PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

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

Radiological Health

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

This proposal was adopted by the Board at its regular meeting on December 16, 1997.

A. *Effective Date*

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

B. *Contact Persons*

For further information, the contact persons are Stuart R. Levin, Chief, Division of Radiation Control, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P. O. Box 8469, Harrisburg, PA 17105-8469, (717) 787-3720; and Mary Lou 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 delegates to the Board the power to adopt the regulations of the Department of Environmental Protection (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, the Governor of the Commonwealth is authorized to enter into agreements with the NRC transferring regulatory authority to the Commonwealth for radiation protection. Presently, Pennsylvania 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 of the Commonwealth 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 at 10 CFR Parts 19—71.

As required by section 301(c)(14) of the act (35 P. S. § 7110.301(c)(14)) 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. The proposal was provided to the Committee for review on August 20, 1997. The Committee provided oral and written comments at the meeting.

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 amendments is provided as follows:

Chapter 215, General Provisions

§ 215.2. Definitions. The definitions of "A_1," "A_2," "misadministration," "prescribed dosage," "prescribed dose," "radiological physicist" and "written directive" were deleted. The following definitions were updated to be compatible with the NRC: "member of the public," "NRC," "occupational dose" and "public dose." A new definition for "reclaiming" was added.

§ 215.12. Inspections. The target inspection frequency for major medical facilities was changed from every 2 years to every 3 years.

§ 215.32 Exempt qualifications. The new Chapter 232 was added to the list of chapters.

Chapter 217. Licensing of Radioactive Material

§ 217.1 (purpose and scope) and § 217.2 (address) were updated to include the new Chapter 232 and the new Department mailing address.

§ 217.42(d) was amended by adding additional requirements for general licenses.

§ 217.58 (financial assurance arrangements for reclaiming sites) is a new section which provides for site cleanup money for certain licensees and is compatible with the NRC regulation.

§ 217.65 (specific licenses for the use of sealed sources in industrial radiography) was updated to be compatible with the NRC regulations.

§ 217.84 (licensing the manufacture and distribution of measuring, gauging or controlling devices) was amended to be compatible with the NRC regulations.

A new Appendix E (quantities for use with § 217.58), and a new Appendix F (criteria relating to use of financial

tests and self guarantees of providing reasonable assurance of funds for decommissioning) were added to support the new § 217.58.

Chapter 219, Standards for Protection Against Radiation

§ 219.3 (definitions) was amended by adding a definition for, "constraint (dose constraint)."

§ 219.21(a) (radiation protection programs) was amended to clarify the scope of the required radiation protection program.

§ 219.21(f) was added for compatibility with the NRC requirement for a constraint on air emissions for radioactive material.

§ 219.51(a)(1) (dose limits for individual members of the public) was amended to be compatible with the NRC.

§ 219.51(a)(2) was deleted and § 219.51(a)(3) was renumbered as (2).

§ 219.51(a)(2) ... (2). The new 219.51(a) was updated for compatibility with the NRC regulations.

§ 219.114 (further restrictions on the use of respiratory protection equipment) was added for compatibility with the NRC.

§ 219.223(2)(vi) was added to the list of reports in § 219.223 (reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits). The phrase "ALARA constraints" was added to 219.223(b)(1)(iv).

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

§§ 220.2 and 220.3 were updated for compatibility with the NRC.

§ 220.8 was updated to reflect the Department's name change from Environmental Resources to Environmental Protection.

Chapter 224. Medical Use of Radioactive Material

§ 224.2 (definitions) was amended by adding definitions for "authorized nuclear pharmacist," "diagnostic clinical procedures manual," "prescribed dosage," "prescribed dose," "recordable event" and "written directive." The definition of "medical use" was amended to add "human research subjects under the supervision of an authorized user." The definition of "misadministration" was updated.

§§ 224.6(2) (license amendments) and 224.7 (notifications) were amended by adding the phrase, "or authorized nuclear pharmacist" A new subsection (b) was added to § 224.6 to be compatible with 10 CFR 35.15 (relating to exemptions regarding Type A specific licenses of broad scope).

§ 224.9 (specific exemptions) was amended by changing the name of the advisory committee from Advisory Committee on Medical Uses of Radioactive Material to Radiation Protection Advisory Committee.

§ 224.10 (provisions for research involving human subjects) and § 224.11 (FDA, other Federal, State requirements) were added for compatibility with the NRC regulations.

§ 224.53(2)(ii) (radiation safety committee) was amended by adding the phrase "an authorized nuclear pharmacist."

§ 224.55 (a) (supervision) was amended by adding two sections regarding the authorized use of radioactive material by auxiliary personal.

§ 224.60 (suppliers) was reworded to be compatible with the NRC regulations.

§ 224.61 (quality management program) was added for compatibility with the NRC regulations.

§ 224.101(b)(3) (possession, use, calibration and check of dose calibrators) was added for compatibility with the NRC regulations.

§ 224.103(1), (2), and (3)(iii) (measurement of pharmaceutical dosages) was amended for compatibility with the NRC regulations.

§ 224.104(1) (authorization for calibration and reference sources) was amended to include 25 millicuries each of accelerator produced material.

§ 224.108(e) (surveys for contamination and ambient radiation exposure rate) was amended for compatibility with the NRC regulations.

§ 224.109 (release of patients containing radiopharmaceuticals or permanent implants) was rewritten to be compatible with the NRC regulations.

§ 224.112 (decay-in-storage) was amended to allow sealed sources of accelerator produced radioactive material with a physical half-life of up to 300 days to be held for decay-in-storage.

§ 224.113 (possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides) was added for compatibility with NRC regulations.

§§ 224.151, 224.201, and 224.251 which involve the use of radiopharmaceuticals for diagnosis and therapy were amended for compatibility with NRC regulations. The radiopharmaceutical may be obtained from a licensed manufacturer, licensed preparer or from an authorized nuclear pharmacist. References to NDA's ("New Drug Application") and IND's ("Notice of Claimed Investigational Exemption for a New Drug") were deleted.

§§ 224.152 and 224.204 regarding the possession of survey instruments was updated for compatibility with NRC regulations.

§§ 224.252, 224.253, 224.305, 224.306, 224.352, 24.406 and 224.408 were updated for compatibility with the NRC regulations.

Subchapter J (training and experience requirements) was amended in two main areas. First, additional certifying bodies were added. They are: the American Board of Medical Physics, the Royal College of Physicians and Surgeons of Canada, American Osteopathic Board of Radiology, and the American Osteopathic Board of Nuclear Medicine. Also, § 224.454(2)(ii)(F) was added for compatibility with the NRC regulations and § 224.465 (recentness of training) was amended for compatibility with NRC regulations.

Second, two new sections, § 224.466 (training for an authorized nuclear pharmacist) and § 224.467 (training for experienced nuclear pharmacists) were added for compatibility with the NRC regulations.

Subchapter K (enforcement) was deleted because it is obsolete.

Chapter 225. Radiation Safety Requirements for Industrial Radiographic Operations

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

§ 225.1 (purpose and scope) was amended to include industrial radiographic operations as well as traditional industrial radiography.

§ 225.2 (definitions) was amended by updating and adding some definitions. Updated definitions are: "cabinet X-ray system," "radiographer," "radiographer's assistant" and "temporary job site." New definitions are: "annual refresher safety training," "associated equipment," "certifying entity," "collimator," "control cable," "control drive mechanism," "crank-out device," "exposure head," "guide tube (projection sheath)," "individual's certification," "lockout survey," "personal supervision" and "radiographic operations," "S-tube," "source assembly," "storage facility" and "transport container."

A new § 225.10 (application for a specific license or registration) was added which requires a person using X-ray machines for industrial radiography to get Department approval before commencing operations.

The heading, "Sealed Source Requirements," was deleted and §§ 225.11 and 225.12 were brought under the heading, "General Provisions." § 225.11 (storage position radiation level limits) was rewritten as "reciprocity" requirements. Section 225.12 (radiation source locks) was rewritten as a prohibition against using radiation sources regulated by Chapter 225 for human use.

§§ 225.13—225.18, 225.21—225.23, 225.31—225.33 and 225.41—225.44 were deleted because they were obsolete.

The heading, "Precautionary Procedures," was replaced by "General Administrative Requirements." Section 225.51 was renamed as "Duties of Personnel." This new section describes the duties of the radiation safety officer, radiographer, radiographer's assistant and radiography trainee.

New §§ 225.71 and 225.72 describe the training and testing requirements for radiographers and radiographer assistants. A new § 225.73 describes the required audits and safety reviews of radiographers and radiographer assistants. A new § 225.74 describes the reporting requirements including those for incidents involving radiographic equipment.

A new heading, "General Technical Requirements," includes requirements for certification of personnel, requirements for an independent certifying organization, requirements for certification programs, requirements for written examinations, permanent radiographic installation, operating requirements, records required at temporary job sites, and operating and emergency procedures. These requirements are in §§ 225.101—225.108 respectively.

A new heading, "Radiation Survey Instrument and Personnel Monitoring," includes requirements for radiation survey meters, radiation survey meter calibration, personnel monitoring control and personal alarm rate meters. These requirements are in §§ 225.151—225.154.

A new heading, "Radiation Producing Machine Requirements," includes requirements for cabinet X-ray systems, shielded room X-ray machine radiography, field site radiography, surveys and survey records, utilization logs, bomb detection and baggage X-ray systems and X-ray calibration systems. These requirements are in §§ 225.201—225.207.

The existing heading, "Sealed Source Requirements," containing §§ 225.11—225.225.18 is replaced with a new group of §§ 225.251—225.261 which are compatible with the NRC radiography regulations. These sections include requirements for performance of radiography equipment, limits on levels of radiation for radiographic exposure devices, locking and relocation of exposure devices, storage precautions, leak testing of and replacement of sealed sources, physical inventories, inspection and maintenance of exposure devices, utilization logs, radiation surveys and records, supervision of radiographer's assistants, and radiographic operations, security and posting.

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

Chapter 226 was renamed "Radiation Safety Requirements for Well Logging."

§ 226.1 (purpose and scope) was generally updated and revised to include persons using uranium sinker bars.

§ 226.2 (definitions) was amended by revising, adding and deleting some definitions. Definitions that were revised are: logging supervisor, personal supervision, radioactive marker and well logging. New definitions are: fresh water aquifer, logging assistant, logging tool, safety review, subsurface casing for protecting fresh water aquifers, temporary jobsite, uranium sinker bar and well. Deleted definitions are: mineral logging and wireline service operation.

Other minor revisions were made to §§ 226.3, 226.11—226.17, 226.19, 226.21—226.23, 226.31, 226.33—226.34, 226.41—226.43 and 226.51 for compatibility with NRC regulations.

A new § 226.20, "radioactive markers and uranium sinker bars," is added for compatibility with the NRC regulations.

Appendix B, "Example of Plaque for Identifying Wells Containing Radioactive Material Abandoned Downhole," was deleted.

Chapter 230. Packaging of and Transportation of Radioactive Material

§ 230.2 (definitions) was amended by revising, adding, and deleting some definitions. Definitions that were revised are: "A2," "exclusive use," "fissile material," "low specific activity material" and "transport index." New definitions are: "containment system," "conveyance," "low toxicity alpha emitters," "maximum normal operating pressure," "natural thorium," "surface contaminated object (SCO)" and "uranium (natural, depleted, enriched)." Deleted definitions are: "closed transport vehicle" and "fissile material package."

§ 230.12 and Appendix A were updated for compatibility with NRC regulations.

§§ 230.25 and 230.26 were deleted. Section 230.41 (fissile material: assumptions as to unknown properties) was deleted and replaced as the section for "applicability of operating controls and procedures" for compatibility with NRC regulations.

A new § 230.48 (opening instructions) was added for compatibility with NRC regulations.

Tables I-IV were deleted and replaced with new Tables A-1 and A-2 for compatibility with NRC regulations.

Chapter 232. Licenses and Radiation Safety Requirements for Irradiators

Chapter 232 is a new chapter which is compatible with 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators."

Subchapter A (general provisions) contains the sections for "purpose and scope" and "definitions."

Subchapter B (specific licensing requirements) contains requirements for addressing application for a specific

license, specific licenses for irradiators, start of construction, applications for exemptions and request for written statements.

