PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 215, 217, 219, 220, 224, 225, 226, 230 AND 232]

Radiological Health

The Environmental Quality Board (Board) proposes to amend Chapters 215, 217, 219, 220, 224—226 and 230 and to add a new Chapter 232. The proposed amendments update the standards for protection against radiation.

This proposal was adopted by the Board at its regular meeting on June 20, 2000.

A. *Effective Date*

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

B. *Contact Persons*

For further information, the contact persons are 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.

C *Statutory Authority*

These amendments are proposed under the authority of the following statutes:

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), which authorizes and directs the Board to adopt regulations necessary for the proper performance of the work of the Department.

D *Background and Purpose*

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 United States Nuclear Regulatory Commission (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 proposed 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 by-product materials, source materials and special nuclear materials in amounts insufficient to form a critical mass.

The proposed 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 18, 1999, the Committee met and reviewed the proposed amendments. The chairperson announced by letter dated May 17, 1999, the Committee's concurrence to send the proposed amendments to the Board.

E. *Summary of Regulatory Requirements*

The proposed amendments revise current radiation protection regulations to reflect compatibility with NRC radiation protection regulations. The revisions are requisite to the Commonwealth's attainment of Agreement State status from the NRC. A description of the proposed regulations is provided as follows:

Chapter 215. General Provisions

Section 215.1 (relating to purpose and scope) is expanded to clarify that the effect of incorporation by reference under subsection (e) would not relieve a person from complying with Pennsylvania law nor would it expand the scope of authority granted the Department under statute in subsection (f). Locations are listed in new § 215.1(g) for purchasing 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. http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199910

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

The following definitions are updated: "NRC," "qualified expert" and "roentgen." The definition of "misadministration" is redefined for X-ray by using the appropriate parts of the NRC proposed definition for "medical event." The definition of "prescribed dose" is changed to "prescribed dose for X-ray therapy" by deleting references to radioactive material modalities. The definition of "written directive" is changed to "written directive for X-ray therapy" by deleting references to radioactive material.

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.

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

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 recordkeeping 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 § 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 employe protection) is added for compatibility with the NRC.

A new § 215.27 (relating to vacating premises) is added to replace § 219.241 (relating to vacating premises). The requirement is extended to all licenses and is in addition to the decommissioning requirements of 10 CFR 30.36 that are incorporated by reference under Chapter 217.

A new § 215.28 (relating to deceptive exposure of a monitoring device) is added to prohibit using a monitoring device to indicate deceptively 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

Section 217.1 (relating to purpose and scope) is amended to include references to Chapters 218 and 232 (relating to 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, Appendix 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.

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 included in incorporation 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 included in 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) is the existing § 217.42 amended to include some Department requirements that are not included in the incorporation by reference.

Section 217.144 (relating to incidental radioactive material produced by a particle accelerator) is the existing § 217.48 amended to include a Department requirement which 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 (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 32) 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 included in incorporation 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 (relating to incorporation by reference) and 217.172 (relating to 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) is the existing Subchapter D and § 217.191 is the existing § 217.101.

A new Subchapter J (relating to reciprocity) is the existing Subchapter F amended to incorporate 10 CFR 150.2 (relating to scope), 10 CFR 150.11 (relating to critical mass) and 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) is deleted because of incorporation by reference of 10 CFR Part 20.

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.

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) consists of §§ 219.51 and 219.52.

Section 219.51 (relating to dose limits for individual members of the public) is amended by incorporation by reference. The current exception that allows individual members of the public in unrestricted areas to receive a higher limit of 0.5 rem per year from medical diagnostic radiation producing machines is eliminated. However, the grandfather clause is retained allowing a higher limit of 0.5 rem per year from any radiation producing machines or other registered radiation sources installed prior to November 18, 1985.

Sections 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) is reserved but the requirements are retained as in addition to those incorporated by reference in 10 CFR Part 20.

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 combined with § 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) is amended by replacing the current text with incorporation by reference of the 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) was renamed to "reports of misadministrations from X-ray."

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 27 mCi (1,000 MBq) apiece of radioactive material. It replaces current § 224.104 that is deleted because of incorporation by reference of 10 CFR 35.57.

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.

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 through K are deleted because of incorporation by reference of 10 CFR Part 35.

Chapter 225. Radiation Safety Requirements for Industrial Radiographic Operations

Chapter 225 is split into two subchapters: Subchapters A and B (relating to general provisions; and radiation producing machines general administrative requirements).

