by the Board at its regular meeting on June 19, 2001.

A. *Effective Date*

These amendments will be effective immediately upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. *Contact Persons*

For further information, the contact persons are Louis Ray Urciuolo, Chief, Licensing Section, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P. O. Box 8469, Harrisburg, PA 17105-8469, (717) 787-3720; and Marylou Barton, Assistant Counsel, Bureau of Regulatory Counsel, Rachel Carson State Office Building, 9th Floor, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. This proposal is also available electronically through 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, respectively, direct 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 delegate to the Board the power to adopt the regulations of the Department to implement the act.

Section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20) authorizes and directs the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background and Summary*

In 1995, the Board updated 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 as an agreement state. These updates were published at 25 Pa.B. 5088 and 5206 (November 18, 1995). Technological advances in the use of radioactive material and the need to establish and maintain radiation protection standards at least as stringent as the NRC standards provide the basis for these revisions to the existing radiological health regulations.

The amendments are necessary for the Commonwealth to acquire agreement state status from the NRC. Under section 201 of the act (35 P. S. § 7110.201), the Governor is authorized to enter into agreements with the NRC transferring regulatory authority to the Commonwealth for radiation protection. Presently, the Commonwealth is responsible for the regulation of naturally occurring and accelerator-produced radioactive material (NARM) and radiation producing equipment. Under the Atomic Energy Act of 1954 (42 U.S.C.A. § 2021), the NRC is authorized to enter into an agreement with the Governor to discontinue NRC regulatory authority with respect to most byproduct materials, source materials and special nuclear materials in amounts insufficient to form a critical mass.

The amendments are based on the current NRC radiation protection regulations in 10 CFR Parts 19—150.

As required by section 301(c)(14) of the act (35 P. S. § 7110.301), the Department provided the Radiation Protection Advisory Committee (Committee) with an opportunity to review the proposed amendments and to advise the Department prior to submittal to the Board. On March 1, 2001, the Committee met and reviewed the draft final rulemaking. The chairperson announced by letter dated March 1, 2001, the Committee's concurrence to send the draft final rulemaking to the Board.

A description of the amendments is provided as follows:

Chapter 215. General Provisions

Section 215.1 (relating to purpose and scope) is expanded to clarify the scope of incorporation by reference and list any exceptions. Subsections (e) and (f) provide notification that this does not relieve a person from complying with Pennsylvania law nor does it expand the scope of authority already granted the Department under statute. Locations are listed in new subsection (g) for the purchase of copies of the *Code of Federal Regulations* (Title 10 Chapter I) to be incorporated by reference. An electronic version is also available on the United States Government Printing Office world wide web site at http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199910. New subsection (h) describes the relationship between certain commonly used terms of the Department and the NRC.

Section 215.2 (relating to definitions) The following definitions were deleted because they are incorporated by reference: "ALARA," "A1," "A2," "absorbed dose," "agreement state," "airborne radioactive material," "airborne radioactivity area," "background radiation," "becquerel," "byproduct material," "calendar quarter," "collective dose," "committed dose equivalent," "committed effective dose equivalent," "controlled area," "curie," "deep dose equivalent," "depleted uranium," "dose," "dose equivalent," "dose limits," "effective dose equivalent," "embryo/fetus," "exposure," "exposure rate," "external dose," "extremity," "eye dose equivalent," "generally applicable environmental radiation standards," "gray," "high radiation area," "individual monitoring," "individual monitoring devices," "internal dose," "licensed material," "lost or missing licensed or registered source of radiation," "member of the public," "minor," "misadministration," "monitoring," "normal form," "occupational dose," "personnel monitoring equipment," "prescribed dosage," "public dose," "rad," "radiation area," "radiopharmaceutical," "rem," "research and development," "restricted area," "sealed source," "SI," "shallow dose equivalent," "sievert," "site boundary," "source material," "special form," "special nuclear material," "special nuclear material in quantities not sufficient to form a critical mass," "survey," "TEDE," "unrefined and unproc-

essed ore," "unrestricted area," "week," "whole body," "worker," "working level," "working level month" and "year."

The following definitions are updated: "NRC," "qualified expert" and "roentgen." The definition of "prescribed dose" is changed to "prescribed dose for therapy using radiation-producing machines" because references to radioactive material modalities now covered by incorporation by reference have been removed. Likewise, the definition of "written directive" is changed to "written directive for therapy using radiation-producing machines" following the deletion of references to radioactive material. It is clarified that electron and other particle beams are included in addition to X-ray. Although the term "misadministration" has been deleted, a similar concept called "medical event" that is restricted to radiation producing machine therapy is newly defined in § 219.3 (relating to definitions).

Section 215.3 (relating to units of exposure and dose) is amended to delete units of dose already incorporated by reference in 10 CFR 20.1004 (relating to units of radiation).

Section 215.4 (relating to units of activity) is deleted because it is replaced by incorporation by reference of 10 CFR 20.1005 (relating to units of radioactivity).

Section 215.5 (relating to effect of incorporation of the *Code of Federal Regulations*) is added for clarification.

Section 215.11 (relating to records) is amended to clarify the separate record keeping requirements of licensees and registrants.

Section 215.12 (relating to inspections) is amended to change the target inspection frequency for major medical facility X-ray operations from every 2 years to every 3 years.

Section 215.15 (relating to additional requirements) was amended by incorporating the requirements of the rescinded § 219.73 (orders requiring furnishing of bioassay services).

A new § 215.25 (relating to deliberate misconduct) is added for compatibility with the NRC.

A new § 215.26 (relating to employee protection) is added for compatibility with the NRC.

A new § 215.27 (relating to vacating premises) contains the provisions of § 219.241 (relating to vacating premises), which is relocated to this chapter. The requirement is extended to all licensees and is in addition to the decommissioning requirements of 10 CFR 30.36 (relating to expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas) that are incorporated by reference under Chapter 217 (relating to licensing of radioactive material).

A new § 215.28 (relating to deliberate exposure of a monitoring device) is added to prohibit using a monitoring device to indicate falsely high or low doses to individuals.

Section 215.32 (relating to exempt qualifications) is amended to add the new Chapter 232 (relating to licenses and radiation safety requirements for irradiators) to the list of chapters.

Chapter 217. Licensing of Radioactive Material

Subsection 217.1(b) is amended to include references to Chapters 218, 230 and 232 (relating to fees; packaging and transportation of radioactive material; and licenses and radiation safety requirements for irradiators).

Section 217.2 (relating to address for communications) is updated with the new Department name and address.

Sections 217.11—217.18, 217.21—217.24, 217.31, 217.32, 217.41—217.49, 217.51—217.57, 217.65, 217.71—217.74, 217.81—217.93, 217.101, 217.121 and 217.122, Appendices A, B and D are deleted and replaced by new sections and new tables for NARM and renamed subchapters that incorporate applicable portions of 10 CFR Parts 30, 31, 32, 33, 40, 70 and 150 by reference.

A new Subchapter B (general provisions for radioactive material) is created to incorporate 10 CFR 30 (relating to rules of general applicability to domestic licensing of byproduct material).

Sections 217.131 and 217.132 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 30) explain incorporation by reference.

Section 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*) is the existing § 217.24, which is deleted.

Section 217.134 (relating to filing application for specific licenses) is the existing § 217.51(d) and alerts the applicant for a license that a fee is required.

Section 217.135 (relating to renewal of licenses) is similar to the existing § 217.55 and is amended to alert the licensee to the Department's renewal requirements.

Section 217.136 (relating to exempt concentrations) and Table 1 replaced the existing requirements of § 217.12 and Appendix A for NARM isotopes, which are not incorporated by reference.

Section 217.137 (relating to exempt quantities) and Table 2 replace the existing requirements of § 217.13 and Appendix B for NARM isotopes, which are not incorporated by reference.

A new Subchapter C (relating to general licenses for radioactive material) is created to incorporate 10 CFR 31 (relating to general domestic licenses for byproduct material).

Sections 217.141 and 217.142 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 30) explain the incorporation by reference.

Section 217.143 (relating to certain measuring, gauging or controlling devices) incorporates 10 CFR 31.5 and adds some Department requirements that are not included in the incorporation by reference for sources subject to registration under 10 CFR 31.5(c)(13)(i) and certain NARM sources.

Section 217.144 (relating to incidental radioactive material produced by a particle accelerator) is the existing § 217.48, amended to include a Department requirement regarding disposal that is not included in the incorporation by reference.

A new Subchapter D (relating to specific licenses to manufacture or transfer certain items containing radioactive material) is created to incorporate 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material) and to also include NARM radioactive material.

The requirements of existing Subchapter D (relating to transfer of radioactive material) are moved to new Subchapter I with the same title.

Sections 217.151 and 217.152 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 32) explain the incorporation by reference.

Section 217.153 (relating to licensing the incorporation of NARM into gas and aerosol detectors) is the existing § 217.83, amended to include a Department requirement for using radium-226 that is not included in the incorporation by reference.

Section 217.154 (relating to special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226) is the existing § 217.86, amended to include a Department requirement for using radium-226 that is not included in the incorporation by reference.

Section 217.155 (relating to manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license) is the existing § 217.88, amended to include Department requirements for using NARM that are not included in the incorporation by reference.

A new Subchapter F (relating to specific domestic licenses of broad scope for radioactive material) is created to incorporate 10 CFR Part 33 (relating to specific domestic licenses of broad scope for byproduct material). This replaces deleted §§ 217.71—217.74 and Appendix D for licenses of broad scope.

Sections 217.161 and 217.162 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 33) explain the incorporation by reference.

Section 217.163 (relating to types of specific licenses of broad scope) and Table 3 replace the existing requirements of §§ 217.71—217.73 and Appendix D for NARM isotopes, which are not incorporated by reference.

A new Subchapter G (relating to licensing of source material) is created to incorporate 10 CFR Part 40 (relating to domestic licensing of source material).

Sections 217.171 and 217.172 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 40) explain the incorporation by reference.

A new Subchapter H (relating to licensing of special nuclear material) is created to incorporate 10 CFR 70 (relating to domestic licensing of special material).

Sections 217.181 and 217.182 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 70) explain the incorporation by reference.

A new Subchapter I (relating to transfer of radioactive material) replaces existing Subchapter D. New § 217.191 (relating to transfer of material) incorporates 10 CFR 30.41 (relating to transfer of byproduct material) by reference, expands the scope to include NARM and replaces existing § 217.101.

A new Subchapter J (relating to reciprocity) is the existing Subchapter F amended to incorporate 10 CFR 150.1 (relating to purpose), 10 CFR 150.2 (relating to scope), 10 CFR 150.3 (relating to definitions), 10 CFR 150.11 (relating to critical mass) and certain sections of 10 CFR 150.20 (relating to recognition of Agreement State licenses).

Sections 217.201 and 217.202 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 150) explain the incorporation by reference.

Section 217.203 (relating to reciprocity of licenses of naturally occurring and accelerator-produced radioactive material) is the existing § 217.122.