Subchapter C (design and performance requirements for irradiators) contains requirements for addressing performance criteria for sealed sources, access control, shielding, fire protection, radiation monitors, control of source movement, irradiator pools, source rack protection, power failures, design requirements, and construction monitoring and acceptance testing.

Subchapter D (operation of irradiators) contains requirements for addressing training, operating and emergency procedures, personnel monitoring, radiation surveys, detection of leaking sources, inspection and maintenance, pool water purity, attendance during operation, entering and leaving the radiation room, and irradiation of explosive or flammable materials.

Subchapter E (records) contains requirements for addressing records and retention periods, and reports.

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.

Compliance Costs

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

Compliance Assistance Plan

Compliance assistance is available to all existing holders of a license through the use of NRC guidance which they use currently.

Paperwork Requirements

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

G. *Sunset Review*

These amendments will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the amendments effectively fulfill the goals for which they were intended.

H. *Regulatory Review Act*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on January 20, 1998, the Department submitted a copy of the proposed amendments 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 the Committee have objections to any portion of the proposed amendments, they will notify the Department within 20 days of the close of the public comment period.

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' comment 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 April 15, 1998 (within 60 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 April 8, 1998 (within 60 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-form 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 April 8, 1998. 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: 7-335. 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

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§ 215.2. Definitions.

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

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

[A_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.]

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Member of the public—An individual **[in a controlled or unrestricted area. An individual is not a member of the public during any period in which the] except when that** individual **[receives] is receiving** an occupational dose.

* * * * *

[*Misadministration*—The administration to a human being of:

(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 both 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 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.]

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

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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 exposure to individuals administered radioactive material and released in accordance with § 224.109 (relating to release of patients containing radiopharmaceu-**

ticals or permanent implants), from voluntary participation in medical research programs or as a member of the public.

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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 any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

***Prescribed dose*—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] radiation sources under the control of the licensee or registrant.** The term does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices**, from exposure to individuals administered radioactive material and released in accordance with § 224.109,** or dose from voluntary participation in medical research programs.

* * * * *

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

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

(ii) Has a bachelor's degree in one of the physical sciences or engineering and 3 years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties shall include duties involving the calibration and spot checks of a medical accelerator or a teletherapy unit.

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

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***Reclaiming*—Returning property to a condition where the property no longer presents a public health or safety hazard or threat to the environment. The term includes but is not limited to those activities necessary to decommission the licensed facility (that is, to remove the facility safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license).**

* * * * *

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

(i) For any 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 all 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, tube potential and filtration and overall treatment period.

(viii) 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.]

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RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 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.

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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.

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(b) A licensee is subject to Chapters 215, 219 and 220 (relating to general provisions; standards for protection against radiation; and notices, instructions and reports to workers; inspections). A licensee engaged in industrial 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 radiation safety requirements for **[wireline service operations and subsurface tracer studies] well logging). A licensee using irradiators is subject to Chapter 232 (relating to licenses and radiation safety requirements for irradiators).**

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§ 217.2. Address.

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.**

Subchapter C. LICENSES

GENERAL LICENSES: MATERIAL OTHER THAN SOURCE MATERIAL

§ 217.42. Certain measuring, gauging or controlling devices.

* * * * *

(d) A person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device under the general license in subsection (a):

* * * * *

(10) Shall conduct a physical inventory every 6 months to account for all sources or devices, or both, received and possessed under subsection (a) 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 practical, 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.

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

(i) A person who initiates acquisition of a portable device and does not already hold a license under subsection (a) shall notify the Department within 15 days of their action.

(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 for ensuring 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 for that authorization such as training certificates. 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 against access by unauthorized personnel when not under the direct surveillance of an individual authorized to use the device.

(v) The 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 portable device the following applicable information:

(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.

* * * * *

SPECIFIC LICENSES—GENERAL CONDITIONS

§ 217.58. Financial assurance arrangements for reclaiming sites.

(a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater that 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix E (relating to quantitites for use with § 217.58) shall submit a decommissioning funding plan as described in subsection (e). The decommissioning funding plan shall also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix E.

(b) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in subsection (d) shall do one of the following:

(1) Submit a decommissioning funding plan.

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by subsection (d) using one of the methods described in subsection (f). For an applicant, this certification may state that the appropriate assurance shall be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirement of subsection (f) shall be submitted to the Department before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of subsection (f).

(c) Each holder of a specific license shall do one of the following:

(1) If the license was issued on or after _____ (*Editor's Note*: The blank refers to the effective date of adoption of this proposal), which is of a type described in subsection (a) or (b), the licensee shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(2) If the license was issued before _____ (*Editor's Note*: The blank refers to the effective date of adoption of this proposal) and of a type described in subsection (a), the licensee shall submit, on or before _____ (*Editor's Note*: The blank refers to a date 1 year after the effective date of adoption of this proposal) a decommissioning funding plan as described in subsection (e) or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in an application for license renewal.

(3) If a specific license was issued before _____ (*Editor's Note*: The blank refers to the effective date of the adoption of this proposal), and of a type described in subsection (b) the licensee shall submit, on or before _____ (*Editor's Note*: The blank refers to a date 1 year after the effective date of adoption of this proposal), a decommissioning funding plan as described in subsection (e), or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(d) If the required amounts of financial assurance for decommissioning by quantity of material is:

(1) Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix E in unsealed form (for a combination of isotopes, if R, as defined in subsection (a), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1), the required amount is $ 750,000.

(2) Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix E in unsealed form (for a combination of isotopes, if R, as defined in subsection (a), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1), the required amount is $150,000.

(3) Greater than 10^{10} times the applicable quantities of Appendix E in sealed sources or plated foils (For a combination of isotopes, if R, as defined in subsection (a), divided by 10^{10} is greater than 1), the required amount is $75,000.

(e) Each decommissioning funding plan shall contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from subsection (f), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. The commissioning funding plan shall also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirement of subsection (f).

(f) Financial assurance for decommissioning shall be provided by one or more of the following methods:

(1) *Prepayment.* Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets so that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities in a form approved by the Department.

(2) *A surety method.* A surety method, insurance or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F (relating to criteria relating to use of official tests and self guarantees of providing reasonable assurance of funds for decommissioning). A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions:

(i) The surety method or insurance shall be open-ended or, if written for a specified term, such as 5 years, shall be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Department, the beneficiary and the licensee of its intention not to renew. The surety method or insurance shall also provide that the full face amount be automatically paid to the beneficiary prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance shall remain in effect until the Department has terminated the license.

(3) *An external sinking fund.* An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being

accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities in a format approved by the Department. The surety or insurance provision shall be as stated in subsection (f)(2).

(4) *Statement of intent.* In the case of Federal, State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on subsection (d), and indicating that funds for decommissioning will be obtained when necessary.

(5) *Alternate financial assurance arrangements.* Alternate financial assurance arrangements not listed in this section may be accepted by the Department, provided the alternate arrangements are submitted to the Department in writing and approval for the alternate arrangement is granted by the Department in writing.

(g) Each person licensed under this article shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with §§ 217.51—217.57 (relating to specific licenses—general conditions), licensees shall transfer all records described in this subsection to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records shall include any known information on identification of involved nuclides, forms and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, or both, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after a leak) or radioactive material having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated restricted areas as defined in § 215.2 (relating to definitions).

(ii) All areas outside of restricted areas that require documentation under paragraph (1).

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under § 219.209 (relating to records of waste disposal).

(iv) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under § 219.182 (relating to method of obtaining approval of proposed disposal procedures).

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of funding method used for assuring funds if either a funding plan or certification is used.

(h) the following specific licensees are required to make financial surety arrangements:

(1) Major processors.

(2) Waste handling licensees.

(3) Former United States Atomic Energy Commission or NRC licensed facilities.

(4) All others except persons exempt under subsection (i).

(i) The following persons are exempt from the requirements of subsection (a):

(1) Persons authorized to possess no more than 1,000 times the quantity specified in Appendix B (relating to exempt quantities).

(2) Persons authorized to possess radioactive noble gasses in sealed sources with no radioactive daughter product with half-live greater than 30 days.

§ 217.65. Specific licenses for the use of sealed sources in industrial radiography.

In addition to the requirements of § 217.52 (relating to general requirements for the issuance of specific licenses), a specific license for use of sealed sources in industrial radiography will be issued if:

(1) The applicant has an adequate program for training radiographers and radiographer's assistants and submits to the Department a schedule or description of the program which specifies the following:

(i) Initial training.

(a) After May 28, 1999, an applicant need not describe its initial training and examination program for radiographers in the subjects outlined in Appendix A, Chapter 225 (relating to radiation safety requirements for industrial uses and radiographic operations).

(b) From _____ (*Editor's Note*: The blank refers to the effective date of adoption of this proposal) to May 28, 1999, an applicant may affirm that all individuals acting as industrial radiographers will

be certified in radiation safety by a certifying entity before commencing duty as radiographers. This affirmation substitutes for a description of its initial training and examination program for radiographers in the subjects outlined in Appendix A, Chapter 225 (relating to radiation safety requirements for industrial uses and radiographic operations).

* * * * *

(vi) The procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

(vii) The inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months, as described in § 225.73 (relating to audits and safety reviews of radiographers and radiographers' assistants).

* * * * *

(5) The applicant who desires to conduct the required leak tests **of sealed sources or of exposure devices containing depleted uranium** personally has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the Department a description of the procedures to be used including the following:

* * * * *

(8) The applicant identifies and lists the qualifications of the individual designated as the radiation safety officer under § 225.51(a) (relating to radiation safety officer for industrial radiography) and potential designees responsible for ensuring that the applicant's radiation safety program is implemented in accordance with approved procedures.

(9) If the applicant intends to perform "in-house" calibrations of survey instruments, the description of the methods to be used and the relevant experience of the individual who will perform the calibrations. Calibrations shall be performed according to the procedures described and at the frequency described in § 225.152 (relating to radiation survey meter calibration requirements).

(10) The applicant identifies and describes the locations of all field stations and permanent radiographic installations.

(11) The applicant identifies the locations where all records required by this article and Chapter 225 (relating to radiation safety requirements for industrial uses and radiographic operations) will be maintained.

§ 217.84. Licensing the manufacture and distribution of measuring, gauging or controlling devices.

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under § 217.42 (relating to certain measuring, gauging or controlling devices) or equivalent regulations of the NRC, an agreement state or a licensing state will be approved if:

* * * * *

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions and potential hazards of the device to provide reasonable assurance that:

* * * * *

(ii) Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that a person will receive in a period of **[one calendar quarter] 1 year [a dose in excess of 10% of the limits specified in the table in § 219.11(a) (Reserved)] a dose in excess of 10% of the annual limits specified in § 219.31 (relating to occupational dose limits for adults).**

* * * * *

(*Editor's Note*: Appendices E and F are proposed to be added. They are printed in regular type to enhance readability).

APPENDIX E

QUANTITIES FOR USE WITH § 217.58

Material	*Microcuries*
American -241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10

Material	*Microcuries*
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-50	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-106	100
Palladium-108	100
Phosphorus-33	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	10
Promethium-147	10
Promethium-149	10
Radium-236	.01
Rhenium-136	100
Rhenium-138	100
Rhodium-103m	100
Rhodium-106	100
Rubidium-66	10
Rubidium-87	10
Rubidium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-106	10
Silver-110m	1
Silver-111	111
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural) [2]	100
Uranium-233	.01
Uranium-234 and Uranium 235	.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Yttrium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10

Material	*Microcuries*
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition.	0.01
Any radionuclide other that alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition.	0.1

(1) Based of alpha disintegration rate of TH-232, TH-230 and their daughter products.

(2) Based of alpha disintegration rate of U-233, U-234 and U-235.

Note—-For purposes of § 217.58(a) (relating to financial assurance arrangements for reclaiming sites), where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of the ratios for all the isotopes in the combination equals "R."

APPENDIX F

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEES OF PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. *Introduction.*

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this Appendix,. The terms of the self-guarantee are in Section III of this Appendix. This Appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. *Financial Test.*

A. To pass the financial test, a company must meet all of the following criteria:

1. Tangible net worth at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. Assets located in the United States amounting to at least 90% of total assets or least 10 times the total current decommissioning cost estimate (for the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

3. A current rating for its most recent bond issuance of AAA, AA or A as issued by Standard and Poors (S&P), or AAA, AA or A as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in the financial statement, in connection with that procedure. The licensee shall inform the Department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

c. If the licensee no longer meets the requirements of Section II, A, of this Appendix, the licensee shall send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's regulations within 120 days of such notice.