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 heading, "General Administrative Requirements," that includes new §§ 225.71—225.76 (relating to definitions; duties of personnel; training of personnel; training and testing; audits and safety reviews of radiographers and radiographer assistants; and reporting requirements).

Definitions introduced in Subchapter B are "cabinet radiography," "cabinet X-ray system," "certified cabinet X-ray system," "industrial radiography," "permanent radiographic installation," "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 (relating to permanent radiographic installations; operating requirements; records required at temporary job sites; 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).

A new heading, "Radiation Producing Machine Requirements," includes §§ 225.101—225.104 (relating to cabinet X-ray systems and baggage/package X-ray systems; shielded room X-ray machine radiography; temporary job site radiography; and X-ray detection systems for explosives, weapons and illegal items).

Chapter 226. Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies

Current Chapter 226 is renamed as "Licenses and Radiation Safety Requirements for Well Logging" to parallel 10 CFR Part 39.

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 renamed "abandonment of a sealed source." Current requirements are deleted and replaced by incorporation by reference of 10 CFR Part 39 and current 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.

New heading "Particle Accelerators" is created.

Section 226.34 (relating to particle accelerators) is 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.

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 subsection (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 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 "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.

F. *Benefits Costs and Compliance*

Executive Order 1996-1 requires a cost/benefit analysis of the proposed 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 employes but will also protect the general public. The Commonwealth will also be able to continue pursuit of agreement state status with the NRC which will lead to an overall reduction in license fees for NRC licensees of this Commonwealth.

Compliance Costs

There are no compliance costs because licensees are currently complying with these regulations by virtue of their NRC licenses.

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.

Paperwork Requirements

The proposed amendments will not change paperwork requirements because licensees are already complying with NRC requirements.

G. *Sunset Review*

These 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.

H. *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 the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department. A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department within 10 days of the close of the Committees' review period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review by the Department, the Governor and the General Assembly before final publication of the regulations.

I. *Public Comments*

Written Comments—Interested persons are invited to submit comments, suggestions or objections regarding the proposed amendments to the Environmental Quality Board, P. O. Box 8477 Harrisburg, PA. 17105-8477 (express mail: Rachel Carson State Office Building, 15th floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by September 25, 2000 (within 30 days of publication in the *Pennsylvania Bulletin*). Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must be received by September 25, 2000 (within 30 days following publication in the *Pennsylvania Bulletin*). The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulation will be considered.

Electronic Comments—Comments may be submitted electronically to the Board at RegComments@dep.state.pa.us and must also be received by the Board by September 25, 2000. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgment of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

JAMES M. SEIF,
Chairperson

Fiscal Note: 7-350. No fiscal impact; (8) recommends adoption.

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.

* * * * *

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and 150 of the CFR is incorporated by reference. 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).

(f) If a provision of the CFR incorporated by reference in this article includes a section which is inconsistent with the *Pennsylvania Code*, the *Pennsylvania Code* 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.

§ 215.2. Definitions.

The **definitions in 10 CFR Chapter I 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:

* * * * *

[*ALARA—As low as is reasonably achievable*—Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this article as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of

improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

$A_1$1—The maximum activity of special form radioactive material permitted in a Type A package.

$A_2$2—The maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Chapter 230, Appendix A (relating to packaging and transportation of radioactive materials), Table I, or may be derived in accordance with the procedure prescribed in Chapter 230, Appendix A.

Absorbed dose—The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.]

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[*Agreement state*—A state with which the NRC or the AEC has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954 (42 U.S.C.A. § 2021(b)).

Airborne radioactive material—Radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors or gases.

Airborne radioactivity area—A room, enclosure or area in which radioactive materials exist in concentrations as set forth in one of the following:

(i) In excess of the derived air concentrations (DACs) specified in Chapter 219, Appendix B, Table I (relating to occupational values).

(ii) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6% of the annual limit on intake (ALI) or 12 DAC-hours.

Background radiation—Radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. The term does not include sources of radiation from radioactive materials regulated by the Department.

Becquerel (Bg)—The SI unit of activity. One becquerel is equal to one disintegration or transformation per second (dps or tps).]

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[*Byproduct material*—The term includes one of the following:

(i) Radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

(ii) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

Calendar quarter—Not less than 12 consecutive weeks, nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January, and subsequent calendar quarters shall be arranged so that no day is included in more than one calendar quarter and no day in one year is omitted from inclusion within a calendar quarter. No licensee or registrant may change the method observed by him of determining calendar quarters for purposes of this article except at the beginning of a calendar year.