Chapter 219. Standards for Protection Against Radiation

Section 219.3 (relating to definitions) deletes all existing definitions because of the incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation) in this chapter. A new definition of "medical reportable event for radiation-producing machine therapy" is created to replace, in part, the definition of "misadministration" in § 215.2 which has been deleted following incorporation by reference of the definitions in 10 CFR 35.2 (relating to definitions).

Section 219.4 (relating to implementation) is deleted because it is obsolete.

Sections 219.5 and 219.6 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 20) are added to clarify the differences between Chapter 219 and 10 CFR Part 20.

Section 219.7 (relating to effect of incorporation of 10 CFR 20.1403) is added to clarify license termination under restricted conditions.

Sections 219.21 and 219.31—219.38 are deleted because of incorporation by reference of 10 CFR Part 20.

Existing Subchapter D (relating to radiation dose limits for individual members of the public) consisting of §§ 219.51 and 219.52 is amended as follows.

Section 219.51 (relating to dose limits for individual members of the public) is rewritten in its entirety to incorporate by reference 10 CFR Part 20, Subpart D (relating to dose limits for individual members of the public). The result includes the elimination of current § 219.51(a)(2) that allows individual members of the public in unrestricted areas to receive exposures up to 0.5 rem per year from medical diagnostic radiation producing machines.

Section 219.52 (compliance with dose limits for individual members of the public) is deleted because of the incorporation by reference of 10 CFR Part 20.

Existing Subchapter E (relating to testing for leakage or contamination of sealed sources) consists of § 219.61 which is amended to include incorporation by reference of 10 CFR Part 20 as an additional requirement.

Existing Subchapter F (relating to surveys and monitoring) is deleted. Sections 219.71 and 219.72 are deleted because of incorporation of 10 CFR Part 20 by reference. The current § 219.73 is deleted and the requirements are moved to § 215.15 (relating to additional requirements).

Existing Subchapter G (relating to control of exposure from external sources in restricted areas) consisting of §§ 219.91—219.93 is deleted because of incorporation of 10 CFR Part 20 by reference.

Existing Subchapter H (relating to respiratory protection and controls to restrict internal exposure in restricted areas) consisting of §§ 219.111—219.113 is deleted because of incorporation of 10 CFR Part 20 by reference.

Existing Subchapter I (relating to storage and control of licensed or registered sources of radiation) is amended so that existing §§ 219.131 and 219.132 now apply only to radiation-producing machines, while incorporation of 10 CFR Part 20 by reference applies to radioactive material.

Existing Subchapter J (relating to precautionary procedures) is amended as follows:

Sections 219.151—219.158 were deleted because of incorporation of 10 CFR Part 20 by reference.

Section 219.159 (relating to posting of radiation producing machines) is amended by changing the words "The registrant" at the beginning of the first sentence to "The registrant or licensee" because accelerators are now licensed.

Section 219.160 (relating to exceptions to posting requirements) is amended by deletion of those sections for radioactive materials that are superceded through incorporation by reference of 10 CFR Part 20.

Sections 219.161 and 219.162 (relating to exemptions from labeling requirements; and procedures for receiving and opening packages) are deleted because of incorporation of 10 CFR Part 20 by reference.

Existing Subchapter K (relating to waste disposal) with §§ 219.181—219.186 is deleted because of incorporation of 10 CFR Part 20 by reference.

Existing Subchapter L (relating to records) with §§ 219.201—219.211 is deleted because of incorporation of 10 CFR Part 20 by reference.

Existing Subchapter M (relating to reports) consists of §§ 219.221—219.228.

Section 219.221 (relating to reports of stolen, lost or missing licensed or registered sources of radiation) is amended by deletion of those sections for radioactive materials that are superseded through incorporation by reference of 10 CFR Part 20.

Section 219.222 (relating to notification of incidents and reportable events) is renamed and amended by replacing the current text with incorporation by reference of the specific requirements for the notification of incidents under 10 CFR Part 20. The scope of the reference is also expanded to apply to radiation producing machines and NARM.

Sections 219.223—219.226 are deleted as a result of incorporation by reference of 10 CFR Part 20.

Existing § 219.227 (relating to reports of leaking or contaminated sealed sources) is retained.

Section 219.228 (relating to reports of misadministrations) is renamed to "reports of medical reportable events for radiation-producing machine therapy." References to "misadministration from X-ray" are replaced by "medical reportable event from radiation-producing machine therapy."

New § 219.229 (relating to other medical reports) is added to require reporting of certain harmful exposures to patients that are not reported under § 219.228.

Existing Subchapter N (relating to additional requirements) which consists of § 219.241 (relating to vacating premises) is deleted. The conditions are transferred to new § 215.27 and expanded to apply to all licensees.

Chapter 219, Appendices A—C (relating to protection factors for respirators; annual limits on intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage; and quantities of licensed or registered material requiring labeling) are deleted by incorporation by reference of 10 CFR Part 20.

Chapter 220. Notices, Instructions and Reports to Workers; Inspections and Investigations

Because of incorporation by reference of 10 CFR Part 19, the title of Chapter 220 has been expanded to include "Investigations."

Section 220.2 (relating to posting of notices to workers) is updated for compatibility with the NRC.

Sections 220.3—220.8 are deleted because of incorporation by reference of 10 CFR Part 19.

Sections 220.9 and 220.10 (relating to incorporation by reference; effect of incorporation of 10 CFR Part 19) are added to clarify the differences between Chapter 220 and 10 CFR Part 19.

Chapter 224. Medical Use of Radioactive Material

Sections 224.2—224.9 are deleted because of incorporation by reference of 10 CFR Part 35.

New §§ 224.10 and 224.11 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 35) are added to clarify the differences between Chapter 224 and 10 CFR Part 35.

Subchapter B (relating to general administrative requirements) is renamed "other requirements."

New § 224.21 (relating to supervision) clarifies which auxiliary personnel may handle radioactive material. It replaces current § 224.55 (supervision) that is deleted by incorporation by reference of 10 CFR Part 35.

New § 224.22 (relating to authorization for calibration and reference sources) allows sealed sources up to 1,110 MBq (30 mCi) apiece of radioactive material. It replaces current § 224.104 that is deleted because of incorporation by reference of 10 CFR 35.57 (relating to authorization for calibration and reference sources).

New § 224.23 (relating to decay-in-storage) allows sealed sources of radioactive material with a physical half-life of up to 300 days to be held for decay-in-storage. It replaces current § 224.112 (relating decay-in-storage) that is deleted by incorporation by reference of 10 CFR 35.92 (relating to decay-in-storage).

Current §§ 224.51—224.60 are deleted because of incorporation by reference of 10 CFR Part 35. The requirements of current § 224.55 (relating to supervision) are now found in new § 224.21 (relating to supervision).

Current §§ 224.101—224.112 comprising all of Subchapter C are deleted because of incorporation by reference of 10 CFR Part 35. The requirements of current § 224.104 (relating to authorization for calibration and reference sources) are now found in new § 224.22 (relating to authorization for calibration and reference sources). The requirements of current § 224.112 (relating to decay-in-storage) are now found in new § 224.23 (relating to decay-in-storage).

Sections 224.151—224.501 comprising all of Subchapters D—K are deleted because of incorporation by reference of 10 CFR Part 35.

Chapter 225. Radiation Safety Requirements for Industrial Uses and Radiographic Operations

Chapter 225 is split into two subchapters: Subchapters A and B (relating to general provisions; and radiation producing-machines). The chapter title is expanded to include industrial uses.

Existing § 225.1 (relating to purpose and scope) is expanded upon. An addition to subsection (a) clarifies applicability. New subsection (b) is added to exempt persons using only radiation-producing machines from the requirements of 10 CFR Part 34 incorporated by reference except as may be noted in Subchapter B. New subsection (c) is added to clearly indicate that Chapter 225 does not apply to medical diagnosis or therapy.

Existing §§ 225.2, 225.11—225.18, 225.21—225.23, 225.31—225.33, 225.41—225.44 are deleted because of incorporation by reference of 10 CFR Part 34.

Existing §§ 225.51—225.53 are deleted because of incorporation by reference of 10 CFR Part 34 with the requirements of existing § 225.52 (relating to security) being transferred to new § 225.87 (relating to security) and existing § 225.53 (relating to posting) being transferred to new § 225.88 (relating to posting).

Existing Appendix A is retained.

New §§ 225.2a and 225.3a (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 34) are added to clarify the differences between Chapter 225 and 10 CFR Part 34.

Section 225.4a (relating to radiation safety programs) is added for radiation-producing machine users only. This section includes a requirement that a person using radiation-producing machines for industrial radiography shall have Department approval before commencing operations.

Section 225.5a (relating to reciprocity) is added to alert out-of-State users of radiation-producing machines to the requirements of § 216.7 (relating to out-of-State radiation producing machines).

Section 225.6a (relating to prohibitions) is added to clarify that the use of radiation-producing machines covered under this chapter is not permitted for diagnosis or therapy on humans or animals.

New Subchapter B (relating to radiation-producing machines) requirements are added to apply to those persons who only have radiation-producing machines because radiation-producing machines do not fall under the requirements of sealed source radiography incorporated through reference of 10 CFR Part 34.

Subchapter B begins with a new undesignated center heading, "General Administrative Requirements," that includes new §§ 225.71—225.76. The new sections in this subchapter provide for definition of terms, duties of personnel, training of personnel, specification of training and testing, audits and safety reviews of radiographers and radiographer assistants, and reporting requirements of incidents and overexposures.

The definitions introduced in § 225.71 (relating to definitions) are "cabinet radiography," "cabinet X-ray system," "certified cabinet X-ray system," "DRD—direct reading dosimeter," "industrial radiography," "permanent radiographic installation," "personnel dosimeter," "personal supervision," "radiation safety officer," "radiographer," "radiographer's assistant," "radiographer trainee," "radiographic operations," "shielded room radiography" and "temporary job site."

A new heading, "General Technical Requirements," includes §§ 225.81—225.88. The new sections provide requirements for permanent radiographic installations, operation outside of permanent radiographic installations, records at temporary job sites, general operating and emergency procedures, surveys and survey records, utilization logs, security, and posting.

A new heading, "Radiation Survey Instrument and Personnel Monitoring," includes §§ 225.91—225.93 (relating to radiation survey meter requirements; radiation survey meter calibration requirements; and personnel monitoring control). These new sections specify the use of operable calibrated survey meters, personnel dosimeters and direct reading dosimeters, survey meter calibration requirements, and associated records.

A new heading, "Radiation Producing Machine Requirements," includes §§ 225.101—225.104.

Section 225.101 (relating to cabinet X-ray systems and baggage/package X-ray systems) replaces and updates existing § 225.21 (relating to cabinet x-ray systems).

Section 225.102 (relating to shielded room X-ray machine radiography) replaces and updates existing § 225.22 (relating to shielded room radiography).