III. *Company Self-Guarantee.*

The terms of a self-guarantee which an applicant or licensee furnishes shall provide that:

a. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by return receipt.

b. The licensee shall provide alternative financial assurance as specified in the Department's regulations within 90 days following receipt by the Department of a notice of cancellation of the guarantee.

c. The guarantee and financial test provisions shall remain in effect until the Department has terminated the license or until another financial as assurance method acceptable to the Department has been put in effect by the licensee.

D. The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission under the requirement of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provided notice in writing of that fact to the Department with 20 days after publication of the change by the rating services. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moody's the licensee no longer meets the requirements of Section II, A, of this Appendix.

F. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

§ 219.3. Definitions.

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

* * * * *

***Constraint (dose constraint)*—A value above which specified licensee actions are required.**

* * * * *

Subchapter B. RADIATION PROTECTION PROGRAMS

§ 219.21. Radiation protection programs.

(a) The licensee or registrant shall develop, document and implement a radiation protection program **commensurate with the scope and extent of the licensee's or registrant's activities and** sufficient to ensure compliance with this chapter.

* * * * *

(f) To implement the ALARA requirements of subsection (b) and notwithstanding the requirements in § 219.51 (relating to dose limits for individual members of the public), a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees so that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedence as provided in § 219.223 (relating to reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits) and promptly take appropriate corrective action to ensure against recurrence.

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

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

(a) The licensee or registrant shall conduct operations so that the following conditions are met:

(1) **[Except as provided in paragraph (2), the] The** total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose **[contribution] contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with § 224.109 (relating to release of patients containing radiopharmaceuticals or permanent implants), from voluntary participation in medical research programs and** from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with § 219.183 (relating to disposal by release into sanitary sewerage).

[(2) The total effective dose equivalent to individual members of the public in unrestricted areas from exposure to radiation from diagnostic radiation machines does not exceed 5 mSv (0.5 rem).]

[(3)] (2) The dose in any unrestricted area from external sources **exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 224.109, (relating to release of patients containing radiopharmaceuticals or permanent implants)** does not exceed 0.02 mSv (0.002 rem) in any 1 hour, if an individual were continuously present in the area.

* * * * *

Subchapter H. RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

§ 219.114. Further restrictions on the use of respiratory protection equipment.

The Department may impose restrictions in addition to those in §§ 219.112 and 219.113 (relating to use of other controls; and use of individual respiratory equipment) and Appendix A to:

(1) Ensure the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive material.

(2) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

Subchapter M. REPORTS

§ 219.223. Reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits.

(a) *Reportable events.* In addition to the notification required by § 219.222 (relating to notification of incidents), each licensee or registrant shall submit a written report within 30 days after learning of one or more of the following occurrences:

* * * * *

(2) Doses in excess of one or more of the following:

* * * * *

(vi) The ALARA constraints for air emissions established under § 219.21(f) (relating to radiation protection programs).

* * * * *

(b) *Contents of reports.*

(1) Each report required by subsection (a) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

* * * * *

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, **ALARA constraints,** generally applicable environmental standards, and associated license or registration conditions.

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

§ 220.2. Posting of notices to workers.

* * * * *

(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.

* * * * *

§ 220.3. Instructions to workers.

(a) An individual **[working in or frequenting a portion of a restricted area] who is likely to receive in a year an occupational dose in excess of 100 mrem(1 mSv)** shall be:

(1) Informed of the storage, transfer or use of radiation sources **[in the portion of the restricted area].**

* * * * *

(b) The extent of the instruction shall be commensurate with potential radiological health protection problems in the **[restricted area] work place.**

§ 220.8. Inspections not warranted; informal review.

(a) If the Bureau of Radiation Protection determines that an inspection is not warranted for a complaint made under § 220.7 (relating to requests by workers for inspections) because there are no reasonable grounds to believe that a violation exists or has occurred, the Bureau of Radiation Protection will notify the complainant in writing of the determination. The complainant may obtain review of the determination by submitting a written statement of position to the Office of the Secretary, Department of Environmental **[Resources] Protection.** The Department will provide the licensee or registrant with a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Department which will provide the complainant with a copy of the statement by certified mail.

* * * * *

CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 224.2. Definitions.

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

* * * * *

***Authorized nuclear pharmacist*—A pharmacist who meets one of the following requirements:**

(i) Is board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties.

(ii) Is identified as an authorized nuclear pharmacist on a Department, NRC or agreement state license that authorizes the use of radioactive material in the practice of nuclear pharmacy.

(iii) Is identified as an authorized nuclear pharmacist on a permit issued by the Department, NRC or agreement state specific license of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.

* * * * *

***Diagnostic clinical procedures manual*—A collection of written procedures that describes each method—and other instructions and precautions—by which the licensee performs clinical diagnostic procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical dosage and route of administration.**

* * * * *

Medical use—In the practice of medicine, the intentional administration (external or internal) of radioactive material, or the radiation therefrom, to human beings **or human research subjects under the supervision of an authorized user.**

* * * * *

Misadministration—The administration of one of the following:

[(i) A radiopharmaceutical or radiation from a radiation source other than the one intended or prescribed.

(ii) A radiopharmaceutical or radiation therapy to a wrong patient.

(iii) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician or radiation therapy to an organ other than that prescribed by the physician.

(iv) A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50%.

(v) A therapy dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10%.

(vi) A therapy radiation dose from a radiation source such that errors in the source calibration, time of exposure and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10%.

(vii) Radioactive material not specifically authorized for human use, or medical irradiation by sources whose characteristics do not meet established criteria for that type of radiation source.]

(i) A radiopharmaceutical dosage greater than 30 µCi (1.11 MBq) of either sodium iodide I-125 or I-131 under one of the following conditions:

(A) Involving the wrong individual or wrong pharmaceutical.

(B) When both 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 µCi (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 individual, 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 individual 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 individual, 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 individual, 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 uCi (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 individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage.

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

* * * * *

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 any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose—One of the following:

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

(ii) For teletherapy, 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.

* * * * *

Recordable event—The administration of:

(i) A radiopharmaceutical or radiation without a written directive when a written directive is required.

(ii) A radiopharmaceutical or radiation when a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation in the appropriate record.

(iii) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

(A) The administered dosage differs from the prescribed dosage by more than 10% of the prescribed dosage.

(B) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries.

(iv) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10% of the prescribed dosage.

(v) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15% or more of the weekly prescribed dose.

(vi) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10% of the prescribed dose.

* * * * *

Written directive—An order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in subparagraph (vi), containing the following information:

(i) For any administration of quantities greater than 30 µCi (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 all other brachytherapy the following apply:

(A) Prior to implantation: the radioisotope, number of sources and source strengths.

(B) 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).

§ 224.6. License amendments.

(a) A licensee shall apply for and receive a license amendment before it:

* * * * *

(2) Permits anyone, except a visiting authorized user described in § 224.56 (relating to visiting authorized user), to work as an authorized user **or authorized nuclear pharmacist** under the license.

* * * * *

(b) A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) Subsection (a)(2).

(2) Subsection (a)(5) regarding additions to or changes in the areas of use only at the addresses specified in the license.

§ 224.7. Notifications.

A licensee shall notify the Department by letter within 30 days when an authorized user, radiation safety officer or teletherapy physicist **or authorized nuclear pharmacist** permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes. The licensee shall mail the report to the appropriate address identified in § 224.5(c) (relating to application for license, amendment or renewal).

§ 224.9. Specific exemptions.

The Department may, upon application of an interested person or upon its own initiative, grant exemptions from this article as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Department will review requests for exemptions from training and experience requirements with the assistance of its **Radiation Protection** Advisory Committee **[on the Medical Uses of Radioactive Material].**

§ 224.10. Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using radioactive material if the research is conducted, funded, supported or regulated by a Federal agency which has implemented the Federal policy for the protection of human subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting the research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "institutional review board" in accordance with the meaning of these terms as defined in the Federal policy for the protection of human subjects.

§ 224.11. FDA, other Federal and State requirements.

This chapter does not relieve the licensee from complying with applicable FDA, other Federal and State requirements governing radioactive drugs or devices, and 49 Pa. Code Chapter 27 (relating to State Board of Pharmacy).

Subchapter B. GENERAL ADMINISTRATIVE REQUIREMENTS

§ 224.53. Radiation safety committee.

A medical institution licensee shall establish a radiation safety committee (committee) to oversee the use of radioactive material.

* * * * *

(2) To oversee the use of licensed material, the committee shall:

* * * * *

(ii) Review, on the basis of safety and with regard to the training and experience standards in Subchapter J (relating to training and experience requirements), and approve or disapprove an individual who is to be listed as an authorized user, the radiation safety officer, **an authorized nuclear pharmacist** or a teletherapy physicist before submitting a license application or request for amendment or renewal.

* * * * *

§ 224.55. Supervision.

(a) A licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by § 224.4(b) (relating to license required) shall:

* * * * *

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

(5) 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 employe qualifications.

* * * * *

§ 224.60. Suppliers **for sealed sources or devices for medical use.**

A licensee may use the following for medical use only:

(1) **[Radioactive material manufactured, labeled, packaged and distributed in accordance with a license issued under Chapter 217 (relating to licensing of radioactive material) or the equivalent regulations of an agreement state or the NRC.] Sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under Chapter 217 (relating to licensing of radioactive material), the equivalent regulations of an agreement state or the NRC.**

[(2) Reagent kits that have been manufactured, labeled, packaged and distributed in accordance with an approval by the Department under § 217.91 (relating to manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals), an agreement state or the NRC, under equivalent regulations for the preparation of radiopharmaceuticals for medical use.]

[(3)] (2) * * *

§ 224.61. Quality management program.

(a) An applicant or licensee under this chapter, as applicable, shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

(1) Except as provided in subsections (h)—(j) that, prior to administration, a written directive is prepared for:

(i) Any teletherapy radiation dose.

(ii) Any gamma sterotactic radiosurgery dose.

(iii) Any brachytherapy radiation dose.

(iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

(v) Any therapeutic administration of radiopharmaceutical other than sodium iodide I-125 or I-131.

(2) That, prior to each administration the patient's identity is verified by more than one method as the individual named in the written directive.

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy and gamma stereotactic radiosurgery are in accordance with the respective written directives.

(4) That each administration is in accordance with the written directive.

(5) That an unintended deviation from the written directive is identified and evaluated and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of the following:

(i) A representative sample of patient administrations.

(ii) All recordable events.

(iii) All misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months.

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of subsection (a).

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for 3 years.

(c) The licensee shall evaluate and respond within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause.

(2) Identifying what, if any, corrective action is required to prevent further recurrence.

(3) Retaining a record, in an auditable form for 3 years of the relevant facts and the corrective action taken if any was taken.

(d) The licensee shall retain:

(1) Each written directive.

(2) A record of each administered radiation dose or radiopharmaceutical dosage when a written directive is required in subsection (a)(1), in an auditable form, for 3 years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the program's efficiency so long as the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate regional office within 30 days after the modification has been made.

(f) An applicant for a new license as applicable shall submit to the Department a quality management program as part of the application for a license and implement the program upon issuance of the license.

(g) An existing licensee shall submit to the Department a written certification that the quality management program has been implemented along with a copy of the program.

(h) If, because of the patient's condition, a delay in order to provide a written revision to an existing written direction would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, so long as the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(i) A written revision to an existing written directive may be made for any diagnostic or therapeutic procedure so long as the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next teletherapy fractional dose.

(j) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, so long as the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

Subchapter C. GENERAL TECHNICAL REQUIREMENTS

§ 224.101. Possession, use, calibration and check of dose calibrators.

* * * * *

(b) A licensee shall:

* * * * *

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and **[10] 30** microcuries (**[370 kBq] 1.1 MBq).**

* * * * *

§ 224.103. Measurement of radiopharmaceutical dosages.

A licensee shall do the following:

(1) Measure the activity of each radiopharmaceutical **[dosage that contains more than 10 microcuries (370 kBq)]** of a photon-emitting radionuclide before medical use.