Collective dose—The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Committed dose equivalent ($H_{T,50}$)—The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent ($H_{E,50}$)—The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum w_T, H_{T,50}$).

Controlled area—An area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

Curie (Ci)—The special unit or quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps).

Deep dose equivalent (H_d), which applies to external whole body exposure—The dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

Depleted uranium—The source material uranium in which the isotope uranium-235 constitutes less than .711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

Dose—A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent or total effective dose equivalent. For purposes of this article, "radiation dose" is an equivalent term.

Dose equivalent (H_T)—The product of the absorbed dose in tissue, quality factor and other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

Dose limits—The permissible upper bounds of radiation doses established in accordance with this article. For purposes of this article, "limits" is an equivalent term.

Effective dose equivalent (H_E)—The sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).

Embryo/fetus—The developing human organism from conception until the time of birth.]

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[*Exposure*—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 special unit of exposure is the roentgen (R). See § 215.3 (relating to units of exposure and dose) for the SI equivalent.

Exposure rate—The exposure per unit of time, such as R per minute or mR per hour.

External dose—That portion of the dose equivalent received from a source of radiation outside the body.

Extremity—A hand, elbow, arm below the elbow, foot, knee or leg below the knee.

Eye dose equivalent—The external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm2).]

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[*Generally applicable environmental radiation standards*—Standards issued by the EPA under the authority of the Atomic Energy Act of 1954 (42 U.S.C.A. §§ 2011—22g-4) that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Gray (Gy)—The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

High radiation area—An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from a source of radiation or from a surface that the radiation penetrates.]

* * * * *

[*Individual monitoring*—The assessment of one of the following:

(i) Dose equivalent by the use of individual monitoring devices or survey data.

(ii) Committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. See the definition of DAC-hours in § 219.3 (relating to definitions).

Individual monitoring devices—Devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this article, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers and personal air sampling devices.]

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[*Internal dose*—That portion of the dose equivalent received from radioactive material taken into the body.]

* * * * *

[*Licensed material*—Radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.]

* * * * *

[*Lost or missing licensed or registered source of radiation*—A licensed or registered source of radiation whose location is unknown. The term includes licensed material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

Member of the public—An individual in a controlled or unrestricted area. An individual is not a member of the public during a period in which the individual receives an occupational dose.

Minor—An individual under 18 years of age.]

Misadministration ***(medical event) from X-ray***—The administration to a human being [of:], except for administrations resulting from the 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) [A radiopharmaceutical dosage greater than 30 microcuries (1.11 MBq) of either sodium iodide I-125 or I-131 under one of the following conditions:

(A) Involving the wrong patient or wrong pharmaceutical.

(B) When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage, and the difference between the administered and prescribed dosage exceeds 30 microcuries (1.11 MBq).

(ii) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131 under one of the following conditions:

(A) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration.

(B) When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage.

(iii) A gamma stereotactic radiosurgery radiation dose under one of the following conditions:

(A) Involving the wrong patient or wrong treatment site.

(B) When the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose.

(iv) A teletherapy radiation dose under one of the following conditions:

(A) Involving the wrong patient, wrong mode of treatment or wrong treatment site.

(B) When the treatment consists of three or fewer fractions and the calculated total administered

dose differs from the total prescribed dose by more than 10% of the total prescribed dose.

(C) When the calculated weekly administered dose is 30% greater than the weekly prescribed dose.

(D) When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

(v) A brachytherapy radiation dose under one of the following conditions:

(A) Involving the wrong patient, wrong radioisotope or wrong treatment site—excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site.

(B) Involving a sealed source that is leaking.

(C) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure.

(D) When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose.

(vi) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries (1.11 MBq) of either sodium iodide I-125 or I-131, when the conditions in clauses (A) and (B) apply:

(A) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration or when the administered dosage differs from the prescribed dosage.

(B) When the dose to the patient exceeds 5 rem (50 mSv) effective dose equivalent or 50 rems (0.5 Sv) dose equivalent to any individual organ.

(vii) An X-ray therapy dose (with energies less than 1 MeV) under one of the following conditions:

(A) Involving the wrong patient, wrong mode of treatment, wrong treatment site, wrong tube potential or wrong filtration.

(B) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the prescribed dose.

(C) When the calculated weekly administered dose is 30% greater than the weekly prescribed dose.

(D) When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

(viii) A radiation therapy dose using X-rays or electron beams with energies of 1 MeV and above under one of the following conditions:

(A) Involving the wrong patient, wrong mode of treatment, wrong treatment site, wrong photon or electron beam energy, wrong applicator or wrong treatment geometry.