Section 225.103 (relating to temporary jobsite radiography) replaces and updates existing § 225.23 (relating to other radiography).

Section 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items) is new and provides for special requirements for the use of X-ray in the search for contraband.

Chapter 226. Licenses and Radiation Safety Requirements for Well Logging

Current Chapter 226 is renamed as "Licenses and Radiation Safety Requirements for Well Logging" to parallel 10 CFR Part 39 (relating to licenses and radiation safety requirements for well logging).

Section 226.1 (relating to purpose and scope) is generally updated and revised to include persons using uranium sinker bars.

Section 226.2 (relating to definitions) is deleted because of incorporation by reference of 10 CFR Part 39.

Current § 226.3 (relating to prohibition) is deleted. It is replaced by new § 226.3a (relating to abandonment of a sealed source) to incorporate by reference 10 CFR Part 39 and to add a reference to § 78.111 (relating to abandonment).

Sections 226.4 and 226.5 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 39) are added to clarify the differences between Chapter 226 and 10 CFR Part 39.

A new undesignated center heading "Particle Accelerators" is created.

The provisions of § 226.34 (relating to particle accelerators) are reworded and renumbered to § 226.61, and a reference to licensing provisions of Chapter 228 (relating to radiation safety requirements for particle accelerators) is added.

Sections 226.11—226.51 and Appendixes A and B are deleted because of incorporation by reference of 10 CFR Part 39.

Chapter 230. Packaging and Transportation of Radioactive Material

Sections 230.2, 230.11, 230.12, 230.14, 230.21—230.26, 230.41—230.46, 230.51, Appendix A and Tables I—IV are deleted because of incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive material).

In Subchapter A (relating to scope and definitions), the phrase "and definitions" is dropped from the title because of the deletion of § 230.2 (relating to definitions).

Sections 230.3 and 230.4 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 71) are added to clarify the differences between Chapter 230 and 10 CFR Part 71.

Section 230.5 (relating to communications) is added to ensure that communications are sent to the Department's address.

Section 230.13 (relating to transportation of licensed material) is amended to include only the requirements of existing § 230.13(b) and incorporation by reference of 10 CFR Part 71.

Section 230.47 (relating to advance notification of transport of nuclear waste) is amended to ensure that the Governor or the Governor's designee and the Department will receive the required notifications and information.

Chapter 232. Licenses and Radiation Safety Requirements for Irradiators

Chapter 232 is a new chapter that is compatible with 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators).

Section 232.1 (relating to purpose and scope) explains that this chapter applies only to the use of radioactive material in sealed sources to irradiate objects or materials with gamma radiation.

Sections 232.2 and 232.3 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 36) clarify the differences between Chapter 232 and 10 CFR Part 36.

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

The notice of proposed rulemaking was published at 30 Pa.B. 4503 (August 26, 2000) and included a 30-day comment period that ended on September 25, 2000. The Board received five responses during the comment period. The Independent Regulatory Review Commission (IRRC) also provided comments on the proposed rulemaking through a letter dated October 26, 2000.

The Department prepared a comment and response document that summarizes and responds to the aforementioned comments. A copy of the comment and response document is available upon request from the contact person listed in Section B of this Preamble.

A summary of the comments received and the Department's responses follow. The revisions that resulted from the comments as well as those made on the initiative of the Department are described thereafter.

The comments are of two kinds, those that address a specific reference and those that refer to the format of incorporation by reference in general.

One comment was suggested that to improve clarity, more specificity be provided in defining the linkage to regulations incorporated by reference. It was suggested that a list of either each provision incorporated by reference or each provision not incorporated by reference be cited. Because listing the individual regulations incorporated by reference is lengthy and therefore impractical, the Department chose to list the exceptions to incorporation.

Section 215.1(e) lists by part, rather than section, the NRC regulations incorporated by reference, except for Part 150. A part in the NRC regulations is roughly equivalent to a chapter in Title 25 of the *Pennsylvania Code*. The reference has been augmented to list each section or subunit of a referenced part of the NRC regulations that is not incorporated by reference. References to all the NRC regulations incorporated by reference are displayed in § 215.1. However, for convenience of the reader, each chapter displays a list in modified format that is limited to the NRC regulations corresponding to the subject of the chapter.

Section 215.1(h) is added to enhance clarity by showing the relationship between certain commonly used terms in the *Code of Federal Regulations* and their counterparts in these regulations. The applicable relationships are repeated in each chapter for convenience. Section 215.1(h)(5) is repeated in §§ 217.132(5), 217.142(5), 217.152(5), 217.162(5), 217.172(5), 217.182(5), 217.202(5), 219.6(7), 220.10(4), 224.11(6), 225.3a(5), 226.5(5), 230.4(5) and 232.3(4).

Section 215.2 as proposed is modified. Since a definition of "misadministration involving radioactive materials" has been incorporated by reference, under proposed rulemaking the existing definition of misadministration was to be renamed and redefined as "misadministration (medical event) from X-ray" to treat events involving X-ray separately from those involving radioactive material. However, a commentator noted that the purpose of the definition was to support a reporting requirement, and the definition should therefore appear in Chapter 219 instead of Chapter 215. It was also commented that in light of incorporation by reference of a similar term, the name given to the definition was confusing and also inaccurate. For these reasons, the definition of "misadministration" is deleted from § 215.2 at final rulemaking, and a new definition, "medical reportable event for radiation-producing machine therapy," has been added in § 219.3. This is explained further under the discussion of § 219.3. At final rulemaking, the term "prescribed dose for X-ray therapy" has been changed to "prescribed dose for therapy using radiation-producing machines," to show that electron as well as other particle beam therapy is included in addition to x-ray. For the same reasons, the proposed term "written directive for X-ray therapy" has been clarified to read "written directive for therapy using radiation-producing machines." The definition of "worker" has also been deleted in the final-form rule since an applicable definition of "worker" is incorporated by reference.

Sections 215.12 and 215.26 show an editorial change of "employe" and "employes" to "employee" and employees."

Section 215.27 refers to the requirements for vacating premises that contained areas where access was restricted due to the presence of radioactive material. One commentator suggested that acceptable criteria for decontamination be stated in the regulation. The regulation is not changed. The Department does not believe it is wise to lock in values for acceptable levels of residual contamination in the regulation. In some cases it may not always be possible to satisfy a given limit. License termination plans are subject to as low as reasonably achievable (ALARA) and are addressed on a case-by-case basis. The matter of limits is addressed through guidance to provide the flexibility necessary to handle diverse conditions.

Section 215.28 is changed for clarity. Objection was taken to the use of the word "deceptive." "Deceptive exposure of a monitoring device" is changed to "Deliberate exposure of a monitoring device" for the purpose of "falsely" rather than "deceptively" indicating the dose to an individual.

Section 217.1(b) was amended to show the descriptions of the referenced chapters as an editorial correction for clarity.

Sections 217.132(4), 217.142(4), 217.172(4), 217.182(4), 217.202(4) and 224.11(3) change "the definition of licensed material" to "a reference to byproduct material" as an

editorial correction since the corresponding parts of the CFR refer to byproduct material rather than licensed material. Similarly, the sentence "The definition of licensed material includes NARM" has been deleted from §§ 217.152(4) and 217.162(4) as the phrase "licensed material" is not found in the corresponding parts of the CFR.

A correction to § 217.143 changed the NRC reference from 10 CFR 30.5 to 10 CFR 31.5. The scope of the regulation was also clarified by adding that the additional requirements contained in the section apply only to generally licensed sources that are subject to registration under 10 CFR 31.5(c)(13i) and certain specified NARM sources.

Section 217.191 (relating to transfer of material) has been amended at final-form rulemaking. The existing text is replaced by incorporation by reference of 10 CFR 30.41 because the CFR is equivalent. Three concerns were raised to items in this section. One objection related to the provision for verification of a licensee's authority to receive material by using data supplied from parties other than the Department or the licensee. Another commentator felt even more strongly that direct contact with the licensee should be the only form of permissible verification. The Department disagrees with the first two comments because they were based on the misconception that the transferor was accountable for not allowing the transferee's inventory to exceed the transferee's license possession limits. The transferor need only verify that the material to be transferred does not exceed the limits listed in the transferee's license. The transferee is responsible for ensuring that current inventory (which may fluctuate on a day-to-day basis) never exceeds the license limits. The third concern questioned what constituted "verbal" certification. These regulations are not new, and the requirements are not being altered. They are currently in force and are identical to the CFR. They have been in place for a sufficient time for the Department to note that there is no indication that the regulated community has a problem understanding or complying with the regulations, and no significant problems have arisen that could be attributed to defects in the regulations. No one has approached the Department as yet to compile a third-party verification service. If this did happen, it would have to be approved by the Department. Verbal certification has no special legal definition and must be followed up in writing anyway. In summary, the Department has not changed the existing requirements. However, the text of these requirements is now 10 CFR 30.41, incorporated by reference.

A commentator also asked for clarification on three parts of § 217.191 that also apply to 10 CFR 30.41. First, regarding § 217.191(a)(3), the regulation should indicate who would be exempt and how an exemption is granted. As discussed in the comment and response document, the Department believes the description of exempted parties and the provision for exemptions is adequately addressed in the regulation, so no change has been made. Second, in § 217.191(a)(4), the commentator asked what documents in other jurisdictions are equivalent to general and specific licenses. The regulation was not modified because there is no one-to-one relationship that holds for all jurisdictions. An equivalent authorization may go by different names, such as a permit or a registration, and the regulatory equivalency does not hold to begin with. Some jurisdictions may require the equivalent of a general license for what is specifically licensed in another jurisdiction. It is up to the licensee to uncover the requirements before transferring radioactive material. Third, under § 217.195(a)(5), the commentator asked who would be subject to being "otherwise authorized in writing by the Department." This rule is not changed because it cannot be elaborated further. It is a catch-all provision for unspecified situations. For example, under § 217.22 a requirement for prior authorization in writing may be invoked, if deemed appropriate, before transfer of ownership of radioactive material is allowed during a corporate merger.

Section 219.3 (relating to definitions) is retained at final-form rulemaking for the purpose of the new definition, "medical reportable event for radiation-producing machine therapy." The new definition is the renamed successor to the definition of "misadministration" for events not involving radioactive material. Several additional concerns were raised regarding the definition. These concerns involved clarity of scope, interpretation and limits. The resolution of these issues resulted in a significant rewrite of the proposed regulation. The proposed regulation closely followed the anticipated form of the NRC's new definition of medical event, with the exception of being slanted toward invasive therapy. The final rule is closer to the traditional form of the Council of Radiation Control Directors Suggested State Regulations for teletherapy. The result is a rule that better addresses the comments and provides more flexibility to the regulated community. The rule was simplified by removing such issues as wrong site, errors of precision, wrong beam energy, wrong mode or wedge factor. The criteria is that controllable exposures to areas inside or outside the treatment volume do not exceed a certain percentage of the prescription regardless of the cause. The percentage is based upon the total dose and, as suggested by a commentator, the weekly dose rather than an individual dose fraction.