[(2) Measure the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries (370 kBq) or less of a photon-emitting radionuclide before medical use to verify that the dosage does not exceed 10 microcuries (370 kBq).] Measure by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or beta-emitting radionuclide prior to medical use except for unit dosages obtained from a manufacturer or preparer licensed under § 217.90 (relating to manufacture and distribution of radiopharmaceuticals for medical use under group licenses) or equivalent agreement state requirements.

(3) Retain a record of the measurements required by this section for 3 years. To satisfy this requirement, the record shall contain the following:

* * * * *

(iii) The prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than **[10] 30** microcuries **[(370 kBq)] (1.1 MBq).**

* * * * *

§ 224.104. Authorization for calibration and reference sources.

A person authorized by § 224.4 (relating to license required) for medical use of radioactive material may receive, possess and use the following radioactive material for check, calibration and reference use:

(1) Sealed sources manufactured and distributed by a person licensed under § 217.92 (relating to manufacture and distribution of sources or devices containing radioactive material for medical use), the NRC or equivalent agreement state regulations and that do not exceed 15 millicuries (555 mBq) each **of byproduct material or 25 millicuries each of accelerator produced material.**

* * * * *

§ 224.105. Requirements for possession of sealed sources and brachytherapy sources.

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(f) A licensee is not required to perform a leakage test on the following sources:

* * * * *

(4) Sources stored and not being used. The licensee shall, however, test these sources for leakage before the use or transfer unless it has been leakage-**[treated] tested** within 6 months before the date of use or transfer.

* * * * *

§ 224.108. Surveys for contamination and ambient radiation exposure rate.

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(e) A licensee shall survey for removable contamination **[each day of use the areas] once each week** where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

* * * * *

§ 224.109. Release of patients containing radiopharmaceuticals or permanent implants.

(a) **[A licensee may not authorize release from confinement for medical care a patient administered a radiopharmaceutical until one of the following conditions have been met:**

(1) The measured dose rate from the patient is less than 5 millirem (50 µSv) per hour at a distance of 1 meter.

(2) The activity in the patient is less than 30 millicuries (1.11 GBq)]. The licensee may authorize the release from its control of an individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to another individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).

(b) **[A licensee may not authorize release from confinement for medical care of a patient administered a permanent implant until the measured dose rate from the patient is less than 5 millirems (50 µSv) per hour at a distance of 1 meter.] The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA if the total effective dose equivalent to another individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breastfeeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast feeding, the instructions shall also include both of the following:**

(1) Guidance on the interruption or discontinuation of breast feeding.

(2) Information on the consequences of failure to follow guidance.

(c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by any one of the following:

(1) Using the retained activity, rather than the activity administered.

(2) Using an occupancy factor less than 0.25 at 1 meter.

(3) Using the biological or effective half-life.

(4) Considering the shielding by tissue.

(d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breastfeeding woman if the radiation dose to the infant or child from continued breastfeeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

§ 224.112. Decay-in-storage.

(a) A licensee may hold **sealed sources of accelerator produced radioactive material with a physical half-life of up to 300 days and any** radioactive material with a physical half-life of less than 65 days for

decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 219.181 (relating to general requirements) if it:

* * * * *

§ 224.113. Possession, use, calibration and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

(a) This section does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed under § 217.90 (relating to manufacture and distribution of radiopharmaceuticals for medical use under group licenses) or equivalent.

(b) For other than unit dosages obtained to subsection (a), a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall do both of the following:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary.

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

Subchapter D. UPTAKE, DILUTION AND EXCRETION

§ 224.151. Use of radiopharmaceuticals for uptake dilution and excretion studies.

A licensee may use radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion **[for which the FDA has accepted "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA)] that is either:**

(1) Obtained from a manufacturer or preparer licensed under § 217.90 (relating to manufacture and distribution of radiopharmaceuticals for medical use under group licenses) or equivalent NRC or agreement state requirements.

(2) Prepared by an authorized nuclear pharmacist, who meets the training criteria specified in § 224.466 (relating to training for an authorized nuclear pharmacist) or § 224.467 (relating to training for experienced nuclear pharmacists), a physician who is an authorized user and who meets the requirements specified in § 224.453 (relating to training for uptake, dilution and excretion studies) or an individual under the supervision of either specified in § 224.55 (relating to supervision).

§ 224.152. Possession of survey instrument.

A licensee authorized to use radioactive material for uptake, dilution and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 μSv) per hour to **[50] 100** millirem (**[0.5] 1.0** mSv) per hour.

Subchapter E. IMAGING AND LOCALIZATION

§ 224.201. Use of radiopharmaceuticals**[, generators and reagent kits]** for imaging and localization studies.

[(a)] A licensee may use **for imaging and localization studies any unsealed** radioactive material **[in a diagnostic radiopharmaceutical or a generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material provided for which the FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" or approved a "New Drug Application"] prepared for medical use that is either:**

[(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.]

(1) Obtained from a manufacturer or preparer licensed under § 217.91 (relating to manufacture and distribution of generator or reagent kits) or equivalent NRC or agreement requirements.

(2) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in § 224.454 (relating to training for imaging and localization studies) or an individual under the supervision of either specified in § 224.55 (relating to supervision).

§ 224.204. Possession of survey instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to **[50] 100** millirem (**[0.5] 1.0** mSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 μSv) per hour to 1000 millirem (10 mSv) per hour.

Subchapter F. RADIOPHARMACEUTICALS FOR THERAPY

§ 224.251. Use of radiopharmaceuticals for therapy.

A licensee may use **[a radioactive material in a radiopharmaceutical and for a therapeutic use for which the FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.] for therapeutic administration any unsealed radioactive material prepared for medical use that is:**

(1) Obtained from a manufacturer or preparer licensed under § 217.92 (relating to manufacture and distribution of sources or devices for medical use) or equivalent NRC or agreement state requirements.

(2) Prepared by an authorized nuclear pharmacist, who meets the training criteria specified in § 224.466 (relating to training for an authorized nuclear pharmacist) or § 224.467 (relating to train-

ing for experienced nuclear pharmacists), a physician who is an authorized user and who meets the requirements specified in § 224.454 (relating to training for imaging and localization studies) or an individual under the supervision of either specified in § 224.55 (relating to supervision).

§ 224.252. Safety instruction.

* * * * *

(1) Patient **or human research subject** control.

§ 224.253. Safety precautions.

(a) For each patient receiving radiopharmaceutical therapy and hospitalized in compliance with § 224.109 (relating to release of patients containing radiopharmaceuticals or permanent implants), a licensee shall:

* * * * *

[(6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public ALARA before authorizing release of the patient.]

[(7)] (6) * * *

[(8)] (7) * * *

* * * * *

Subchapter G. SOURCES FOR BRACHYTHERAPY

§ 224.305. Safety precautions.

(a) For each patient **or human research subject** receiving implant therapy, a licensee shall comply with the following conditions:

(1) The patient may not be quartered in the same room with a patient who is not receiving radiation therapy **[unless the licensee can demonstrate compliance with § 219.51 (relating to dose limits for individual members of the public) at a distance of 1 meter from the implant].**

* * * * *

[(5) The patient shall be provided with radiation safety guidance that will help to keep radiation dose to household members and the public ALARA before releasing the patient if the patient was administered a permanent implant.]

* * * * *

[(c) Nonoccupationally exposed individuals having incidental contact with patients having implanted or applied sealed sources—for example, visitors nurses and other patients—may not receive doses in excess of doses specified in 219.51 (relating to dose limits for individual members of the public) as a result of their contact with the patients.]

§ 224.306. Possession of survey instrument.

A licensee authorized to use radioactive material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 µSv) per hour to **[50] 100** millirem (**[0.5] 1.0** mSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 µSv) per hour to 1000 millirem (10 mSv) per hour.

Subchapter H. SEALED SOURCES FOR DIAGNOSIS

§ 224.352. Availability of survey instrument.

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1 µSv) per hour to **[50] 100** millirem (**[0.5] 1.0** mSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 µSv) per hour to 1000 millirem (10 mSv) per hour. The instrument shall have been calibrated in accordance with § 224.102 (relating to calibration and check of survey instruments).

Subchapter I. TELETHERAPY

§ 224.406. Possession of survey instrument.

A licensee authorized to use radioactive material in a teletherapy unit shall have in its possession a portable radiation detection survey instrument capable of detecting a dose rate over the range of 0.1 millirem (1 µSv) per hour to **[50] 100** millirem (**[0.5] 1.0** mSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 µSv) per hour to 1000 millirem (10 mSv) per hour.

§ 224.408. Full calibration measurements.

* * * * *

(b) To satisfy the requirement of subsection (a), full calibration measurements shall include determination of the following:

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(6) The accuracy of **all** distance measuring and localization devices in medical use.

* * * * *

Subchapter J. TRAINING AND EXPERIENCE REQUIREMENTS

§ 224.451. Radiation safety officer.

Except as provided in § 224.452 (relating to training for experienced radiation safety officer), the licensee shall require an individual fulfilling the responsibilities of the radiation safety officer as provided in § 224.54 (relating to statements of authority and responsibilities) to be an individual who meets one of the following requirements:

(1) Is certified by one of the following:

* * * * *

(vi) The American Board of Medical Physics.

(vii) The Royal College of Physicians and Surgeons of Canada in Nuclear Medicine.

(viii) The American Osteopathic Board of Radiology.

(ix) The American Osteopathic Board of Nuclear Medicine.

* * * * *

§ 224.453. Training for uptake, dilution and excretion studies.

Except as in § 224.463 or § 224.464 (relating to training for experienced authorized users; and physician training in a 3-month program), the licensee shall require the authorized user of a radiopharmaceutical in § 224.151 (relating to use of radiopharmaceuticals for uptake, dilu-

tion and excretion studies) to be a physician who meets one of the following requirements:

(1) Is certified in one of the following:

* * * * *

(iii) Diagnostic radiology **or radiology** by the American Osteopathic Board of Radiology.

(iv) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(v) American Osteopathic Board of Nuclear Medicine in nuclear medicine.

§ 224.454. Training for imaging and localization studies.

Except as provided in §§ 224.463 and 224.464 (relating to training for experienced authorized users; and physician training in a 3-month program), the licensee shall require the authorized user of a radiopharmaceutical, generator or reagent kit in § 224.201(a) (relating to use of radiopharmaceuticals, generators and reagent kits for imaging and localization studies) to be a physician who meets one of the following requirements:

(1) Is certified in one of the following:

* * * * *

(iii) Diagnostic radiology **or radiology** by the American Osteopathic Board of Radiology.

(iv) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(v) American Osteopathic Board of Nuclear Medicine in nuclear medicine.

(2) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators and reagent kits, work experience and has had supervised clinical experience as follows:

* * * * *

(ii) Five hundred hours of supervised clinical experience under the supervision of an authorized user and that includes the following:

* * * * *

(f) Eluting Technetium-99^{m} from generator systems, measuring and testing the eluate for Molybdenum-99 and Alumina contamination and processing the eluate with reagent kits to prepare Technetium-99^{m} labeled radiopharmaceuticals.

* * * * *

§ 224.455. Training for therapeutic use of radiopharmaceuticals.

Except as provided in § 224.463 (relating to training for experienced authorized users), the licensee shall require the authorized user of radiopharmaceuticals in § 224.251 (relating to use of radiopharmaceuticals for therapy) to be a physician who meets one of the following requirements:

(1) Is certified by one of the following:

* * * * *

(iii) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(iv) The American Osteopathic Board of Radiology after 1984.

* * * * *

§ 224.458. Training for use of brachytherapy sources.

Except as provided in § 224.463 (relating to training for experienced authorized users), the licensee shall require the authorized user of a brachytherapy source listed in § 224.301 (relating to use of sources for brachytherapy) to be a physician who meets one of the following requirements:

(1) Is certified in one of the following:

(i) Radiology or therapeutic radiology **or radiation oncology** by the American Board of Radiology.

* * * * *

§ 224.460. Training for use of sealed sources for diagnosis.

Except as provided in § 224.463 (relating to training for experienced authorized users), the licensee shall require the authorized user of a sealed source in a device listed in § 224.351 (relating to use of sealed sources for diagnosis) to be a physician, dentist or podiatrist who meets one of the following requirements:

(1) Is certified in one of the following:

(i) Radiology, diagnostic radiology or therapeutic radiology **or radiation oncology** by the American Board of Radiology.

* * * * *

(iv) Nuclear Medicine by the Royal College of Physicians and Surgeons of Canada.