(B) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the prescribed dose.

(C) When the calculated weekly administered dose is 30% greater than the weekly prescribed dose.

(D) When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.]

An administration of a dose to the wrong individual.

(ii) An administration of a dose that results in or is likely to result in functional damage to tissue unless the damage is an expected outcome of the prescribed procedure or the damage can not be avoided without compromising the efficacy of the procedure.

(iii) An administration of a dose for therapy to the wrong site or by the wrong treatment mode (photon versus electron), wrong effective energy, wrong applicator or wrong treatment geometry when one of the following applies:

(A) The deviation results in a dose to an area outside of the intended treatment site that exceeds 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

(B) The result is an increase in the total expected treatment doses inside the area of the intended treatment site (other than the primary treatment target), for organs, tissue or skin that exceeds the larger of 20% of the expected dose or 0.5 Sv (50 rem).

(iv) A total dose delivered to the treatment site identified in a written directive for therapy that differs from the prescribed dose by more than 20%, or for a fractionated dose, any individual dose fraction that differs from the prescribed single fraction dose by more than 50%.

[*Monitoring*—The measurement of radiation levels, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this article, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.]

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

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[*Normal form*—aterial in any form that does not qualify as "special form."

Occupational dose—The dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant or another person. The term does not include dose received: from background radiation, as a patient from medical practices, from voluntary participation in medical research programs or as a member of the public.]

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[*Personnel monitoring equipment*—See the definition of "individual monitoring devices."]

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[*Prescribed dosage*—The quantity of radiopharmaceutical activity as documented in one of the following methods:

(i) In a written directive.

(ii) Either in the diagnostic clinical procedures manual or in an appropriate record in accordance with the directions of the authorized user for diagnostic procedures.]

Prescribed dose ***for X-ray therapy***—**[** One of the following:

(i) For gamma stereotactic radiosurgery, the total dose as documented in the written directive.

(ii)] For **[teletherapy,]** X-ray therapy and electron beam therapy, the total dose and dose per fraction as documented in the written directive.

[(iii) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

***Public dose*—The dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. The term does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices or dose from voluntary participation in medical research programs.]**

Qualified expert—**[An individual having the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs. Examples include relevant certification by the American Board of Health Physics, the American Board of Radiology, or the equivalent.]**

(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.

[*Rad*—The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).]

* * * * *

[*Radiation area*—An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from a surface that the radiation penetrates.]

* * * * *

[*Radiopharmaceutical*—A pharmaceutical containing radioactive material.]

* * * * *

[*Rem*—The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

***Research and development*—One of the following:**

(i) Theoretical analysis, exploration or experimentation.

(ii) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. The term does not include the internal or external administration of radiation or radioactive material to human beings.

***Restricted area*—An area to which access is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. The term does not include areas used for residential quarters, although a separate room in a residential building may be set apart as a restricted area.]**

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

[*Sealed source*—Radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

***SI*—The abbreviation for the International System of Units.**

***Shallow dose equivalent (Hs), which applies to the external exposure of the skin or an extremity*—The dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm) averaged over an area of 1 square centimeter.**

***Sievert (Sv)*—The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).**

***Site boundary*—That line beyond which the land or property is not owned, leased or otherwise controlled by the licensee or registrant.**

***Source material*—Uranium or thorium, or a combination thereof, in a physical or chemical form or ores which contain by weight .05% or more of uranium, thorium or a combination thereof. The term does not include special nuclear material.**

***Special form*—Radioactive material which satisfies the following conditions:**

(i) The material is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule.

(ii) The piece or capsule has at least one dimension not less than 5 millimeters (.197 inch).

(iii) The material satisfies the test requirements of regulations of the United States Department of Transportation 49 CFR 173.469. Special form encapsulations designed in accordance with the requirements of 49 CFR 173.389(g) in effect on June 30, 1983, and constructed prior to July 1, 1985 may continue to be used. Special form encapsulations either designed or constructed after June 30, 1985 shall meet the requirements of this subparagraph.