In the final-form rulemaking, the issue of harmful events arising from exposure to diagnostic radiation and unintended functional damage to tissue, diagnostic or therapeutic, is addressed by removing them from the definition of medical reportable event for radiation-producing machine therapy and creating new § 219.229 (relating to other medical reports). This simplified the definition of medical reportable event for radiation-producing machine therapy yet retained the proposed requirement for reporting any unintended functional damage from medical radiation. The Department considers it unnecessary and overly prescriptive to set limits for these events or to specify who makes the determination of a reportable event or who submits the report of an event. The licensee or registrant is responsible and the determination of a reportable event is a medical judgment made by physicians and medical physicists using generally accepted clinical protocol and is reported under the administrative structure of the licensee or registrant.

Section 219.7 is added at final-form rulemaking to clarify the requirements of incorporation by reference of 10 CFR 20.1403 (relating to license termination under restricted conditions) for license termination under restricted conditions. This is a regulatory option of last resort that the Department would not exercise without scrutiny, so the existing requirements were more fully detailed.

Section 219.222 is renamed at final-form rulemaking to "Notification of Incidents and Reportable Events" to more clearly describe the content. The specific references to the CFR are clarified as well as the linkage to a 30-day reporting requirement.

Section 219.228 is renamed in final-form rulemaking to "Reports of Medical Reportable Events for Radiation-Producing Machine Therapy" for clarity and consistency. Previous references to "misadministration" are replaced with "event."

Section 219.229 (relating to other medical reports) is new at final rulemaking. The reporting requirements for certain events of interest involving unintended harm from medical radiation that had been proposed under the definition of "medical event" have been moved here for the reasons described previously in the discussion of "medical event."

Section 220.2(a)(3) relating to posting of procedures was questioned. A commentator believed that certain procedures, such as activities involving wet chemistry, could be too complex to post. The Department believes the commentator misinterpreted the requirement. Safe working procedures, not analytical procedures, must be posted. In any case, there is an option to post the location at which the procedures can be found rather than the procedures. For these reasons, no change has been made.

Section 220.10(3) is added at final rulemaking to clarify the applicability to registered sources of radiation.

Chapter 224 relates to the incorporation by reference of 10 CFR 35 for the medical use of radioactive material. One commentator did not express confidence in the NRC's handling or general competence in regulating this area and suggested the Department formulate its own regulations. The Department recognizes the tension that has historically existed between the NRC and the medical community. However, the Department is committed to incorporation by reference as the best method to insure compatibility. Some latitude exists in the degree of compatibility required for specific regulations, and the Department has and will continue to make use of that latitude as practical to make incorporation by reference viable.

In § 225.71 (relating to definitions), definitions of "direct reading dosimeter" and "personnel dosimeter" have been added at final rulemaking in response to confusion expressed over the inconsistent use of names used to describe terms for individual monitoring devices. A commentator also took exception to including the words "An RSO shall have the authority to suspend or terminate radiographic operations" in the definition of "RSO." The Department concurred and removed this language in the final rulemaking because it is a substantive requirement that already exists in § 225.72 (relating to duties of personnel).

Regarding § 225.74 (relating to training and testing), a commentator requested that minimum hours of training be specified and standardized tests be required. The Department disagrees. The rule is written for flexibility, and training requirements and times vary with the complexity of the operation and the ability of the student. In any case, the program will be subject to review upon inspection by the Department or prior to the issuance of a license.

In § 225.76, general references to Chapter 220 are replaced by specific references for clarity. The applicability to licensees is also clarified in subsection (b), as well as the requirement to provide a 30-day follow-up letter under subsection (c) for information "to the extent known."

In §§ 225.82(c)(3) and (4), 225.83(5) and 225.84(5), the new terms "direct reading dosimeter" and "personnel dosimeter" described previously are substituted for references to other devices used by individuals requiring monitoring.

Section 225.85 is amended at final-form rulemaking to limit retention of surveys used to determine personnel exposure to the period in which a license or registration is active. This is in response to a comment questioning when the Department would authorize their disposition.

Section 225.91 is clarified in the final rulemaking to show that adequate radiation survey instrumentation is required by licensees as well as registrants.

Section 225.93 at final-form rulemaking changes references to various individual monitoring devices to the newly defined terms "direct reading dosimeter" and "personnel dosimeter," as appropriate, and the requirements were further clarified to include licensees as well as registrants. Under § 225.93(d)(1), it was questioned what was meant by recharging a direct reading dosimeter daily and at the start of each work shift. In response, the requirement was reduced and rewritten to rezero the dosimeter at the start of each work shift. An editorial change was made to subsection (d)(3) changing the required accuracy of response for direct reading dosimeters from 30 % to 20 %.

Section 225.101(b) is amended at final-form rulemaking. One commentator was not sure of the intent of the phrase "It may not be possible to energize." This was rewritten to clarify that a cabinet X-ray machine may not be energized when the operating conditions necessitate the area surrounding it to be restricted to maintain radiation exposure levels that are appropriate for members of the public. An editorial correction was also made to § 225.101(d) changing the reference from 10 CFR 20.1201 to 10 CFR 20.1301.

A commentator objected to the wording that requires safety and warning devices to be repaired "in a timely manner," preferring that a specific time limit be set in § 225.104 (relating to X-ray detection systems for explosives, weapons and illegal items). The Department disagrees and has not changed the final rulemaking. The activity engaged in is inherently more dangerous than the risk of exposure to radiation. The regulation recognizes this and provides additional flexibility to the regulated community.

Section 230.13 (relating to transportation of licensed material) is amended at final-form rulemaking to elaborate on the parts of the Federal and Commonwealth transportation agency regulations that are referenced. A commentator believed the provision to be vague, and the Department concurred and made additional clarification.

F. *Benefits Costs and Compliance*

Executive Order 1996-1 requires a cost/benefit analysis of the final-form amendments.

Benefits

As set forth in this proposal, users of radioactive material will be required to comply with radiation protection standards that will not only protect employees but will also protect the general public. The Commonwealth will also be able to continue pursuit of agreement state status with the NRC that will lead to an overall reduction in license fees for NRC licensees of this Commonwealth. The regulation will also generally reduce the records retention requirement from 5 years to 3 years for registrants and licensees of the Department.

Compliance Costs

There are no additional compliance costs because licensees either currently comply with these regulations by virtue of their NRC licenses or through licenses issued by the Department which incorporate similar requirements by condition. There is no additional compliance cost for registrants as the generally applicable standards for radiological health already apply to them.

Compliance Assistance Plan

Compliance assistance is available to all existing license holders through the use of a comprehensive set of regulatory guides published by the NRC.

Compliance with the amended regulations should impose no difficulty or costs because they are either essentially unchanged or simplified from present requirements. In addition to the publication in the *Pennsylvania Bulletin*, notification of the regulatory changes will be enclosed with annual fee invoices to licensees and registrants, and Department inspectors will bring the changes to the attention of licensees and registrants during inspections.

Paperwork Requirements

The final-form regulations will not change paperwork requirements for current NRC licensees because they are already complying with NRC requirements. The retention period for most records will be reduced for registrants and Department licensees.

G. *Pollution Prevention*

The major purpose of the Bureau of Radiation Protection is to reduce public and occupational exposure to radiation. An educational, compliance assistance approach has been used for many years. However, over 90% of the radiation sources regulated emit controlled beams of photon or particle radiation directed at a patient or object for various medical or industrial purposes. Any unwanted radiation is controlled by shielding, adherence to operational rules, inventory procedures, and the like. Materials licensees working with radioisotopes that are not sealed in liquid and gas tight containers are required to follow Department-approved procedures to ensure that the material is not spilled or otherwise released (hoods, absorbent material in metal trays, and the like) and to frequently survey work areas to detect any contamination. The final-form regulations include risk-based release limits.

H. *Sunset Review*

These final-form regulations 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 8, 2000, the Department submitted a copy of the proposed rulemaking to IRRC and the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In compliance with section 5(b.1) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of the comments, as well as other documentation.

In preparing these final-form regulations, the Department has considered the comments received from IRRC and the public. These comments are addressed in the comment and response document and Section E of this Preamble. The Committees did not provide comments on the proposed rulemaking.

These final-form regulations were deemed approved by the House Environmental Resources and Energy Committee on July, 17, 2001, and were deemed approved by the Senate Environmental Resources Committee and Energy Committee on July 17, 2001. IRRC met on July 26, 2001, and approved the final-form regulations in accordance with section 5(c) of the Regulatory Review Act.

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 in 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 regulations do not enlarge the purpose of the proposal published at 30 Pa.B. 4503 (August 26, 2000).

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

K. *Order*

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

(a) The regulations of the Department, 25 Pa. Code Chapters 215, 217, 219, 220, 224, 225, 226, 230 and 232, are amended by amending §§ 215.1—215.3, 215.11, 215.12, 215.15, 215.32, 217.1, 217.2, 219.3, 219.51, 219.61, 219.131, 219.132, 219.159, 219.160, 219.221, 219.222, 219.228, 220.2, 225.1, 226.1, 230.13 and 230.47; adding §§ 215.5, 215.25—215.28, 217.131—217.137, 217.141—217.144, 217.151—217.155, 217.161—217.163, 217.171, 217.172, 217.181, 217.182, 217.191, 217.201—217.203, 219.5—219.7, 219.71—219.73, 219.91—219.93, 219.111—219.113, 219.229, 220.9, 220.10, 224.10, 224.11, 224.21—224.23, 225.2a, 225.3a, 225.4a, 225.5a, 225.6a, 225.71—225.76, 225.81—225.88, 225.91—225.93, 225.101—225.104, 226.3a, 226.4, 226.5, 226.61, 230.3—230.5 and 232.1—232.3; and by deleting 215.4, 217.11—217.18, 217.21—217.24, 217.31, 217.32, 217.41—217.49, 217.51—217.57, 217.65, 217.71—217.74, 217.81—217.93, 217.101, 217.121, 217.122, Appendices A, B and D, 219.4, 219.21, 219.31—219.38, 219.52, 219.151—219.158, 219.161, 219.162, 219.181—219.186, 219.201—219.211, 219.223—219.226, 219.241, Appendices A—C, 220.3—220.8, 224.2—224.9, 224.51—224.60, 224.101—224.112, 224.151, 224.152, 224.201—224.204, 224.251—224.254, 224.301—224.306, 224.351, 224.352, 224.401—224.414, 224.451—224.465, 224.501, 225.2, 225.11—225.18, 225.21—225.23, 225.31—225.33, 225.41—225.44, 225.51—225.53, 226.3, 226.11—226.19, 226.21—226.23, 226.31—226.34, 226.41—226.43, 226.51, Appendices A and B, 230.2, 230.11, 230.12, 230.21—230.26, 230.41—230.46, 230.51, Appendix A, Tables I—IV, to read as set forth in Annex A.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of the 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 in the *Pennsylvania Bulletin*.