* * * * *

§ 224.461. Training for teletherapy.

Except as provided in § 224.463 (relating to training for experienced authorized users), the licensee shall require the authorized user of a sealed source listed in § 224.401 (relating to use of a sealed source in a teletherapy unit) in a teletherapy unit to be a physician who meets one of the following requirements:

(1) Is certified in one of the following:

(i) Radiology or therapeutic radiology **or radiation oncology by** the American Board of Radiology.

* * * * *

§ 224.462. Training for teletherapy physicist.

The licensee shall require the teletherapy physicist to be an individual who meets one of the following requirements:

* * * * *

(3) **Is certified by the American Board of Medical Physics in radiation oncology.**

§ 224.465. Recentness of training.

The training and experience specified in this chapter shall have been obtained within the **[5] 7** years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

§ 224.466. Training for an authorized nuclear pharmacist.

(a) The licensee shall require the authorized nuclear pharmacist to be a pharmacist who meets one of the following requirements:

(1) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties.

(2) Has completed 700 hours in structured educational program consisting of both of the following:

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation.

(B) Radiation protection.

(C) Mathematics pertaining to the use and measurement of radioactivity.

(D) Chemistry of byproduct material for medical use.

(E) Radiation biology.

(ii) Supervised experience in a nuclear pharmacy involving the following:

(A) Shipping, receiving and performing related surveys.

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides.

(C) Calculating, assaying and safely preparing dosages for patients or human research subjects.

(D) Using administrative controls to avoid mistakes in the administration of byproduct material.

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures.

(b) A pharmacist meeting the requirements of subsection (a)(2) shall obtain written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the pharmacist has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

§ 224.467. Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in § 224.466(a)(2) (relating to training for an authorized nuclear pharmacist) before _____(*Editor's Note*: The blank refers to the effective date of adoption of this proposal), and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with §§ 224.465 and 224.466(b) (relating to recentness of training) to qualify as an authorized nuclear pharmacist.

[Subchapter K. ENFORCEMENT] (RESERVED)

§ 224.501. **[Resolution of conflicting requirements during transition period] (Reserved).**

[If this chapter conflicts with the licensee's radiation safety program as identified in its license, and if that license was approved by the Department before June 20, 1992 and has not been renewed since June 20, 1992, the requirements in the license apply. However, if that licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under § 224.58 (relating to radiation safety program changes), the portion changed shall comply with this chapter. At the time of license renewal and thereafter, this chapter applies.]

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

GENERAL PROVISIONS

§ 225.1. Purpose and scope.

(a) This chapter establishes radiation safety requirements for persons utilizing radiation sources for industrial **[radiography] uses and radiographic operations**. Licensees and registrants who use radiation sources for industrial **[radiography] uses and radiographic operations** shall comply with this chapter. The requirements of this chapter are in addition to and not a substitution for other applicable requirements of this article. **This chapter does not apply to medical diagnosis or therapy.**

(b) Persons who use particle accelerators to perform radiographic operations shall also comply with Chapter 228 (relating to particle accelerators).

§ 225.2. Definitions.

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

***Annual refresher safety training*—A review conducted or provided by the licensee or registrant for its employes on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employes to ask safety questions.**

***Associated equipment*—Equipment used in conjunction with a radiographic exposure device to make radiographic exposures when the equipment drives, guides or comes into contact with the source.**

Cabinet X-ray system—An X-ray system with the X-ray tube installed in an enclosed, interlocked cabinet, **designed to exclude personnel from its interior during operation. The term includes X-ray ststems designed primarily for the inspection of baggage or packages. The term does not include an X-ray tube used within a shielded part of a building or X-ray equipment which may temporarily or occasionally incorporate portable shielding.**

* * * * *

***Certifying entity*—An independent certifying organization meeting the requirements of § 225.102 (relating to requirements for an independent certifying organization) or an agreement state which meets the same requirements as § 225.102.**

***Collimator*—A radiation shield made of lead, tungsten or other heavy metal which is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size and**

shape of the radiation beam when the sealed source is moved into position to make a radiographic exposure.

***Control cable*—The cable which is connected to the source assembly and used to drive the source to and from the exposure location. The term may be also referred to as the drive cable.**

***Control drive mechanism*—The device that enables the source assembly to be moved to and from the exposure device.**

***Crank-out device*—The cable, protective sheath and handcrank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.**

***Exposure head*—A device that locates the gamma radiography sealed source in the selected working position. An exposure head is also known as a source stop.**

***Guide tube (projection sheath)*—A flexible or rigid tube (that is, "J"-tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.**

***Individual's certification*—Written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing and experience criteria.**

* * * * *

***Lock-out survey*—A radiation survey performed to determine that a sealed source is in its shielded position.**

* * * * *

***Personal supervision*—The provision of guidance and instruction to a radiographer's assistant 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.

* * * * *

Radiographer—An individual who performs, or **[provides personal supervision of,] who, while in attendance at the site where the radiation source is being used, personally supervises** industrial radiographic operations **and who is responsible to the licensee or registrant for assuring compliance with this part and the conditions of the license or registration.**

Radiographer's assistant—An individual who, under the personal supervision of a radiographer, uses **radiographic exposure devices,** radiation sources, related handling tools or radiation survey instruments in industrial radiography.

* * * * *

***Radiographic operations*—All activities associated with the presence of radiation sources in a radiographic exposure device or in a radiation-producing machine during use of the device or machine or transport (except when being transported by common carrier or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.**

***S-tube*—A tube through which the radioactive source travels when inside a radiographic exposure device.**

* * * * *

***Source assembly*—A component to which the sealed source is affixed or in which the sealed source is contained. The source assembly includes the sealed source.**

* * * * *

***Storage facility*—A location, area or vehicle which is used to store, transport or secure a radiographic exposure device, a storage container, or a sealed source when it is not in use, and which is locked or has a physical barrier to prevent accidental or inadvertent exposure, tampering with or unauthorized removal of the device, container or source.**

* * * * *

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 specific license or registration.

***Transport container*—A package that is designed and constructed to provide radiation safety and security when a sealed source is transported and which meets applicable provisions of Chapter 230 (relating to packaging and transportation of radioactive material).**

§ 225.10. Application for a specific license or registration.

(a) A person who intends to use sealed sources in industrial uses or radiographic operations shall file an application in accordance with §§ 217.51 and 217.65 (relating to filing application for specific license; and specific licenses for the use of sealed sources in industrial radiography).

(b) A person who intends to use X-ray machines for industrial radiography shall have a program for training personnel, written operating and emergency procedures, an internal review system, and an organizational structure which includes specified delegations of authority and responsibility for operation of the program. This program shall be approved by the Department before commencing industrial radiography.

[SEALED SOURCE REQUIREMENTS] GENERAL PROVISIONS

§ 225.11. **[Storage position radiation level limits.] Reciprocity.**

[(a) Radiographic exposure devices that have the sealed source storage position located less than 4 inches (10 centimeters) from an exterior surface of the device shall have radiation levels not exceeding 50 milliroentgens (12.9 µC/kg) per hour at 6 inches (15 centimeters) from an exterior surface of the device when the sealed source is in the shielded—off—position.

(b) Radiographic exposure devices that have the sealed source storage position located more than 4

inches (10 centimeters) from an exterior surface of the device, and storage containers for sealed sources or outer containers for radiography exposure devices, shall have radiation levels not exceeding 200 milliroentgens (51.6 µC/kg) per hour and not exceeding 10 milliroentgens (2.58 µC/kg) per hour at 1 meter from an exterior surface when the sealed source is in the shielded—off—position.]

Out-of-State users of sealed source radiographic exposure devices or X-ray machines shall meet the requirements of § 216.7 or 217.121 (relating to out-of-state radiation producing machines; and reciprocity of licenses of by-product, source, and special nuclear materials in quantities not sufficient to form a critical mass), as appropriate.

§ 225.12. **[Radiation source locks] Prohibitions.**

[(a) A radiation source shall be kept in a lockable radiographic exposure device or in a lockable source changer to prevent unauthorized removal of, or accidental exposure from, the radiation source. The radiographic exposure device, source changer and storage container shall be kept locked when containing a radiation source except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized under § 225.52 (relating to security).

(b) Radiographic exposure devices, source changers and storage containers, prior to being moved from one location to another and also prior to being secured at a given location shall be locked and surveyed to assure that the sealed source is in the shielded position.]

Human use of the radiation sources covered by this chapter is not permitted.

(*Editor's Note*: Sections 225.13—225.18, 225.21—225.23, 225.31—225.33 and 225.41—225.44 are proposed to be deleted. The current versions of these sections appear at pps. 225-6—225-17, *Pennsylvania Code* serial pps. (203960)—(203971)).

§§ 225.13—225.18. (Reserved).

[RADIATION-PRODUCING MACHINE REQUIREMENTS]

§§ 225.21—225.23. (Reserved).

[RADIATION SURVEY INSTRUMENTS AND LOGS]

§§ 225.31—225.23. (Reserved).

[OPERATOR'S PERSONAL SAFETY REQUIREMENTS]

§§ 225.41—225.44. (Reserved).

[PRECAUTIONARY PROCEDURES] GENERAL ADMINISTRATIVE REQUIREMENTS

§ 225.51. **[Permanent radiographic installation] Duties of personnel.**

[Permanent radiographic installations having high radiation area entrance controls of the types described in §§ 219.91 and 219.154 (relating to control of access to high radiation areas; and posting of high radiation areas) 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 visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.

(2) The control device or alarm system shall be tested for proper operation at the beginning of each day of use.]

(a) The radiation safety officer (RSO) shall be an individual who shall ensure that radiation safety activities are being performed in accordance with approved procedures and requirements in the daily operation of the licensee's or registrant's program, and in compliance with Department requirements, and who has the authority to suspend or terminate operations which are not being conducted in accordance with license or registration conditions.

(b) The radiographer shall be an individual who performs or who is in attendance at a site where a source is being used, who personally supervises radiographic operations, and who is responsible to the licensee or registrant for ensuring compliance with this article and conditions of a license or registration.

(c) The radiographer's assistant shall be an individual who, under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or X-ray machines, related handling tools or radiation survey instrumentation.

(d) The radiography trainee is an individual who is in the process of becoming a radiographer's assistant or a radiographer, in accordance with a licensee's or registrant's procedures. The trainee is not permitted to operate radiographic exposure devices, sealed sources or X-ray machines, or radiation survey instrumentation.

§ 225.71. Training of personnel.

A licensee or registrant may not allow an individual to act as a radiographer or assistant radiographer unless that individual meets the requirements of § 225.72 (relating to training and testing), appropriate license or registration requirements, and operating and emergency procedures.

§ 225.72. Training and testing.

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

(1) Has been instructed in the subjects outlined in Appendix A (relating to subjects to be covered during instruction of radiographs).

(2) Is certified through a radiographer's certification program by a certifying entity in accordance with the criteria specified in §§ 225.102 and 225.103 (relating to requirements for an independent certifying organization; and requirements for certification programs). An independent organization that would like to be recognized as a certifying entity shall submit its request to the Department. The licensee or registrant may allow an individual who has not met the certification requirements to act as

a radiographer, so long as the individual has received the training required under this subchapter. This allowance expires _____(*Editor's Note:* The blank refers to a date 2 years after the effective date of adoption of this proposal).

(3) Has received copies of this chapter, Chapters 219, 220 and 230. A copy of the license or certificate of registration issued to the licensee or registrant and copies of the licensee's or registrant's operating and emergency procedures.

(4) Has been instructed in the use of the licensee's or registrant's sources of radiation, radiographic exposure devices, radiation-producing machines, related handling tools, radiation survey instruments, regulations, and operating and emergency procedures.

(5) Has demonstrated, to the satisfaction of the licensee or registrant, competency and understanding of the information as evidenced by having successfully completed a written test and a field examination.

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

(1) Has received copies of, and instruction in, the licensee's or registrant's operating and emergency procedures.

(2) Has been instructed in the use, and has demonstrated, to the satisfaction of the licensee or registrant, that when the individual is under the direct personal supervision of the radiographer, the individual is competent in the use of sources of radiation, radiographic exposure devices, related handling tools and radiation survey instruments that will be used.

(3) Has demonstrated, to the satisfaction of the licensee or registrant, an understanding of the information as evidenced by having successfully completed 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 5 years following termination of employment by the individual or until the radioactive material license or certificate of registration is terminated.