***Special nuclear material*—Plutonium, uranium 233, uranium enriched in the isotope 233 or the isotope 235; material artificially enriched in plutonium, uranium 233, uranium enriched in the isotope 233 or the isotope 235. The term does not include source material.**

***Special nuclear material in quantities not sufficient to form a critical mass*—Uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or a combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of the ratios for all of the kinds of special nuclear material in combination may not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation:**

$$\frac{\text{175 (grams contained U-235)}}{\text{350}} + \frac{\text{50 (grams U-233)}}{\text{200}} + \frac{\text{50 (grams Pu)}}{\text{200}} = 1$$

***Survey*—An evaluation of the production, use, release, disposal or presence of radiation sources under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, the evaluation includes, but is not limited to, tests, physical examinations and measurements of levels of radiation or concentrations of radioactive material present.**

***TEDE—Total effective dose equivalent*—The sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.]**

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[*Unrefined* and *unprocessed ore*—Ore in its natural form prior to processing, such as grinding, roasting, beneficiating or refining.

***Unrestricted area*—An area to which access is neither limited nor controlled by the licensee or registrant. For purposes of this article, "uncontrolled area" is an equivalent term.]**

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[*Week*—Seven consecutive days starting on Sunday.

***Whole body*—For purposes of external exposure, the head, trunk including male gonads, arms above the elbow, or legs above the knee.]**

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[*Working level (WL)*—A combination of radon-222 daughters in one liter of air which will result in the ultimate emission of 1.3 x 10^5 million electron volts of alpha particle energy.

***Working level month (WLM)*—The exposure resulting from inhalation of air containing a radon daughter concentration of 1 WL for 170 working hours.]**

Written directive ***for X-ray therapy***—An order in writing for a specific patient, dated and signed by an authorized user **or licensed practitioner** prior to the administration of **[a radiopharmaceutical or radiation, except as specified in subparagraph (vi), containing the following information]** an X-ray therapy treatment:

(i) **[For the administration of quantities greater than 30 microcuries (1.11 MBq) of either sodium iodide I-125 or I-131: the dosage.**

(ii) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage and route of administration.

(iii) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern and total dose.

(iv) For teletherapy: the total dose, dose per fraction, treatment site and overall treatment period.

(v) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site and total dose.

(vi) For other brachytherapy the following apply:

(1) Prior to implantation: the radioisotope, number of sources; source strengths; and number, type and size of applicator.

(2) After implantation but prior to completion of the procedure: the radioisotope; treatment site; and total source strength and exposure time (or, equivalently, the total dose).

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

[(viii)] (ii) For X-ray and electron 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.

[*Year*—The period of time beginning in January used to determine compliance with this article. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant if the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.]

§ 215.3. Units of exposure **[and dose]**.

[(a)] 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.**

[(b) As used in this article, the units of dose are:

(1) Gray (Gy), which is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

(2) Rad, which is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 Gy).

(3) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

(4) Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

(c) As used in this article, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	*Quality Factor (Q)*	*Absorbed Dose Equal to a Unit Dose Equivalent*[a]
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] **Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.**

(d) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in subsection (c), 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of this article, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron Energy (MeV)	*Quality Factors (Q)*	*Fluence per Unit Dose Equivalent*[b] *(neutrons cm^{-2} rem^{-1}*	*Fluence per Unit Dose Equivalent*[b] *(neutrons cm^{-2} Sv^{-1})*
(thermal) 2.5E-8	2	980E+6	980E+8
1E-7	2	980E+6	980E+8
1E-6	2	810E+6	810E+8
1E-5	2	810E+6	810E+8
1E-4	2	840E+6	840E+8
1E-3	2	980E+6	980E+8
1E-2	2.5	1010E+6	1010E+8
1E-1	7.5	170E+6	170E+8
5E-1	11	39E+6	39E+8
1	11	27E+6	27E+8
2.5	9	29E+6	29E+8
5	8	23E+6	23E+8

Neutron Energy (MeV)	*Quality Factors (Q)*	*Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1}*	*Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})*
7	7	24E+6	24E+8
10	6.5	24E+6	24E+8
14	7.5	17E+6	17E+8
20	8	16E+6	16E+8
40	7	14E+6	14E+8
60	5.5	16E+6	16E+8
1E+2	4	20E+6	20E+8
2E+2	3.5	19E+6	19E+8
3E+2	3.5	16E+6	16E+8
4E+2	3.5	14E+6	14E+8

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.]

§ 215.4. [Units of activity] (Reserved).

[For purposes of this article, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of airborne curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(1) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

(b) One curie (Ci) = 3.7 x 10^{10} disintegrations or transformations per second (dps or tps) = 3.7 x 10^{10} becquerel (Bq) = 2.22 x 10^{12} disintegrations or transformations per minute (dpm or tpm).]

§ 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.

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.11. Records.

[Licensees and registrants shall maintain records showing the receipt, transfer and disposal of radiation sources.]