DAVID E. HESS,
Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 31 Pa.B. 4503 (August 11, 2001).)

Fiscal Note: Fiscal Note 7-350 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

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, 150.20(a)(1), 150.20(a)(2) and 150.20(b) of the CFR is 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 31.3, 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, 35.990 and 35.991 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), 40.38, 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, 71.47, 71.51, 71.52, 71.53, 71.55, 71.59, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.83, 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 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:

AEC—United States Atomic Energy Commission.

Accelerator-produced material—Material made radioactive by a particle accelerator.

Act—The Radiation Protection Act (35 P. S. §§ 7110.101—7110.703).

Bioassay—The determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this article, "radiobioassay" is an equivalent term.

Brachytherapy—A method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary or interstitial application.

Entrance or access point—An opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radiation sources. The term includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

FDA—The Federal Food and Drug Administration.

Human use—The internal or external administration of radiation or radioactive material to human beings.

Inspection—An official examination or observation including, but not limited to, tests, surveys and monitoring to determine compliance with this article, rules, orders, requirements and conditions of the Department.

Ionizing radiation—Radiation consisting of directly ionizing charged particles—such as electrons, protons, alpha particles and the like—having sufficient kinetic energy to produce ionization by collision, or consisting of either indirectly ionizing uncharged particles—such as neutrons—or photons which can liberate directly ionizing particles or can initiate a nuclear transformation.

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

(i) *General license*—Permission to possess and use radioactive material without the formal review and issuance of documents by the Department.

(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 radioactive material.

Licensed practitioner of the healing arts—An individual licensed by the Commonwealth to practice the healing arts, which for the purposes of this article shall be limited to medicine, surgery, dentistry, osteopathy, podiatry and chiropractic.

Licensee—A person who is licensed by the Department under this article and the act.

Licensing state—A state that has regulations equivalent to the Suggested State Regulations for Control of Radiation (United States Department of Health and Human Services) relating to, and has an effective program for, the regulatory control of NARM and which has been granted final designation as a licensing state by the Conference of Radiation Control Program Directors, Inc.

NARM—A naturally occurring or accelerator-produced radioactive material. The term does not include byproduct, source or special nuclear material.

NORM—Naturally occurring radioactive material—A nuclide which is radioactive in its natural physical state—that is, not man-made—but does not include source or special nuclear material.

NRC—United States Nuclear Regulatory Commission or its authorized representatives.

Person—An individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency or political subdivision of this Commonwealth; another state or political subdivision or agency thereof; and a legal successor, representative, agent or agency of the entities listed in this paragraph. The term does not include Federal government agencies.

Pharmacist—An individual licensed by the Commonwealth to compound and dispense drugs, prescriptions and poisons.

Physician—An individual licensed by the Commonwealth to practice medicine or osteopathy in this Commonwealth.

Prescribed dose for therapy using radiation-producing machines—For X-ray, electron or other particle beam therapy, the total dose and dose per fraction as documented in the written directive.

Qualified expert—

(i) 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) With reference to the calibration of radiation therapy equipment, an individual having, in addition to the qualifications in subparagraph (i), training and experience in the clinical applications of radiation physics to radiation therapy; for example: individuals certified in therapeutic radiological physics or X-ray and radium physics by the American Board of Radiology, or radiation oncology physics by the American Board of Radiology, or radiation oncology physics by the American Board of Medical Physics or those having equivalent qualifications.

Radiation—Ionizing radiation.

Radiation producing machine—A device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

Radiation safety officer—An individual who has the knowledge and responsibility to apply appropriate radiation protection regulations.

Radiation source—An apparatus or material, other than a nuclear power reactor and nuclear fuel located on a plant site, emitting or capable of emitting ionizing radiation.

Radioactive material—A material—solid, liquid or gas—which emits radiation spontaneously.

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

Radiological physicist—An individual who complies with one of the following:

(i) Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics or x- and gamma-ray physics.

(ii) Has a bachelor's degree in one of the physical sciences or engineering and 3 years full-time experience

working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties shall include duties involving the calibration and spot checks of a medical accelerator or a teletherapy unit.

(iii) Has a master's or a doctor's degree in physics, biophysics, radiological physics, health physics or engineering; has had 1 year's full-time training in therapeutic radiological physics; and has had 1 year's full-time work experience in a radiotherapy facility where that person's duties involve calibration and spot checks of a medical accelerator or a teletherapy unit.

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

Registration—The act of registering with the Department under this article.

Roentgen (R)—The special unit of exposure to external X-ray and gamma radiation. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air. See § 215.3 (relating to units of exposure).

Traceable to a National standard—A system which has been calibrated by the National Institute of Science and Technology or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine.

Waste handling licensees—Persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

Written directive for therapy using radiation-producing machines—An order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiation therapy treatment:

(i) For X-ray therapy at potentials less than 1 MeV: the total dose, dose per fraction, treatment site, field sizes, tube potential and filtration, and overall treatment period.

(ii) For X-ray, electron or other particle beam therapy at energies of 1 MeV and above: the total dose, dose per fraction, treatment site, field size, beam type and energy, applicator, use of beam blocking or shaping devices, treatment geometry and overall treatment period.

§ 215.3. Units of exposure.

As used in this article, the unit of exposure to external X-ray and gamma radiation expressed in standard international (SI) units is the coulomb per kilogram (C/kg) of air. This represents the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The "roentgen" is a special unit of exposure. One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air. One milliroentgen (mR) is equal to 1/1000 roentgen.

§ 215.4. (Reserved).

§ 215.5. Effect of Incorporation of the CFR.

(a) *Title and name changes.* 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 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."

(b) *Forms and documents.* References to forms in the Federal regulations incorporated by reference will be replaced by the appropriate forms prescribed by the Department.

(c) *Notifications, reports and correspondence.* 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.

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.11. Records.

(a) Registrants shall maintain records showing the receipt, transfer and disposal of radiation producing machines.

(b) Licensees shall maintain records showing the receipt, transfer and disposal of radioactive material as described in 10 CFR 30.51 (relating to records).

§ 215.12. Inspections.

(a) *Maintenance of records.* Licensees and registrants shall maintain records under this article and have these records available for inspection by the Department.

(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 by the Department.*

(1) The Department, its employees and agents may conduct inspections of the facilities of registrants of radiation-producing machines and licensees of radioactive material at the following frequencies:

(i) For major medical facilities, including hospitals, at least once every 3 years for X-ray operations.

(ii) For all other facilities, at least once every 4 years for X-ray operations.

(iii) For licensees, at the frequencies recommended by the NRC.

(d) *Additional inspections.* The Department, its employees and agents may conduct additional follow-up inspections 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.

§ 215.15. Additional requirements

The Department may impose upon a person requirements additional to those established in this article which it may deem reasonable and necessary to protect the public health and safety. As an example, when necessary or desirable to determine the extent of an individual's exposure to concentrations of radioactive material, the Department may require a licensee to provide to the individual appropriate bioassay services, medical services and the services of a qualified expert and to furnish a copy of the reports of these services to the Department.

PROHIBITIONS AND RESTRICTIONS

§ 215.25. Deliberate misconduct.

The requirements under 10 CFR 30.10 (relating to deliberate misconduct) are incorporated by reference. This requirement also applies to registrants.

§ 215.26. Employee protection.

The requirements under 10 CFR 30.7 (relating to employee protection) are incorporated by reference. This requirement also applies to registrants.

§ 215.27. Vacating premises.

In addition to the decommissioning requirements of 10 CFR 30.36 (relating to expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas) that are incorporated by reference under Chapter 217 (relating to licensing of radioactive material), a licensee shall notify the Department in writing of intent to vacate at least 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the licensee's activities. When deemed necessary by the Department, the licensee shall decontaminate the premises as the Department may specify.

§ 215.28. Deliberate exposure of a monitoring device.

The deliberate exposure of an individual monitoring device or area monitoring device to falsely indicate the dose delivered to an individual is prohibited.

EXEMPTIONS

§ 215.32. Exemption qualifications.

The following sources, uses and types of users are exempt from Chapters 216—232:

(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 217. LICENSING OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 217.1. Purpose and scope.

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

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

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

§ 217.2. Address for communications.

An application for a license, license renewal and license amendments and other communications under this chapter shall be addressed to the Bureau of Radiation Protection, Department of Environmental Protection, Post Office Box 8469, Harrisburg, Pennsylvania 17105-8469.

§§ 217.11—217.18. (Reserved).

§§ 217.21—217.24. (Reserved).

§ 217.31. (Reserved).

§ 217.32. (Reserved).

§§ 217.41—217.49. (Reserved).

§§ 217.51—217.57. (Reserved).

§ 217.65. (Reserved).

§§ 217.71—217.74. (Reserved).

§§ 217.81—217.93 (Reserved).

§ 217.101. (Reserved).

§ 217.121. (Reserved).

§ 217.122. (Reserved).

Appendix A (Reserved)

Appendix B (Reserved)

Appendix D (Reserved)

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

Sec.

§ 217.131. Incorporation by reference.

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

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

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

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

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

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

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

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

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

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

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

§ 217.134. Filing application for specific licenses.

In addition to incorporation by reference, an application for a specific license shall be accompanied by the fee required under Chapter 218 (relating to fees).

§ 217.135. Renewal of licenses.

(a) An application for renewal of a specific license shall be filed under § 217.134 (relating to filing application for specific licenses).

(b) If a renewal application is filed prior to 30 days before the expiration of a license, the existing license does not expire until definitive notice has been given by the Department of its action on the renewal application. This subsection also applies to new license applications incorporating other licenses.

§ 217.136. Exempt concentrations.

In addition to the parts of 10 CFR 30 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 reciprocity), 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
Cadmium (48)	Cd-109		2E-03
Cesium (55)	Cs-129		3E-03
Europium (63)	Eu-154		2E-04
Gallium (31)	Ga-67		2E-03

Element (atomic number)	*Isotope*	*Column I Gas concentration µCi/ml*	*Column II Liquid and solid concentration µCi/ml*
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

§ 217.137. Exempt quantities.

In addition to the parts of 10 CFR 30 incorporated by reference, the following requirements apply:

(1) A person may receive, possess, use, transfer, own or acquire radioactive material in individual quantities each of which is less than those listed in Table 2 if the person does not produce, package or repackage radioactive material for purposes of commercial distribution or incorporate radioactive material into products intended for commercial distribution.

(2) Except under a specific license issued by the Department or the NRC under 10 CFR 32.18 (relating to manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license), a person may not, for purposes of commercial distribution, transfer radioactive material for distribution to persons exempt under paragraph (1) or equivalent regulations of the NRC, an agreement state or licensing state.