§ 225.73. Audits and safety reviews of radiographers and radiographers' assistants.

(a) The licensee or registrant shall provide safety reviews for radiographers and radiographer's assistants at least once during each calendar year.

(b) The licensee or registrant shall conduct an annual inspection program for the job performance of each radiographer and radiographer's assistant to ensure that this title, license or certificate of registration requirements and the licensee's or registrant's operating and emergency procedures 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 inspection, the individual's performance shall be observed and recorded when the individual next participates in a radiographic operation.

(c) The licensee or registrant shall maintain records of the training required in subsections (a) and (b) to include certification documents, written and field examinations, annual safety reviews and annual audits of job performance. These records shall be maintained by the licensee or registrant for inspection by the Department for 5 years following termination of employment by the individual or until the radioactive material license or certificate of registration is terminated.

§ 225.74. Reporting requirements.

(a) In addition to the reporting requirements in Chapter 219 (relating to standards for protection against radiation), each licensee or registrant shall provide to the Department, within 30 days of its occurrence, a written report on the following incidents involving radiographic equipment used for industrial radiography:

(1) Unintentional disconnection of the source assembly from the control cable.

(2) Inability to retract or secure a sealed source to its fully shielded position.

(3) Failure of a component critical to the safe operation of a radiographic exposure device to perform its intended function properly.

(4) Inability to terminate irradiation with an X-ray machine.

(5) Failure of an interlock in shielded room radiography.

(b) The licensee or 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, time and date of the incident.

(5) The action taken to reestablish normal operations.

(6) The corrective action taken or planned to prevent reoccurrence.

(7) The names and qualifications of personnel involved.

(c) Reports of overexposures, required under § 219.222 (relating to notification of incidents) or of excessive exposures, required under § 219.223 (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

§ 225.101. Certification of personnel.

Radiographers and assistant radiographers shall meet the examination criteria in the license application and procedures defined in the license application.

§ 225.102. Requirements for an independent certifying organization.

An independent certifying organization shall meet the following conditions:

(1) Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography or nondestructive testing.

(2) Make its membership available to the general public Nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability.

(3) Have a certification program open to nonmembers.

(4) Be an incorporated, Nationally-recognized organization, that is involved in setting National standards of practice within its fields of expertise.

(5) Have an adequate, full-time staff, a viable system of financing its operations, and a policy- and decisionmaking review board.

(6) Have a set of written organizational bylaws and policies that provide adequate assurances of lack of conflict or interest and a system of monitoring and enforcing those bylaws and policies.

(7) Have a committee, whose members can carry out their responsibilities impartially, to review and improve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program.

(8) Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions.

(9) Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program.

(10) Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified, and any sanctions imposed against certified individuals.

(11) Have procedures for proctoring examinations, including qualifications for proctors. These procedures shall ensure that the individuals proctoring each examination are not employed by the same company or corporation or a wholly-owned subsidiary of the company or corporation as any of the examinees.

(12) Exchange information about certified individuals with the Department, other independent certifying organizations, the NRC or agreement states.

(13) Allow periodic review of its certification program and its related records.

(14) Provide a description to the Department of its procedures for choosing examination sites and for providing an appropriate examination environment.

§ 225.103. Requirements for certification programs.

Certification programs shall meet the following conditions:

(1) Require that individuals meet the following:

(i) Receive training in the topics in Appendix A (relating to subjects to be covered during the instruction of radiographers).

(ii) Complete satisfactorily a written examination covering the topics in Appendix A.

(2) Require applicants for certification to provide documentation that demonstrates that the applicant has met the following:

(i) Received training in the topics in Appendix A.

(ii) Completed satisfactorily a minimum period of on-the-job training.

(iii) Received verification by an agreement state or NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer.

(3) Include procedures to ensure that all examination questions are protected from disclosure.

(4) Include procedures for denying an application, revoking, suspending and reinstating a certificate.

(5) Provide a certification period of not less than 3 years nor more than 5 years.

(6) Include procedures for renewing the certifications and, if the procedures allow renewals without examination, require evidence of recent active, full-time employment and annual refresher training.

(7) Include procedures whereby an individual's certification may be revoked, suspended or restricted for willful or significant failure to comply with his employer's operating and emergency procedures, or the Department's, the NRC's or an agreement state's regulations.

(8) Provide for automatic suspension of an individual's certification, based on the Department's, NRC's or an agreement state's action prohibiting the individual from acting as a radiographer.

(9) Provide the sanctions imposed against the certified individuals that are at least as severe as any action taken by the Department, NRC or an agreement state.

(10) Provide a timely response to inquiries, by telephone, letter or electronic means, from members of the public, about an individual's certification status.

§ 225.104. Requirements for written examinations.

Examinations shall meet the following conditions:

(1) Be designed to test an individual's knowledge and understanding of the topics listed in Appendix A (relating to subjects to be covered during the instruction of radiographers) or equivalent NRC or agreement state requirements.

(2) Be written in a multiple-choice format.

(3) Have test items drawn from a question bank containing psychometrically valid questions based on the material in Appendix A.

§ 225.105. Permanent radiographic installation.

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in §§ 219.91 and 219.154 (relating to control of access to high radiation areas; and posting of high radiation areas) 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 source is exposed or when the X-ray tube is energized. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed or the X-ray tube 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 so long as the licensee or registrant implements the continuous surveillance of §§ 225.52 and 225.53 (relating to security; and posting) and, if the permanent radiographic installation uses sealed sources, § 225.261 (relating to radiographic operations, security and posting) 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 5 years.

§ 225.106. Operating requirements.

(a) When radiography is performed at a location other than a permanent radiographic installation, a minimum of two radiographic personnel shall be present to operate the radiographic exposure device. At least one of the radiographic personnel shall be a certified radiographer. The other individual may be either a certified radiographer or a radiographer's assistant.

(b) Collimators shall be used in industrial radiographic systems that use crank-out devices except when physically impossible.

(c) 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.

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

(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 ("film badge" or "TLD") for each worker.

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

(5) An operable, calibrated alarm rate meter for each worker who performs industrial radiography with a sealed source.

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

§ 225.107. Records required at temporary job sites.

Each licensee or registrant using a source of radiation at a temporary job site shall maintain and have available at that job site, for inspection by the Department, the following records or documents:

(1) The radioactive materials license, certificate of registration or equivalent document and 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) If sealed sources are used at the site, daily alarm rate meter records for the period of operation at the site.

(7) Both the latest radiation survey meter calibration records and sealed source leakage or contamination test records for specific devices in use at the site. Acceptable records include tags or labels that are affixed to the device or survey meter and decay charts showing leakage or contamination test results for the sources that have been manufactured within the last 6 months.

§ 225.108. Operating and emergency procedures.

The licensee's or registrant's operating and emergency procedures 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 the radiation surveys.

(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 if of an ionization chamber (that is, "pocket dosimeter") is found to be off-scale.

(6) Transportation to field locations, including packing of sources of radiation in the vehicle, placarding of the vehicle if necessary, and control of sources of radiation during transport.

(7) Methods and procedures for minimizing exposure of individuals in the event of an accident, including procedures to follow in the event of a disconnect accident, a transportation accident or the loss of a sealed source.

(8) The procedure for notifying proper personnel in the event of an accident or loss of a sealed source.

(9) Maintenance of records required by the Department.

(10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, transportation containers, source guide tubes, crank-out devices and radiation-producing machines.

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

§ 225.151. Radiation survey instruments.

(a) A licensee or 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 exposures and radiation-producing machines are used.

(c) Immediately prior to use, a radiation survey instrument shall be checked to ensure that it is operating properly by bringing it near a source of radiation and observing its response. Instruments that fail to respond may not be used.

§ 225.152. Radiation survey instrument calibration requirements.

(a) In addition to the requirements of § 225.151 (relating to radiation survey instruments), instruments required by this chapter shall be capable of measuring 0.516 µC/kg (2 mR) per hour through 258 µC/kg (1 R) per hour.

(b) Each radiation instrument shall be calibrated:

(1) At energies appropriate for use.

(2) At intervals not to exceed one of the following:

(i) For radioactive materials, 6 months.

(ii) For radiation-producing machines, 6 months.

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

(4) So that accuracy within ±20% can be demonstrated.

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

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

(c) Records of calibration shall be maintained for 5 years after the calibration date for inspection by the Department.

§ 225.153. Personnel monitoring control.

(a) A licensee or 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 combination of direct-reading pocket dosimeter, an operating alarm ratemeter and either a film badge or a thermoluminescent dosimeter (TLD). The individual shall wear the personnel monitors on the trunk of the body. Registrants are exempted from requiring the use of alarm rate meters. Each film badge or TLD shall be assigned to and worn by only one individual.

(b) Film badges shall be replaced at intervals not to exceed 1 month and thermoluminescent dosimeters (TLDs) shall be replaced at intervals not to exceed 3 months.

(c) The use of pocket dosimeters is subject to the following requirements:

(1) Pocket dosimeters shall have a range of 0 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 only be used in place of ion-chamber pocket dosimeters.

(2) Pocket dosimeters shall be read and exposures recorded at least at the beginning and end of each worker's shift involving the use of a source of radiation.

(3) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year, and acceptable dosimeters shall read within ±30% of the true radiation exposure. Records of pocket dosimeter calibration shall be maintained for inspection by the Department for 5 years.

(4) If an individual's pocket dosimeter is discharged beyond its range (that is, "off-scale"), industrial radiographic operations by that individual shall cease immediately and the individual's film badge or TLD shall be sent immediately for processing. The individual may not use sources of radiation until the individual's radiation dose has been determined.

(d) Reports received from film badge or TLD processors and workers with daily pocket dosimeter readings shall be kept for inspection by the Department until the radioactive materials license or certificate of registration 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.

§ 225.154. Personal alarm rate meters.

(a) In addition to other requirements of this subsection, each individual performing radiography with sealed sources shall wear and use an operable and functioning alarm rate meter. Each alarm rate meter shall:

(1) Be checked prior to use at the start of each shift to ensure that the alarm functions properly (sounds).

(2) Be set to give an alarm signal at a preset dose rate of 5 millisievert (500 millirem) per hour or less.

(3) Require special means to change the preset alarm function.

(4) Be checked for proper response to radiation at intervals not to exceed 1 year. The alarm rate shall alarm within ±20% of the true radiation dose rate. Records of alarm rate meter calibration shall be maintained for inspection by the Department for 5 years.

(b) The alarm rate meter shall be used in addition to, and not as substitute for, the portable radiation survey instrument required by this chapter. The alarm rate meter is intended to provide additional assurance that the radiation exposure levels are within regulatory limits.

RADIATION PRODUCING MACHINE REQUIREMENTS

§ 225.201. Cabinet X-ray systems.

(a) It shall be impossible to energize a cabinet X-ray system unless all openings are securely closed and the openings meet the requirements of § 219.31 (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.

(b) 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 system and has demonstrated an understanding of the operating procedures and competency in the use of the cabinet X-ray system.

(c) The registrant shall evaluate the cabinet X-ray system to assure compliance with § 219.31 (relating to occupational dose limits for adults) and with 21 CFR 1020.40 (relating to cabinet X-ray systems) if the system is a certified cabinet X-ray system. The records of these evaluations shall be maintained for inspection by the Department for 5 years after evaluation.

(d) The registrant shall test the on-off switch, the unit interlocks and safety devices at intervals not exceeding 1 year, and make repairs as necessary. Records of these tests shall be maintained for inspection by the Department for 5 years.

(e) Cabinet X-ray systems are exempt from all other provisions of this chapter.

§ 225.202. Shielded room X-ray machine radiography.

(a) A room used for shielded room 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 § 219.91 (relating to control of access to high radiation areas).

(b) A registrant may not permit an individual to operate a radiation-producing machine for shielded room radiography until the individual has received a copy of, and instruction in, the operating procedures for the unit and has demonstrated an understanding of the operating procedures and competency in the use of the unit.

(c) 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 radiography.

(d) The operator shall conduct a physical radiation survey to determine that the radiation machine X-ray tube is de-energized prior to each entry into the radiographic exposure area.

(e) Shielded room radiography using radiation-producing machines shall be exempt from §§ 225.251—225.262 (relating to sealed source requirements).

§ 225.203. Field site radiography.