(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.

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(c) *Inspections by the Department.*

(1) The Department, its employes 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 [2] 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.

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§ 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. Employe 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. Deceptive exposure of a monitoring device.

Exposure of a personnel monitoring device or area monitoring device to deceptively 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—**[230] 232**:

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CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 217.1. Purpose and scope.

* * * * *

(b) A licensee is subject to Chapters 215, **[219], 218—**220 **and 230 [(relating to general provisions; standards for protection against radiation, and notices, instructions and reports to workers; inspections].** 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 **[wireline service operations and subsurface tracer studies] 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).**

* * * * *

§ 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 **[Resources] Protection,** Post Office Box **[2063] 8469**, Harrisburg, Pennsylvania **[17120] 17105-8469**.

(*Editor's Note*: As part of this proposed rulemaking, the Department is proposing to delete the existing text of §§ 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 and Appendices A, B and D which appear at 25 Pa. Code pages 217-2—217-76, serial pages (203810)—(203832), (249215)—(249244) and (203863)—(203884). The existing subchapters are renamed and the following regulations are new and printed in regular type to enhance readability.)

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 (relating to interpretations), 10 CFR 30.6 (relating to communications), 10 CFR 30.8 (relating to information collection requirements: OMB approval), 10 CFR 30.63 (relating to violations) and 10 CFR 30.64 (relating to criminal penalties) 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) The definition of "licensed material" includes NARM.

§ 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
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

Radioactive Material	*Microcuries*
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 31.4 (relating to information collection requirements: OMB approval), 10 CFR 31.13 (relating to violations) and 10 CFR 31.14 (relating to 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) The definition of "licensed material" includes NARM.

§ 217.143. Certain measuring, gauging or controlling devices.

In addition to the parts of 10 CFR 30.5 (relating to interpretations) incorporated by reference, general licensees 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) 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.

(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 (relating to information collection requirements: OMB approval) is 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) The definition of "licensed material" includes NARM.

(5) A reference to byproduct material includes NARM.

§ 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 E. [Reserved]

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

Sec.

§ 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 (relating to information collection requirements: OMB approval), 10 CFR 33.21 (relating to violations) and 10 CFR 33.22 (relating to 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) The definition of "licensed material" includes NARM.

(5) A reference to byproduct material includes NARM.

§ 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 40.5 (relating to communications), 10 CFR 40.6 (relating to interpretations), 10 CFR 40.8 (relating to information collection requirements: OMB approval), 10 CFR Part 40.81 (relating to violations) and 10 CFR Part 40.82 (relating to criminal penalties) 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) The definition of "licensed material" includes NARM.

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 70.5 (relating to communications), 10 CFR 70.6 (relating to interpretations), 10 CFR 70.8 (relating to information collection requirements: OMB approval), 10 CFR 70.71 (relating to violations) and 10 CFR 70.72 (relating to criminal penalties) 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) The definition of "licensed material" includes NARM.

Subchapter I. TRANSFER OF RADIOACTIVE MATERIAL

Sec.
217.191. Transfer of material.

§ 217.191. Transfer of material.

(a) Subject to subsections (b)—(d), a licensee may transfer radioactive material only to one or more of the following:

(1) The Department, but only after receiving prior approval from the Department.

(2) The United States Department of Energy.

(3) A person exempt from this article to the extent permitted under the exemption.

(4) A person authorized to receive the material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the NRC, an agreement state or a licensing state, or to a person otherwise authorized to receive the material by the Federal government or an agency thereof, the Department, an agreement state or a licensing state.

(5) A person otherwise authorized by the Department in writing.

(b) Prior to the receipt of radioactive material that is being transferred to a specific licensee of the Department, of the NRC, of an agreement state, of a licensing state, or to a general licensee who is required to furnish information to the NRC, to an agreement state, to a licensing state, or to the Department under Subchapters C or G (relating to general licenses for radioactive material; and licensing of source material), the licensee transferring the material shall verify that the transferee's license authorizes receipt of the type, form and quantity of radioactive material to be transferred.

(c) The following methods for the verification required by subsection (b) are acceptable:

(1) The transferor may possess a current copy of the transferee's specific license or certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or certificate number, issuing agency and expiration date.

(3) For emergency shipments, the transferor may accept oral certification from the transferee that he is authorized by license or certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or certificate number, issuing agency and expiration date. The oral certification shall be confirmed in writing within 10 days.

(4) The transferor may obtain other sources of information compiled by a reporting service from official records

of the Department, the NRC, the licensing agency of an agreement state or a licensing state as to the identity of licensees and the scope and expiration dates of licenses.