TABLE 2

EXEMPT QUANTITIES

Radioactive Material	*Microcuries*
Actinium-228 (Ac 228)	1
Beryllium-7 (Be 7)	10
Bismuth-207 (Bi 207)	10
Cesium-129 (Cs 129)	100
Cobalt-57 (Co 57)	100
Gallium-67 (Ga 67)	100
Germanium-68	10
Gold-195 (Au 195)	10
Gold-196 (Au 196)	1
Indium-111 (In 111)	100
Iodine-123 (I 123)	100
Iodine-124 (I 124)	1
Iridium-190 (Ir 190)	100
Lead-203 (Pb 203)	100
Lead-210 (Pb 210)	0.1
Lead-212 (Pb 212)	10
Phosphorus-33 (P 33)	10
Potassium-43 (K 43)	10
Protactinium-230 (Pa 230)	10
Protactinium-231 (Pa 231)	0.1
Radium-223 (Ra 223)	1
Radium-224 (Ra 224)	1
Radium-226 (Ra 226)	0.1
Radium-228 (Ra 228)	0.1
Radon-220 (Rn 220)	1
Radon-222 (Rn 222)	1
Rhenium-183 (Re 183)	100
Rhenium-187 (Re 187)	100
Rubidium-81 (Rb 81)	10
Scandium-46 (Sc 46)	10
Sodium-22 (Na 22)	10
Technetium-96m (Tc 96m)	100
Xenon-127 (Xe 127)	1,000
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

Sec.

§ 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 31.3, 31.4 and 31.14 (relating to certain devices and equipment; information collection requirements: OMB approval; and criminal penalties) are not incorporated by reference.

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

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

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

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

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

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

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

§ 217.143. Certain measuring, gauging or controlling devices.

In addition to the parts of 10 CFR 31.5 (relating to certain detecting measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere) incorporated by reference, general licensees subject to registration under 10 CFR 31.5(c)(13)(i) or possessing general licensed devices containing 370 MBq (10 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, shall 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.

§ 217.144. Incidental radioactive material produced by a particle accelerator.

A general license is issued to possess radioactive material produced incidentally to the operation of a particle accelerator. The general license is also subject to the applicable provisions of Chapters 215, 217, 219 and 220. A licensee may transfer this radioactive material only under Subchapter I and Chapter 230 (relating to transfer of radioactive material; and packaging and transportation of radioactive material). A licensee may dispose of this radioactive material only with Department approval.

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

Sec.
217.151. Incorporation by reference.
217.152. Effect of incorporation of 10 CFR Part 32.
217.153. Licensing the incorporation of NARM into gas and aerosol detectors.
217.154. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226.
217.155. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

§ 217.151. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 32 (relating to specific domestic licenses to manufacture or transfer certain items containing byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 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 by reference.

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

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

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

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

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

(4) A reference to byproduct material includes NARM.

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

§ 217.153. Licensing the incorporation of NARM into gas and aerosol detectors.

An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under Subchapter B (relating to general provisions for radioactive material) will be approved if the application satisfies requirements equivalent to those in 10 CFR 32.26—32.29. The maximum quantity of radium-226 may not exceed 0.1 microcuries (3.7 kBq).

§ 217.154. Special requirements for license to manufacture calibration sources containing americium-241, plutonium or radium-226.

In addition to the incorporation by reference of requirements in 10 CFR 32.57 (relating to calibration sources containing americium-241), applicants using plutonium

and radium-226 in the manufacture of calibration or reference sources shall comply with 10 CFR 32.57.

§ 217.155. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.

(a) In addition to the incorporation by reference of requirements in 10 CFR 32.71 (relating to manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license), applicants using cobalt-57 shall prepare for distribution the cobalt-57 in prepackaged units that do not exceed 10 microcuries (370 kBq) of cobalt-57.

(b) A prepackaged unit shall bear a durable, clearly visible label identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) cobalt-57.

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

Sec.
217.161. Incorporation by reference.
217.162. Effect of incorporation of 10 CFR Part 33.
217.163. Types of specific licenses of broad scope.

§ 217.161. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 33 (relating to specific domestic licenses of broad scope for byproduct material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 33.8, 33.21 and 33.23 (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

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

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

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

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

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

(4) A reference to byproduct material includes NARM.

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

§ 217.163. Types of specific licenses of broad scope.

In addition to the incorporation by reference of 10 CFR 33.11 (relating to types of specific licenses of broad scope), the following requirements for licensees using NARM also apply:

(1) A Type A specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the act. The quantities specified exceed those specified in Column I, Table 3 and are usually in the multicurie range.

(2) A Type B specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in Table 3, for an authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column I, Table 3. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column I, Table 3, for that radionuclide; the sum of the ratios for radionuclides possessed under the license may not exceed unity.

(3) A Type C specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in Table 3, for an authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Column II, Table 3. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Column II, Table 3, for that radionuclide; the sum of the ratios for radionuclides possessed under the license may not exceed unity.

TABLE 3

LIMITS FOR BROAD LICENSES

Radioactive Material	*Col. I curies*	*Col. II curies*
Beryllium-7	10	0.1
Cobalt-57	10	0.1
Radium-226	0.01	0.0001
Scandium-46	1	0.01
Sodium-22	0.1	0.001

Subchapter G. LICENSING OF SOURCE MATERIAL

Sec.
217.171. Incorporation by reference.
217.172. Effect of incorporation of 10 CFR Part 40.

§ 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), 40.38, 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.

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

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

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

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

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

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

(5) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR shall be

directed to the Department and, for NRC licenses, to the NRC until agreement state status is in effect.

Subchapter H. LICENSING OF SPECIAL NUCLEAR MATERIAL

Sec.
217.181. Incorporation by reference.
217.182. Effect of incorporation of 10 CFR Part 70.

§ 217.181. Incorporation by reference.

(a) Except as provided in this subchapter, the requirements of 10 CFR Part 70 (relating to domestic licensing of special nuclear material) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 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) and (b)(1), (3) and (4) and (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 by reference.

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

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

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

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

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

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

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

Subchapter I. TRANSFER OF RADIOACTIVE MATERIAL

Sec.
217.191. Transfer of material.

§ 217.191. Transfer of material.

The requirements of 10 CFR 30.41 (relating to transfer of byproduct material) also apply to NARM.

Subchapter J. RECIPROCITY

Sec.
217.201. Incorporation by reference.
217.202. Effect of incorporation of 10 CFR Part 150.
217.203. Reciprocity of licenses of naturally occurring and accelerator-produced radioactive material.

§ 217.201. Incorporation by reference.

Except as provided in this subchapter, the requirements of 10 CFR 150.1, 150.2, 150.3, 10 CFR 150.11 and 10 CFR 150.20(a)(1) (2) and (b) (relating to recognition of Agreement State licenses) 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 authorization 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 of naturally occurring and accelerator-produced radioactive material.

(a) Subject to this article, a person who holds a specific license from a licensing 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 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 or by another licensing 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 a licensing 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 a licensing 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 (relating to general license for radioactive material) 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 (relating to general provisions for radioactive material) within 30 days after the end of the 180-day period.

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

§ 219.3. Definitions.

The following term, when used 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 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%.

§ 219.4. (Reserved).

§ 219.5. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 20 (relating to standards for protection against radiation) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 20.1006, 20.1009, 20.2206(a)(1), (3), (4) and (5), 20.2401 and 20.2402 are not incorporated by reference.

§ 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.

§ 219.7. Effect of incorporation of 10 CFR 20.1403 "Criteria for license termination under restricted conditions."

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

(1) The license is amended to authorize activities necessary to begin decommissioning under the LTP.

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

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

§ 219.21. (Rserved).

§§ 219.31—219.38. (Reserved).

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

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

In addition to incorporation by reference of 10 CFR Part 20 Subpart D (relating to dose limits for individual

members of the public), registrants who met the previous limit (5 mSv or 0.5 REM in 1 year) for locations having existing radiation-producing machines or equipment or other registered radiation sources will not be required to retrofit installations existing before November 18, 1995. The Department does not require the retrofitting of shielding for the replacement of equipment in the facility as long as the equipment is being replaced with similar equipment.

§ 219.52. (Reserved).

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 approved by the Department under §§ 217.81—217.93 (relating to specific license to manufacture, assemble, repair or distribute commodities, products or devices which contain radioactive material), an agreement state, a licensing state or the NRC, except that the maximum interval between leak tests may not exceed 3 years.

(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 approved by the Department under §§ 217.81—217.93, an agreement state, a licensing state or the NRC, except that the maximum interval between leak tests may not exceed 3 years.

(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, except teletherapy and brachytherapy sources, which are stored, are not being used, and are identified as in storage. The licensee shall, however, 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. The maximum interval between tests for leakage or contamination may not exceed 3 years.

(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).

§§ 219.71—219.73. (Reserved).

§§ 219.91—219.93. (Reserved).

§§ 219.111—219.113. (Reserved).

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

§ 219.131. Security of stored sources of radiation.

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

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

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against

radiation), the licensee or registrant shall maintain control of radiation producing machines that are not in storage.

Subchapter J. PRECAUTIONARY PROCEDURES

§§ 219.151—219.158. (Reserved).

§ 219.159. Posting of radiation-producing machines.

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

**"CAUTION—RADIATION
THIS EQUIPMENT PRODUCES RADIATION
WHEN ENERGIZED."**

§ 219.160. Exceptions to posting requirements.

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

§ 219.161. (Reserved).

§ 219.162. (Reserved).

§§ 219.181—219.186. (Reserved).

§§ 219.201—219.211. (Reserved).

Subchapter M. REPORTS

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

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

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

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

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

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

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

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

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

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

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

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

§ 219.222. Notification of incidents and reportable events.

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

§§ 219.223—219.226. (Reserved).

§ 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 as a result of the misadministration, because of delay in notification.

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

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

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

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

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

§ 219.229 Other medical reports.

Within 30 days of the discovery of either actual or suspected acute or long-term functional damage to tissue 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 notification of incidents and reportable events) and any functional damage to patient tissue that was an expected outcome when the causative procedures were prescribed.

§ 219.241. (Reserved).

Appendix A (Reserved)

Appendix B (Reserved)

Appendix C (Reserved)

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 ER-BRP-3, "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.

§§ 220.3—220.8. (Reserved).

§ 220.9. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 19 (relating to notices, instructions and reports to workers; inspections and investigations) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 19.4, 19.5, 19.8, 19.30 and 19.40 are not incorporated by reference.

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

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

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

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

(3) A reference to "license," "licenses," "licensed" and "licensed radioactive material" also include "registration," "registrant" "registered," and "registered source of radiation," respectively.

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

CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§§ 224.2—224.9. (Reserved).

§ 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, 35.990 and 35.991 (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

§ 224.11. Effect of incorporation of 10 CFR Part 35.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 35 (relating to medical use of byproduct material), the following words and phrases shall be substituted for the language in 10 CFR Part 35 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 "byproduct material" includes NARM.

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

(5) A reference to the Advisory Committee on the Medical Uses of Isotopes is synonymous with the Department's Radiation Protection Advisory Committee.

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

Subchapter B. OTHER REQUIREMENTS

§ 224.21. Supervision.