(a) The operator shall conduct a physical radiation survey to determine that the radiation machine X-ray tube is de-energized 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 5 years.

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

(c) Other radiography using radiation-producing machines shall be exempt from §§ 225.251—225.262 (relating to sealed source requirements).

§ 225.204. Surveys and survey records.

(a) A survey with a calibrated radiation survey instrument shall be made after each radiographic exposure to determine that the radiation-producing machine X-ray tube is de-energized.

(b) Records of the surveys required by subsection (a) shall be maintained for inspection by the Department for 5 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.

§ 225.205. Utilization logs.

A registrant shall maintain current logs, which shall be kept available for inspection by the Department for 5 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 location and date of use.

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

§ 225.206. Bomb detection or baggage/package X-Ray systems.

(a) This section applies to X-ray systems that produce an image which may be used to screen packages for the presence of explosive devices or components, weapons, or other contraband or pro-

hibited items. This section does not apply to cabinet X-ray systems designed and used primarily for the inspection of baggage or packages at airports. X-ray systems used for bomb detection or baggage/package screening are exempt from §§ 225.251—225.262 (relating to sealed source requirements).

(b) An X-ray system used for explosives or weapons detection may not be used on human beings or animals. X-ray systems whose purpose is the irradiation of human beings for medical diagnosis are covered under Chapter 221 (relating to X-rays in the healing arts). X-ray systems that irradiate animals for diagnosis or therapy are covered under Chapter 223 (relating to veterinary medicine).

(c) Training shall be as follows:

(1) A registrant shall provide training and safety rules to each individual who operates the radiation-producing machines or equipment under his control, including restrictions of the operating technique required for the safe operation of the particular apparatus, and require that the operator demonstrate familiarity with these rules.

(2) An individual may not operate these X-ray systems unless the individual has received training in, and received a copy of, the operating instructions for the unit and the operating and emergency procedures relevant to the use of these systems. The operator shall demonstrate, to the satisfaction of the registrant, competency in the safe use of this equipment.

(d) Radiographic equipment 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 or exposure or a preset product of exposure time and tube current.

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

(5) 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 containing a similar warning, 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 containing a similar warning. This light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(e) Fluoroscopic equipment shall be as follows:

(1) 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 containing a similar warning, 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 § 219.91 (relating to control of access to high radiation areas).

(4) The equipment shall be so constructed 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) 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 containing a similar warning, near any switch that energizes the X-ray tube.

(7) 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 containing a similar warning. This light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(f) Portable X-ray radiographic equipment operating procedures 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 film shall be used for radiation exposures.

(3) Individuals, other than those whose presence is necessary to conduct the X-ray procedure, shall be located at least 5 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 film or object during radiation exposures.

(g) Fixed radiographic equipment operating procedures are as follows:

(1) A registrant shall test the safety and warning devices, including interlocks, at intervals not to exceed 12 months. Records of these tests shall be maintained for inspection by the Department for 5 years after the test has been conducted.

(2) A safety or warning device which is found not to be functioning properly shall be repaired as necessary.

§ 225.207. X-ray calibration systems.

(a) This section applies to registrants who regularly, or for commercial purposes, calibrate equipment used to measure the output of radiation for medical diagnosis and therapy, or for radiation survey meters and similar instrumentation. X-ray systems used for calibration purposes are exempt from §§ 225.251—225.262 (relating to sealed source requirements).

(b) A room or enclosure used for calibration shall be shielded 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 § 219.91 (relating to control of access to high radiation areas).

(c) A registrant may not permit an individual to operate a radiation-producing machine for shielded room radiography until the individual has received a copy of, an instruction in, the operating procedures for the unit and has demonstrated an understanding of the operating procedures and competency in the use of the unit.

(d) The operator shall conduct a physical radiation survey to determine that the radiation machine X-ray tube is de-energized prior to each entry into the radiographic exposure area.

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

SEALED SOURCE REQUIREMENTS

§ 225.251. Performance requirements for radiography equipment.

Equipment used in industrial radiographic operations shall meet the following minimum criteria:

(1) Each radiographic exposure device, source assembly and sealed source and all associated equipment shall meet the requirements in American National Standards Institute N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," published as NBS Handbook 136 issued January, 1981.

(2) In addition to the requirements in paragraph (1), the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources:

(i) Each radiographic exposure device shall have attached to it by the user, a durable, legible, clearly visible label bearing the following:

(A) The chemical symbol and mass number of the radionuclide in the device.

(B) The activity and the date on which this activity was last measured.

(C) The model number and serial number of the sealed source.

(D) The manufacturer of the sealed source.

(E) The licensee's name, address and telephone number.

(ii) A radiographic exposure device intended for use as a Type B transport container shall meet the applicable requirements of Chapter 230 (relating to transportation of radioactive materials).

(iii) Modification of an exposure device, source changer, source assembly and associated equipment is prohibited, unless the design of any replacement component including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(3) In addition to the requirements specified in paragraphs (1) and (2), the following requirements apply to radiographic exposure devices, source assemblies and associated equipment that allow the source to be moved out of the device for routine operations or to source changers:

(i) The coupling between the source assembly and the control cable shall be designed so that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonable, or foreseeable abnormal, conditions.

(ii) The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation of the exposure device.

(iii) The outlet fittings, lock box and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers which shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(iv) Each sealed source or source assembly shall have attached to it or engraved on it a durable, legible, visible label with the words, "Danger, Radioactive." The label may not interfere with the safe operation of the exposure device or associated equipment.

(v) The guide tube shall be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(vi) Guide tubes shall be used when moving the source out of the device.

(vii) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outmost end of the guide tube during radiographic operations.

(viii) The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432-1980.

(ix) Source changers shall provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(4) Newly manufactured radiographic exposure devices and associated equipment acquired by a licensee after January 10, 1992, shall comply with this section.

(5) Radiographic exposure devices and associated equipment in use after January 10, 1996, shall comply with this section.

(6) Notwithstanding paragraphs (1), (4) and (5), equipment used in inidustrial radiographic operations need not comply with section 8.9.2(c) of the endurance test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

§ 225.252. Limits on levels of radiation for radiographic exposure devices, storage containers and source changers.

(a) Radiographic exposure devices measuring less than 10 centimeters (4 inches) from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 12.9 µC/kg (50 mR) per hour at 15 centimeters (6 inches) from any exterior surface of the device.

(b) Radiographic exposure devices measuring a minimum of 10 centimeters (4 inches) from the sealed source storage position to any exterior surface of the device or for radiographic exposure devices, shall have no radiation level in excess of 51.6 uC/kg (200 mR) per hour at any exterior surface, and 2.58 µC/kg (10 mR) per hour at 1 meter from any exterior surface. The radiation level specified is with the sealed source in its shielded ("off") position.

(c) The maximum exposure rate 1 meter from storage containers and source changers is 51.6 µC/kg (200 mR) per hour at any exterior surface, and 2.58 µC/kg (10 mR) per hour at 1 meter from any exterior surface when the sealed source is in its shielded ("off") position.

(d) Subsection (a) applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers shall meet the requirements of § 225.251 (relating to performance requirements for radiography equipment).

§ 225.253. Locking and relocation of radiographic exposure devices, storage containers and source changers.

(a) A license may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, that is, magenta, purple or black on a yellow background, having a minimum diameter of 25 millimeters, and the wording: "Caution, Radioactive Material, Notify Civil Authorities (or "Name of Company") or "Danger".

(b) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from a shielded position. The exposure device or its container shall be kept locked when not under the direct surveillance of a radiographer or a radiographer's assistant or as otherwise may be authorized in § 225.105 (relating to permanent radiographic installations). During radiographic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(c) Each sealed source storage container and source changer shall have a lock or outer lock container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or radiographer's assistant.

(d) Radiographic exposure devices, source changers and storage containers, before being moved from one location to another, shall have the guide tubes and control cables disconnected, safety plugs or covers applied, be locked and physically secured to prevent accidental loss, tampering or removal of licensed material.

(e) A lock-out survey shall be performed before moving the radiographic exposure device, source changer or storage container to a new location and when securing against unauthorized removal.

§ 225.254. Storage precautions.

Locked radiographic exposure devices, source changers, storage containers and transport containers that contain sealed sources shall be secured to prevent tampering or removal by unauthorized personnel from its permanent storage facility.

§ 225.255. Leak testing and replacement of sealed sources.

(a) Only persons specifically authorized by the Department, the NRC or an agreement state, may replace or leak test a sealed source fastened to or contained in a radiographic exposure device or source changer.

(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. Each sealed source shall be leak tested prior to its first use unless the supplier furnishes a certificate stating that the source has been tested within 6 months prior to its first use.

(c) Each exposure device using depleted (DU) uranium shielding and an "S"-tube configuration shall be tested for DU contamination at intervals not to exceed 12 months.

(d) The leak test required by subsections (a) and (b) shall be capable of detecting the presence of .005 microcuries (185 Bq) of the removable contamination of the test sample. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest acces-

sible point to the sealed source position or other appropriate measuring point by a procedure approved under § 219.65(5) (relating to specific licenses for the use of sealed sources in industrial radiography).

(e) Records of leak test results shall be kept in units of becquerels or microcuries and be maintained for 5 years from the date of the test for inspection by the Department.

(f) A leak test conducted under subsection (b) which reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination is considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and cause it to be decontaminated and repaired or to be disposed of, in accordance with §§ 217.101 and 219.61—219.66. Within 5 days of the test that reveals the leakage, the licensee shall file a report with the Department describing the equipment involved, and the test results and the corrective action taken.

(g) If the testing of an exposure device using depleted uranium shielding reveals the presence of DU contamination, the exposure device shall be removed from use until an evaluation of the wear of the S-tube has been made. If this evaluation reveals that the S-tube is worn through, the device may not be used again.

(h) Sealed sources that are stored and not being used shall be leak tested within 6 months prior to the date of transfer, and the maximum interval between leak tests may not exceed 3 years.

(i) Depleted uranium shielding devices that are stored and not being used need not be tested for depleted uranium contamination while in storage and not in use. The device shall be tested for DU contamination prior to use or transfer of the device if the interval of storage exceeds 12 months. A record of the depleted uranium leak test shall be made in accordance with subsection (e).

(j) A sealed source which is not fastened to or contained in a radiographic exposure device shall have a durable tag permanently attached to it. This tag shall have a dimension of at least 1 inch (2.5 centimeters) square and bear the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger—Radioactive Material—Do not handle—Notify civil authorities if found."

§ 225.256. Physical inventories.

(a) A licensee shall conduct a physical inventory at intervals not to exceed 3 months to account for all sources of radiation received or possessed. The inventory shall cover all sources or radiation, including, but not limited to, sealed sources. source changers and radiographic exposure devices containing depleted uranium as shielding.

(b) Records of the inventories shall be maintained for 5 years from the date of the inventory for inspection by the Department and shall include the manufacturer, model, serial number, radionuclide and activity, if applicable, location of each source of radiation, date of the inventory and the name of the individual performing the inventory.

(c) If, during an inventory, a radiation source cannot be located or accounted, the licensee shall notify the Department as required under § 219.221 (relating to reports of stolen, lost or missing licensed sources of radiation).

§ 225.257. Inspection and maintenance of radiographic exposure devices, storage containers, associated equipment and source changers.

(a) A licensee shall ensure that checks for obvious defects in radiographic exposure devices, transport containers, source changers, source guide tubes and crankout devices are performed at the beginning of each day of use.

(b) At intervals not to exceed 3 months, each licensee shall conduct a program of inspection and maintenance of the radiographic exposure devices, transport containers and source changers to assure proper functioning of components. Appropriate parts shall be maintained in accordance with manufacturer's specifications. The licensee shall have written procedures for the conduct of this program.

(c) A licensee shall have a written program for inspection and maintenance of the Type B packaging used to transport radioactive materials. This program shall include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(d) Records of inspection and maintenance shall be maintained for inspection by the Department for 5 years.

(e) If an inspection conducted under subsection (a) or (b) reveals damage to components critical to radiation safety, the licensee shall remove the device from service until repairs have been made.

(f) Opening, repair or modification of any sealed source shall be performed by persons specifically authorized by the Department.

§ 225.258. Utilization logs.