(d) If none of the methods of verification described in subsection (c) are readily available or if a transferor desires to verify that information received by one of the methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the NRC, the licensing agency of an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with Chapter 230 (relating to packaging and transportation of radioactive material).

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 150.2 (relating to scope), 10 CFR 150.11 (relating to critical mass) and 10 CFR 150.20 (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) The definition of "licensed material" includes NARM.

§ 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.

(*Editors Note*: As part of this proposed rulemaking, the Department is proposing to delete the existing text of §§ 219.3, 219.4, 219.21, 219.31—219.38, 219.51, 219.52,

219.61, 219.71—219.73, 219.91—219.93, 219.111—219.113, 219.131, 219.132, 219.151—219.159, 219.160—219.162, 219.181—219.186, 219.201—219.211, 219.221—219.228, 219.241, Appendix A, Appendix B and Appendix C which appear at 25 Code pages 219-1—219-138, serial pages (252831), (252832), (204035)—(204038), (249251), (249252), (204041), (204042), (249253), (249254), (204045)—(204048), (249255), (249256), (204051)—(204054), (249257), (249258), (204057)—(204062), (249259), (249260), (204065)—(204070), (249261)—(249267), (204077)—(204080), (249269)—(249270) and (204083)—(204170).) The following text is new and has been printed in regular type to enhance readability.)

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

§ 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, 10 CFR 20.1006 (relating to interpretations), 10 CFR 20.1009 (relating to information collection requirements: OMB approval), 10 CFR 20.2401 (relating to violations) and 10 CFR 20.2402 (relating to criminal penalties) 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 this chapter means the United States Department of Energy.

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

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

§ 219.61. 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, and 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, 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 mCi) 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 mCi) 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 mCi) 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 mCi) or less of beta or photon-emitting material or 370 kBq (10 mCi) 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 autho-

rized 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 mCi) or more of removable contamination on any test sample.

(2) Leakage of 37 Bq (0.001 mCi) 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 mCi) 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).

§ 219.131. 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.

§ 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.

§ 219.221. 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.

In addition to incorporation by reference of the requirements in 10 CFR Part 20 (relating to standards for protection against radiation), regarding notification of incidents, those notification requirements also apply to radiation producing machines and NARM.

§ 219.228. Reports of misadministrations from X-ray.

(a) For a misadministration from X-ray, the licensee or registrant shall do the following:

(1) Notify the Department by telephone no later than 24 hours after discovery of the misadministration.

(2) Submit a written report to the Department within 15 days after discovery of the misadministration. 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 misadministration not later than 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 misadministration, 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 misadministration 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 misadministration, 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.

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 **[5] 2** working days after receipt of the documents from the Department; the licensee's or registrant's response shall be posted within 5 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.

(*Editor's Note*: As part of this proposed rulemaking, the Department is proposing to delete the existing version of §§ 220.3—220.8 which appear at 25 Pa. Code pages 220-2—220-7, serial pages (249272), (203893)—(203897). The following text is new and has been printed in regular type to enhance readability.)

§ 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 (relating to interpretations), 10 CFR 19.5 (relating to communications), 10 CFR 19.8 (relating to information collection requirements: OMB approval), 10 CFR 19.30 (relating to violations) and 10 CFR 19.40 (relating to criminal penalties) 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.

CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

(*Editor's Note*: As part of this proposed rulemaking, the Department is proposing to delete the text of §§ 224.2—224.9 and 224.51—224.501 which appear at 25 Pa. Code pages 224-2—224-50, serial pages (203906)—(203954).)

Subchapter A. GENERAL

§ 224.10. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 35.8 (relating to information collection requirements: OMB approval), 10 CFR 35.990 (relating to violations) and 10 CFR 35.991 (relating to 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) The definition of "byproduct material" means radioactive material including 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.

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 27 mCi (1,000 MBq) 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.

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

(*Editor's Note*: As part of this proposed rulemaking, the Department is proposing to delete the text of §§ 225.2, 225.11—225.18, 225.21—225.23, 225.31—225.33, 225.41—225.44 and 225.51—225.53 which appears at 25 Pa. Code pages 225-3—225-18, serial pages (203957)—(203972). Appendix A is retained. The following text is new and has been printed in regular type to enhance readability.)

Subchapter A. GENERAL PROVISIONS

Sec.
225.1. Purpose and scope.
225.2a. Incorporation by reference.
225.3a. Effect of incorporation of 10 CFR Part 34.
225.4a. Radiation safety program.
225.5a. Reciprocity.
225.6a. Prohibitions.