In addition to the incorporation by reference of 10 CFR Part 35 (relating to medical use of byproduct material), the licensee shall also:

(1) Permit only auxiliary personnel who have met the applicable radiologic requirements of 49 Pa. Code, Part I, Subpart A (relating to professional and occupational affairs) to use radioactive materials for diagnostic or therapeutic purposes.

(2) Permit only auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government to use radioactive materials for diagnostic or therapeutic purposes in accordance with written job descriptions and employee qualifications.

§ 224.22. Authorization for calibration and reference sources.

Notwithstanding the incorporation by reference of 10 CFR Part 35, a licensee authorized for medical use radioactive materials may receive, possess and use sealed sources of radioactive material up to 1,110 MBq (30 mCi) apiece for check, calibration and reference use.

§ 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.

§§ 224.51—224.60. (Reserved).

§§ 224.101—224.112. (Reserved).

§ 224.151. (Reserved).

§ 224.152. (Reserved).

§§ 224.201—224.204. (Reserved).

§§ 224.251—224.254. (Reserved).

§§ 224.301—224.306. (Reserved).

§ 224.351. (Reserved).

§ 224.352. (Reserved).

§§ 224.401—224.414. (Reserved).

§§ 224.451—224.465. (Reserved).

§ 224.501. (Reserved).

CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL USES AND RADIOGRAPHIC OPERATIONS

Subchapter A. GENERAL PROVISIONS

Sec.

§ 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.

§ 225.2. (Reserved).

§ 225.2a. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 34 (relating to licenses for industrial radiography and radiation safety requirements for industrial radiographic operations) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 34.5, 34.8, 34.121 and 34.123 are not incorporated by reference.

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

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

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

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

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

(4) The definition of "licensed material" includes NARM.

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

§ 225.4a. Radiation safety program.

A 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.

§ 225.5a. Reciprocity.

Out-of-State users of radiation producing machines shall meet the requirements of § 216.7 (relating to out-of-State radiation-producing machines).

§ 225.6a. Prohibitions.

Use of radiation sources covered under this chapter for diagnosis or therapy on humans or animals is not permitted.

§§ 225.11—225.18. (Reserved).

§§ 225.21—224.23. (Reserved).

§§ 225.31—225.33. (Reserved).

§§ 225.41—224.44. (Reserved).

§§ 225.51—225.53. (Reserved).

Subchapter B. RADIATION-PRODUCING MACHINES

GENERAL ADMINISTRATIVE REQUIREMENTS

GENERAL TECHNICAL REQUIREMENTS

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

RADIATION-PRODUCING MACHINE REQUIREMENTS

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).

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.

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

Temporary job site—A location where industrial radiography is performed for 180 days or less during any consecutive 12 months other than the location listed in a registration.

§ 225.72. Duties of personnel.

(a) The RSO shall assure that the radiation safety program of the registrant or licensee is implemented and

suspend or terminate operations that are not being conducted in accordance with approved procedures or the Department's requirements.

(b) The radiographer is responsible to the registrant or licensee for following the procedures of the registrant or licensee and for complying with the Department's requirements while industrial radiographic operations are being conducted.

(c) The radiographer's assistant shall only use radiation producing machines or radiation survey instrumentation under the personal supervision of a radiographer.

(d) The radiographer trainee is not permitted to operate radiation producing machines or radiation survey instrumentation.

§ 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 temporary job site radiography shall comply with the training requirements in 10 CFR 34, Subpart D (relating to radiation safety requirements).

§ 225.74. Training and testing.

(a) The registrant may not permit an individual to act as a radiographer until that individual has:

(1) Been instructed in the subjects outlined in Appendix A.

(2) Received copies of this chapter, Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations), and copies of the license or certificate of registration and the operating and emergency procedures of the registrant or licensee.

(3) Received instruction covering regulatory requirements, operating and emergency procedures and the use of radiation-producing machines and radiation survey instruments of the registrant or licensee.

(4) Demonstrated competency and understanding of the information in this subsection to the satisfaction of the registrant or licensee as evidenced by the successful completion of a written test and a field examination.

(b) The registrant or licensee may not permit an individual to act as a radiographer's assistant until that individual has:

(1) Received copies of, and instruction in, the applicable operating and emergency procedures and has been instructed in the use of sources of radiation and radiation survey instruments of the registrant or licensee.

(2) Demonstrated that, under direct personal supervision of a radiographer, the individual is competent to use sources of radiation and radiation survey instruments as evidenced by the successful completion of a written or oral test and a field examination on the subjects relevant to being an assistant radiographer.

(c) Records of the training required under subsections (a) and (b), including copies of written tests, dates of oral tests and field examinations, shall be maintained for inspection by the Department for 3 years following termination of employment by the individual or until the registration or license is terminated.

§ 225.75. Audits and safety reviews of radiographers and radiographer's assistants.

(a) The registrant or licensee shall review and provide for the safety and ongoing training needs of radiographers and radiographer's assistants at least once during each calendar year.

(b) The registrant or licensee shall conduct an annual inspection program of the job performance of each radiographer and radiographer's assistant to ensure that operating and emergency procedures and this article and registration or license requirements for the registrant or licensee are followed. This audit program shall:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed 1 calendar year.

(2) Provide that, if a radiographer or radiographer's assistant has not participated in a radiographic operation for more than 6 months since the last annual inspection, the individual's performance shall be observed and recorded when the individual next participates in a radiographic operation.

(c) The registrant or licensee shall maintain records of the training set forth in subsection (b) to include certification documents, written and field examinations, annual safety reviews and annual audits of job performance. Records shall be available for inspection by the Department for 3 years following the termination of employment of the individual or until the registration or license is terminated.

§ 225.76. Reporting requirements.

(a) In addition to the reporting requirements in §§ 219.221 and 219.222 (relating to reports of stolen, lost or missing licensed or registered sources of radiation; and notification of incidents and reportable events), each registrant or licensee shall provide to the Department, within 30 days of its occurrence, a written report on any of the following incidents involving machines or equipment used in radiographic operations:

(1) The inability to terminate irradiation from a radiation producing machine.

(2) An interlock failure during shielded room radiography.

(b) The registrant or licensee shall include the following information in each report submitted under subsection (a):

(1) A description of the equipment problem.

(2) The cause of the incident, if known or determined.

(3) The manufacturer and model number of the equipment involved.

(4) The place, date and time of the incident.

(5) Actions taken to reestablish normal operations.

(6) Corrective actions taken or planned to prevent reoccurrence.

(7) The names and qualifications of personnel involved.

(c) Reports of overexposures, required under 10 CFR 20.2202 (relating to notification of incidents) or of excessive exposures, required under 10 CFR 20.2203 (relating to reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits) which involve the failure of safety components of radiography equipment shall also include, to the extent known, the

information specified under subsection (b). Complete information required in subsection (b) shall be available in the 30-day follow-up report rule under 10 CFR 20.2203 (a).

GENERAL TECHNICAL REQUIREMENTS

§ 225.81. Permanent radiographic installations.

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

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

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

(3) The radiographic exposure system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used provided that the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.52 (relating to surveillance; posting), § 225.83 (relating to operating requirements) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the radiation safety officer or an individual designated by the radiation safety officer shall validate the repair.

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

§ 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 or a radiographer's assistant.

(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 temporary job sites.

Each registrant or licensee conducting radiographic operations at a temporary job 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.

§ 225.84. Operating and emergency procedures.

The operating and emergency procedures of the registrant or licensee shall include instruction in at least the following:

(1) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation in excess of the limits established in Chapter 219 (relating to standards for protection against radiation).

(2) Methods and occasions for conducting radiation surveys and the proper use of survey meters.

(3) Methods for controlling access to areas where radiographic operations are being conducted.

(4) Methods and occasions for locking and securing sources of radiation.

(5) Personnel monitoring and the use of individual monitoring devices, including steps that are to be taken immediately by radiographic personnel when a direct reading dosimeter is found to be off-scale.

(6) Methods and procedures for minimizing exposure to individuals in the event of an accident.

(7) The procedure for notifying proper personnel in the event of an accident.

(8) Maintenance of records required by the Department.

(9) The inspection and maintenance of radiation-producing machines and survey meters.

§ 225.85. Surveys and survey records.

(a) A survey with a calibrated radiation survey instrument shall be made after each radiographic exposure to determine that the emission of radiation has terminated.

(b) Records of the surveys required by subsection (a) shall be maintained (for inspection by the Department) for 3 years. If the survey has been used to determine an individual's exposure, the records of the survey shall be maintained until the Department terminates the registration or license.

§ 225.86. Utilization logs.

A registrant or licensee shall maintain current logs, which shall be kept available for inspection by the

Department for 3 years from the date of the event, showing for each radiation-producing machine, the following applicable information:

(1) The identity (name and signature) of the operator to whom the radiation-producing machine is assigned.

(2) The model and serial number of the radiation-producing machine.

(3) The locations and dates of use.

(4) The technique factors (tube kilovoltage, tube current, exposure time) used for each radiographic exposure.

§ 225.87. Security.

During each radiographic operation, the radiographer or radiographer's assistant shall maintain direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except when one of the following exists:

(1) The high radiation area is equipped with a control device or an alarm system as described in 10 CFR 20.1601 and 20.1902(b) (relating to control of access to high radiation areas; and posting of high radiation areas).

(2) The high radiation area is locked to protect against unauthorized or accidental entry.

§ 225.88. Posting.

Areas in which radiographic operations are being performed shall be conspicuously posted as required by 10 CFR 20.1902 (relating to posting requirements).

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

§ 225.91. Radiation survey meter requirements.

(a) A registrant or licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this chapter and Chapter 219 (relating to standards for the protection against radiation).

(b) A radiographic operation may not be conducted unless calibrated and operable radiation survey instrumentation is available and used at each site where radiographic operations are conducted.

(c) Immediately prior to first use at a site where radiographic operations are conducted and at the beginning of work shift changes thereafter, a radiation survey instrument shall be checked to ensure that it is operating properly by exposing the instrument to a reference source of radiation and observing its response. Instruments that fail to respond as expected may not be used.

§ 225.92. Radiation survey meter calibration requirements.

(a) In addition to the requirements of § 225.91 (relating to survey meter requirements), instruments required by this chapter shall have a range so that 0.516 µC/kg (2 mR) per hour through 258 µc/kg (1 R) per hour can be measured.

(b) Each radiation instrument shall be calibrated:

(1) At energies appropriate for use.

(2) At intervals not to exceed 6 months.

(3) After each instrument servicing, other than battery replacement.

(4) To within an accuracy of +/- 20%.

(5) At two points located approximately one-third and two-thirds of full scale on each scale of linear scale instruments; at mid-range of each decade and at two points of at least 1 decade for logarithmic scale instruments; and for digital instruments, at three points between 0.516 µC/kg (2 mR) and 258 µC/kg (1000 mR) per hour.

(6) By a person authorized by the Department, the NRC or an agreement state.

(c) Calibration records shall be maintained for inspection by the Department for 3 years after the date of calibration.