§ 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.

§ 225.2a. 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 (relating to interpretations), 10 CFR 34.8 (relating to information collection requirements: OMB approval), 10 CFR 34.121 (relating to violations) and 10 CFR 34.123 (relating to criminal penalties) 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.

§ 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.

Subchapter B. RADIATION PRODUCING MACHINES

GENERAL ADMINISTRATIVE REQUIREMENTS

Sec.
225.71. Definitions.
225.72. Duties of personnel.
225.73. Training of personnel.
225.74. Training and testing.
225.75. Audits and safety reviews of radiographers and radiographer's assistants.
225.76. Reporting requirements.

GENERAL TECHNICAL REQUIREMENTS

225.81. Permanent radiographic installations.
225.82. Operating requirements.
225.83. Records required at temporary job sites.
225.84. Operating and emergency procedures.

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

RADIATION PRODUCING MACHINE 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).

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

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.

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. An RSO shall have the authority to suspend or terminate radiographic operations.

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 Chapter 219 (relating to standards for protection against radiation), 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 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 the information specified under subsection (b).

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) A current whole body individual monitoring device, for example, a "film badge" or "TLD" for each worker.

(4) An operable, calibrated pocket ionization chamber, that is, a "pocket dosimeter" with a range of zero to 51.6 µC/kg (200 milliroentgen) for each worker.

(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 pocket ionization chamber 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 personnel monitoring device "pocket 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 authorizes their disposition.

§ 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 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 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 pocket dosimeter and either a film badge, thermoluminescent dosimeter (TLD), optically stimulated luminescent dosimeter (OSLD) or other Department approved personnel monitoring device.

(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 TLD's 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. TLDs and OSLDs shall be replaced at intervals not to exceed 3 months.

(c) Pocket 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 direct reading pocket dosimeters is subject to the following requirements:

(1) Direct reading pocket dosimeters shall have a range of zero to 51.6 µC/kg (200 mR) and shall be recharged at least daily or at the start of each work shift. Electronic personal dosimeters may be used in place of direct reading pocket dosimeters.

(2) As a minimum, at the beginning and the end of each worker's shift involving the use of a source of radiation, direct reading pocket dosimeters or electronic personal dosimeters shall be read and the exposure values recorded.

(3) Direct reading pocket dosimeters and electronic personal 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 +/− 30% 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 direct reading pocket or electronic personal dosimeter 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 film badge, TLD or OSLD 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) It may not be possible to energize a cabinet X-ray system unless all openings are securely closed and the openings meet the requirements of 10 CFR 20.1201 (relating to occupational dose limits for adults). 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 20.1201 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 **[WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES] WELL LOGGING**

(*Editor's Note*: As part of this proposed rulemaking, the Department is proposing to delete the text of §§ 226.1, 226.11—226.51 and Appendixes A and B which appear at 25 Pa. Code pages 226-1—226-15, serial pages (203978)—(203991).)

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.

§ 226.3. **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 (relating to interpretations), 10 CFR 39.8 (relating to information collection requirements: OMB approval), 10 CFR 39.101 (relating to violations) and 10 CFR 36.103 (relating to criminal penalties) 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.

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).

(*Editor's Note*: As part of this proposed rulemaking, the Department is proposing to delete the existing text of §§ 230.2, 230.11, 230.12—230.14, 230.21—230.26, 230.41—230.47, 230.51, Appendix A and Tables I—IV which appear at 25 Pa. Code pages 230-1—230-30, serial pages (204173)—(204176), (245185), (245186), (204179)—(204202). The following text is new and has been printed in regular type to enhance readability.)

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE

§ 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 (relating to interpretations), 10 CFR 71.6 (relating to information collection requirements: OMB approval), 10 CFR 71.99 (relating to violations) and 10 CFR 71.100 (relating to criminal penalties) 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.

§ 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

§ 230.13. 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 Chapter 403 (relating to hazardous materials transportation) or the regulations of the United States Department of Transportation are not applicable 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.

Subchapter D. OPERATING CONTROLS AND PROCEDURES

§ 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 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.

(*Editor's Note*: The following proposed regulations are new and are printed in regular type to enhance readability.)

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, 10 CFR 36.5 (relating to interpretations), 10 CFR 36.8 (relating to information collection requirements: OMB approval), 10 CFR Part 36.91 (relating to violations) and 10 CFR Part 36.93 (relating to criminal penalties) 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.

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