§ 225.93. Personnel monitoring control.

(a) The registrant or licensee may not permit an individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each individual wears a direct reading dosimeter and a personnel dosimeter that is processed and evaluated by an NVLAP processor.

(1) Personnel monitoring devices used to determine compliance with dose limits for the whole body shall be worn on the trunk of the body over the area most likely to receive exposure.

(2) This does not relieve the registrant or licensee from providing peripheral monitoring devices such as ring finger TLDs when appropriate.

(3) Each personnel monitoring device shall be assigned to and worn by only one individual.

(b) Film badges shall be replaced at intervals not to exceed 1 month. Other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at intervals not to exceed 3 months.

(c) Direct reading dosimeters shall meet the criteria as in ANSI N13.5-1972, "Performance Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma-Radiation" published in 1972, exclusive of subsequent amendments or additions.

(d) The use of DRDs is subject to the following requirements:

(1) DRDs shall have a range of zero to 51.6 µC/kg (200 mR) and shall be rezeroed at the start of each work shift.

(2) As a minimum, at the beginning and the end of each worker's shift involving the use of a source of radiation, DRDs shall be read and the exposure values recorded.

(3) Direct reading dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. A dosimeter may not be used for personnel monitoring unless the response is accurate within +/- 20% of the true radiation exposure. Records of dosimeter response checks shall be maintained for inspection by the Department for 3 years.

(4) If an individual's DRD indicates exposure that is "off-scale" beyond the range it can measure, industrial radiographic operations by that individual shall cease immediately and the individual's personnel dosimeter shall be sent immediately for processing. The individual may not use any sources of radiation until the individual's radiation dose has been determined.

(e) Data on personnel exposure reported or recorded from personnel monitoring devices shall be kept for inspection by the Department until the certificate of registration or license is terminated or until the Department authorizes their disposition, in writing, following a determination by the Department that the records contain inaccurate personnel monitoring information.

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, 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 evaluate the cabinet X-ray system to assure compliance with 10 CFR 20.1301 and 21 CFR 1020.40 if the system is a certified cabinet X-ray system. Records of these evaluations shall be maintained for inspection by the Department while the system is in the possession of the registrant or until the evaluation is replaced by an update following modifications.

(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 registrant shall provide personnel monitoring equipment to every individual who operates, positions material for irradiation, or performs maintenance on a radiation-producing machine for shielded room X-ray radiography.

(c) 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.

§ 225.103. Temporary job 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.

§ 225.104. X-ray detection systems for explosives, weapons and illegal items.

(a) This section applies to X-ray systems that produce an image that may be used to screen for the presence of explosive devices or components, weapons, contraband or prohibited items. This section does not apply to cabinet and baggage/package X-ray systems covered under § 225.101 (relating to cabinet X-ray systems and baggage/package X-ray systems).

(b) An X-ray system used for detection of explosives, weapons or illegal items may not be used on human beings or animals without specific permission of the Department. X-ray systems that irradiate human beings for medical diagnosis are covered under Chapter 221 (relating to human use of X-ray machines). X-ray systems that irradiate animals for diagnosis or therapy are covered under Chapter 223 (relating to veterinary medicine).

(c) Radiographic X-ray detection systems shall conform to the following:

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 µc/kg (100 mR) 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.

(2) Portable X-ray systems shall be equipped with collimators which are capable of restricting the useful beam to the area of interest. Collimators shall provide the same degree of protection required in paragraph (1).

(3) A means shall be provided to terminate the exposure after a preset time, a preset to image receptor or a preset product of exposure time and tube current.

(4) The X-ray control shall have a dead-man type exposure switch.

(5) The X-ray controls shall indicate the technique factors, (that is, kilovoltage, tube current and exposure time or the product of tube current and exposure time).

(6) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the words, "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.

(7) For fixed radiographic equipment, an easily visible warning light shall be located adjacent to the X-ray tube and labeled with the words "X-RAY ON" or words having a similar intent. The warning light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(d) Fluoroscopic X-ray detection systems shall conform to the following:

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 µc/kg (100 mR) 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.

(2) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the

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

(3) To the extent practicable, the X-ray system (X-ray tube, imaging system and the object being irradiated) shall be completely enclosed so that every location on the exterior meets conditions for an unrestricted area and the only access to the room or enclosure 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).

(4) The equipment shall be constructed so that, under conditions of normal use, the entire cross-section of the useful beam shall be attenuated by a primary protective barrier permanently incorporated into the equipment.

(5) The X-ray control shall have a dead-man type exposure switch. Activation of the X-ray beam shall be possible only by continuous pressure on the exposure switch.

(6) An easily visible warning light shall be located adjacent to the X-ray tube or on the outside of the enclosure and be labeled with the words "X-RAY ON" or words having a similar intent. This light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(e) Operating procedures for portable radiographic X-ray detection systems are as follows:

(1) To the extent practicable, portable X-ray tube heads shall be supported by a stand.

(2) To the extent practicable, supporting or positioning devices for the image receptor shall be used during radiation exposures.

(3) Individuals, other than those whose presence is necessary to conduct the X-ray procedure, shall be located at least 2 meters away from the X-ray tube and the object being irradiated during exposures.

(4) An individual may not be regularly employed to support the image receptor or object during radiation exposures.

(f) Operating procedures for fixed radiographic X-ray detection systems are as follows:

(1) A registrant shall test the safety and warning devices, including interlocks, at intervals not to exceed 12 months. Test records shall be maintained for inspection by the Department for 3 years after the test has been conducted.

(2) Safety or warning devices that do not function properly shall be repaired in a timely manner.

(3) If an X-ray detection system is required to be operated while in need of repair, procedures shall be modified to maintain the design level equivalent of safety or else the equipment may not be used.

CHAPTER 226. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

GENERAL

§ 226.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons using radiation sources for well logging in a single well, radioactive markers, uranium sinker bars and subsurface tracer studies. Persons who use radiation sources for well logging operations shall comply with this chapter, which is in addition to and not in substitution for other applicable requirements of this article, in particular, the requirements of Chapters 215, 217—220, 228 and 230.

§ 226.2. (Reserved).

§ 226.3. (Reserved).

§ 226.3a. Abandonment of a sealed source.

In addition to incorporation by reference of 10 CFR Part 39 (relating to licenses and radiation safety requirements for well logging), the requirements of § 78.111 (relating to abandonment) shall also be met.

§ 226.4. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 39 (relating to licenses and radiation safety requirements for well logging) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 39.5, 39.8, 39.101 and 39.103 are not incorporated by reference.

§ 226.5. Effect of incorporation of 10 CFR Part 39.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 39, the following words and phrases shall be substituted for the language in 10 CFR Part 39 as follows:

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

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

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

(4) The definition of "licensed material" includes NARM.

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

§§ 226.11—226.19. (Reserved).

§§ 226.21—226.23. (Reserved).

§§ 226.31—226.34. (Reserved).

§§ 226.41—226.43. (Reserved).

§ 226.51. (Reserved).

Appendix A (Reserved)

Appendix B (Reserved)

PARTICLE ACCELERATORS

§ 226.61. Particle accelerators.

(a) A licensee or registrant may not permit aboveground testing of particle accelerators designed for use in well logging which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of 10 CFR 20.1301 (relating to radiation dose to dose limits for individual members of the public) are met.

(b) The use of particle accelerators for well logging shall be conducted under the licensing provisions of Chapter 228 (relating to radiation safety requirements for particle accelerators).

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE

§ 230.2. (Reserved).

§ 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, 71.47, 71.51, 71.52, 71.53, 71.55, 71.59, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.83, 71.99 and 71.100 are not incorporated by reference.

§ 230.4. Effect of incorporation of 10 CFR Part 71.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), the following words and phrases shall be substituted for the language in 10 CFR Part 71 as follows:

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

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

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

(4) The definition of "licensed material" includes NARM.

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

§ 230.5. Communications.

Notwithstanding the incorporation by reference of 10 CFR 71.1 (relating to communications and records), all communications concerning the requirements of this chapter should be sent to the address listed under § 215.41 (relating to address).

Subchapter B. GENERAL

§ 230.11. (Reserved).

§ 230.12. (Reserved).

§ 230.13. Transportation of licensed material.

In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), if 67 Pa. Code Chapters 229, 231 and 403 (relating to interstate motor carrier safety requirements; intrastate motor carrier requirements; and hazardous materials transportation) or the regulations of the United States Department of Transportation in 49 CFR Parts 171—180 and 388—397 do not apply to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

§ 230.14. (Reserved).

§§ 230.21—230.26. (Reserved).

Subchapter D. OPERATING CONTROLS AND PROCEDURES

§§ 230.41—230.46. (Reserved).

§ 230.47. Advance notification of transport of nuclear waste.

In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive materials), the licensee is responsible for the following:

(1) Prior to the transport of nuclear waste specified in 10 CFR 71.97(b) (relating to advance notification of shipment of irradiated reactor fuel and nuclear waste) outside the licensee's facility or other place of use or storage, or prior to delivery to a carrier for transport, each licensee shall provide advance notification of the transport to the Governor, or the Governor's designee, of each state through which the waste will be transported, and to the Department.

(2) The notification required by paragraph (1) shall be made in writing to the office of each appropriate governor, or governor's designee, and to the Department. A notification delivered by mail shall be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger shall reach the office of the governor, or governor's designee, and the Department, at least 4 days before the beginning of the 7-day period during which the departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 3 years.

(3) The licensee shall notify each appropriate governor, or governor's designee, and the Department of changes to schedule information provided under paragraph (1). The notification shall be by telephone to a responsible individual in the office of each appropriate governor, or governor's designee, and the Department. The licensee shall maintain for 3 years a record of the individual contacted.

(4) Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to each appropriate governor, or governor's designee, and to the Department. A copy of the notice shall be retained by the licensee for 3 years.

(5) A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, Office of State Programs, United States Nuclear Regulatory Commission, Washington, DC 20555.

Subchapter E. QUALITY ASSURANCE

§ 230.51. (Reserved).

Appendix A (Reserved)

Tables I—IV (Reserved)

CHAPTER 232. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Sec.
232.1. Purpose and scope.
232.2. Incorporation by reference.
232.3. Effect of incorporation of 10 CFR Part 36.

§ 232.1. Purpose and scope.

(a) This chapter contains the requirements for the issuance of a license authorizing the use of radioactive materials in sealed sources to irradiate objects or materials with gamma radiation.

(b) 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 and 230.

§ 232.2. Incorporation by reference.

(a) Except as provided in this chapter, the requirements of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators) are incorporated by reference.

(b) Notwithstanding the requirements incorporated by reference, §§ 36.5, 36.8, 36.91 and 36.93 are not incorporated by reference.

§ 232.3. Effect of incorporation of 10 CFR Part 36.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 36 (relating to licenses and radiation safety requirements for irradiators), the following words and phrases shall be substituted for the language in 10 CFR Part 36 as follows:

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

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

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

(4) 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.

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