A licensee shall maintain current logs, which shall be kept available for 5 years from the date of the recorded event, for inspection by the Department, at the address specified in the license, showing for each sealed source the following information:

(1) The make, model and serial number of the radiographic exposure device or source container in which the sealed source is located.

(2) The identity and signature of the radiographer to whom assigned.

(3) The plant or site where used and dates of use.

§ 225.259. Radiation surveys and records.

(a) After each radiographic exposure, a survey with a calibrated radiation survey instrument shall be made to determine that the sealed source has returned to the shielded position. The entire perimeter of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a guide tube or collimator, the survey shall include the guide tube or collimator, or both.

(b) A physical radiation survey shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic expo-

sure device or storage container as specified in § 225.253 (relating to locking and relocation or radiographic exposure devices, storage containers and source changers).

(c) Records of the surveys required by subsection (b) shall be maintained for inspection by the Department for 5 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.

§ 225.260. Supervision of radiographer's assistant(s).

Except when a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts physical radiation surveys required under § 225.259(a) and (b) (relating to radiation surveys and records) to determine that the sealed source has returned to the shielded position after an exposure, a radiographer's assistant shall be under the personal supervision or a qualified radiographer. The personal supervision shall include the radiographer's physical presence at the site where the sealed sources are being used at a proximity that immediate assistance can be given if required and watching the performance of the radiographer's assistant.

§ 225.261. Radiographic operations, security and posting.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, a radiographer shall be accompanied by at least one other qualified radiographer or an individual who has at minimum met the requirements of § 225.72(b) (relating to training and testing of radiographer's assistant). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

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

(1) The high radiation area is equipped with a control device or alarm system as described in § 219.91 (relating to control of access to high radiation areas).

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

(c) Areas in which radiography is being performed shall be conspicuously posted as required by § 219.153 or § 219.154 (relating to radiation areas; and high radiation areas), as appropriate.

(d) A licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at the location of use of licensed material or a radiation-producing machine.

(e) A radiographer or an assistant radiographer shall be located near the crank handle of the radiographic exposure device to return the sealed source to its safe position in the event of unauthorized or accidental entry by an individual.

(f) Barricades shall be provided around the perimeter of the restricted area and shall be posted with sufficient conspicuous warning signs to prevent unauthorized entry. Radiation levels at the boundary of the restricted area may not be greater than 0.516 µC/kg (2 mR) in any 1 hour.

APPENDIX A

Subjects to be Covered During the Instruction of Radiographers

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II. Radiation Detection Instrumentation to be Used

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C. Use of personnel monitoring equipment

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2. Thermoluminescent dosimeters **(TLDs)**

3. Pocket dosimeters **and alarm ratemeters**

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CHAPTER 226. RADIATION SAFETY REQUIREMENTS FOR **[WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES] WELL LOGGING**

Subchapter A. SCOPE AND DEFINITIONS

GENERAL

§ 226.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons using radiation sources for **[wireline service operations including mineral logging] well logging in a single well**, radioactive markers**, uranium sinker bars** and subsurface tracer studies. Persons who use radiation sources for **[wireline service] well logging** operations shall comply with this chapter, which is in addition to and not in substitution for other applicable requirements of this article.

§ 226.2. Definitions.

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

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***Fresh water aquifer*—A geologic formation that is capable of yielding fresh water to a well or spring.**

* * * * *

***Logging assistant*—An individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by this chapter.**

Logging supervisor—The individual who **uses radioactive material or** provides personal supervision of the utilization of radiation sources at the **temporary** jobsite**, and who is responsible for assuring compliance with this chapter and license conditions.**

***Logging tool*—A device used beneath the surface to perform well logging.**

[*Mineral logging*—Logging performed for the purpose of mineral exploration other than oil or gas.]

Personal supervision—Guidance and instruction by the supervisor who is physically present at the **temporary** jobsite and watching the performance of the operation in **[such]** proximity **so** that contact can be maintained and immediate assistance given as required.

Radioactive marker—Radioactive material placed beneath the surface or on a structure intended for subsurface use to determine depth or direction. **The term includes radioactive collar markers and radioactive iron nails.**

***Safety review*—The periodic review provided by the licensee for its employes on radiation safety aspects of well logging. This review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed or reported, and opportunities for employes to ask safety questions.**

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***Subsurface casing for protecting fresh water aquifers*—A pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.**

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***Temporary jobsite*—A place where radioactive materials are present for the purpose of performing well logging or subsurface tracer studies.**

***Uranium sinker bar*—A weight containing depleted uranium used to pull a logging tool toward the bottom of a well.**

***Well*—A drilled hole in which well logging may be performed.**

*Well***[-]***logging*—The use of measuring devices or tools which may contain radiation sources in well-bores or cavities to obtain information about the well or adjacent formations, or both. **The term includes subsurface tracer studies.**

[*Wireline service operation*—An evaluation or mechanical service which is performed in the well-bore using logging tools with electrical or electronic cable assemblies.]

§ 226.3. Prohibition.

A licensee may not perform **[wireline service operations] well logging** with a sealed source unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner or drilling contractor that:

* * * * *

EQUIPMENT CONTROL

§ 226.11. Limits on levels of radiation.

The licensee or registrant shall use, store and transport radiation sources in accordance with §§ 219.31—219.38, 219.51 **(relating to occupational dose limits; and radiation dose limits for individual members of the general public)** and Chapter 230 **(relating to packaging and transportation of radioactive material).**

§ 226.12. Storage and transport precautions.

* * * * *

(c) Transport containers shall be **locked and** physically secured to the transporting vehicle to prevent accidental loss, tampering or unauthorized removal of the radiation sources.

§ 226.13. Radiation survey instruments.

(a) *Maintenance.* The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at a site where radiation sources are present to make physical radiation surveys as required by this chapter and by § 219.71 (relating to general). Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nC/kg) per hour through at least 50 milliroentgens (12.9 µC/kg) per hour. **[Survey instruments acquired before December 19, 1987, and capable of measuring 0.1 milliroentgen (25.8 nC/kg) per hour through at least 20 milliroentgens (5.16 µC/kg) per hour also satisfy this requirement until July 14, 1992.]**

(b) *Calibration.*

* * * * *

(3) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least 1 decade; and for digital instruments, at appropriate points.

(c) *Time period.* Calibration records shall be maintained for **[a period of 5] 3** years or until the Department authorizes their disposal.

(d) The licensee shall have available additional calibrated and operable radiation survey instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a source ruptured. The licensee may own these instruments or may have a procedure to obtain them quickly from another person.

§ 226.14. Leak testing of sealed sources.

* * * * *

(b) A sealed source shall be tested for leakage at intervals not to exceed 6 months. The sealed source shall be leak-tested prior to its first use unless the supplier furnishes a certificate stating that the source has been tested within 6 months prior to its first use. If it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage. The leak test shall be capable of detecting the presence of .005 microcuries (185 Bq) of removable contamination on the test sample. An acceptable leak test for sealed sources would be to take the test sample from the surface of the source, source holder or the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries—or becquerels—and maintained for **[5] 3** years from the date of the test or until the Department authorizes their disposal.

* * * * *

(e) The method of testing a sealed source for leakage shall be performed using a leak test kit or method approved by the Department, an agreement state or the NRC. The wipe sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample shall be analyzed for radioactive contamination. The analysis shall be capable of detecting the presence of 185 Bq (.005 µCi) of radioactive material on the test sample and shall be performed by a person approved by the Department, the NRC

or an agreement state to perform the analysis, if the licensee does not possess suitably sensitive equipment.

§ 226.15. **[Quarterly] Physical** inventory.

(a) A licensee or registrant shall conduct a **[quarterly] semiannual** physical inventory of radiation sources **to account for all sources of radiation received or possessed**. Records of inventories shall be maintained for **[5] 3** years from the date of the inventory or until the Department authorizes their disposal **[and]. Records** shall include the quantities and kinds of radiation sources, the location where radiation sources are assigned, the date of the inventory and the name of the individual conducting the inventory.

(b) Physical inventory records may be combined with leak test records.

§ 226.16. Utilization records.

A licensee or registrant shall maintain current records, which shall be kept available for inspection by the Department for **[5] 3** years from the date of the recorded event, showing the following information for each radiation source:

* * * * *

(4) In the case of tracer materials and radioactive markers, the radionuclide and **quantity of** activity used in a particular well **and the disposition of any unused tracer materials**.

§ 226.17. Design**[,] and** performance **[and certification]** criteria for sealed sources **[used in downhole operations]**.

[(a)] A **licensee may not use a** sealed source, except those containing radioactive material in gaseous form, **[used]** in **[downhole operations and manufactured after December 19, 1988, shall be certified by the manufacturer, or other testing organization acceptable to the Department, as meeting the] well logging unless the sealed source meets the** following minimum criteria:

(1) **[Be] Is** of doubly encapsulated construction.

* * * * *

(3) **[Has been individually pressure tested to at least 24,600 pounds per square inch absolute (170 MN/m^2) without failure] The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:**

(i) The test source shall be held at −40°C for 20 minutes, 600°C for 1 hour, and then subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(ii) A 5 kg steel hammer, 2.5 cm in diameter, shall be dropped from a height of 1 meter onto the test source.

(iii) The test source shall be subject to a vibration from 25 Hz to 500 Hz at 5g amplitude for 30 minutes.

(iv) A 1 gram hammer and pin, 0.3 cm pin diameter, shall be dropped from a height of 1 meter onto the test source.

(v) The test source shall be subjected to an external pressure of 24,600 pounds per square inch absolute (1.695 × 10^7 pascals).

[(b) For a sealed source, except one containing radioactive material in gaseous form, acquired after December 19, 1988, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of subsection (a), the sealed source may not be put into use until the determinations and testing have been performed.

(c) A sealed source, except those containing radioactive material in gaseous form, used in downhole operations after December 19, 1989, shall be certified by the manufacturer or other testing organization acceptable to the Department as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N542, *Sealed Radioactive Sources, Classification.*

(d) Certification documents shall be maintained for a period of 5 years after source disposal or until the Department authorizes their disposal. If the source is abandoned downhole, the certification documents shall be maintained until the Department authorizes their disposition.]

§ 226.19. Inspection and maintenance.

(a) A licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers**, uranium sinker bars** and injection tools to assure **[proper labeling and physical condition] that the required labeling is legible and that no physical damage is visible**. Records of inspection and maintenance shall be maintained for **[a period of 5] 3** years or until the Department authorizes their disposal.

(b) If any inspection conducted under subsection (a) reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made. **A record shall be made, listing the following information:**

(1) The date of the check.

(2) The name of the inspector.

(3) The equipment involved.

(4) Defects found.

(5) Repairs made.

* * * * *

(d) Records required under subsection (b) shall be maintained for 3 years after the defect is found.

(e) Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed under § 226.22 (relating to operating and emergency procedures) has been approved by the Department, the NRC or an agreement state or a licensing state.

(f) If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting or chiseling, on the source

holder unless the licensee is specifically approved by the Department, the NRC or an agreement state to perform the actions.

§ 226.20. Radioactive markers and uranium sinker bars.

(a) The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed radioactive material not exceeding those quantities specified in Chapter 217 Appendix B (relating to exempt quantities). The use of markers is subject only to the requirements of § 226.15 (relating to physical inventories).

(b) The licensee may use a uranium sinker bar in well logging only if it is legibly impressed with the words, "Caution—Radioactive—Depleted Uranium" and "Notify Civil Authorities (or name of company) if Found."

REQUIREMENTS FOR PERSONNEL SAFETY

§ 226.21. Training requirements.

(a) **[No] A** licensee or registrant may **not** permit an individual to act as a logging supervisor as defined in § 226.2 (relating to definitions) until the individual has:

* * * * *

(b) The demonstrated competence required under subsection (a)(1) and (2) shall be determined by the individual's successful completion of a written test. The demonstrated competence required under subsection(a)(3) shall be determined by the successful competion of a field evaluation of the individual.

[(b) No] (c) A licensee or registrant may **not** permit an individual to assist in the handling of radiation sources until the individual has:

(1) Read or received instruction in the licensee's or registrant's operating and emergency procedures**, this chapter and applicable sections of Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers)** and demonstrated an understanding thereof.

* * * * *

(3) The demonstrated understanding required under paragraph (1) shall be determined by the individual's successful completion of a written or oral test. The demonstrated competence required under paragraph (2) shall be determined by the individual's successful demonstration by a field evaluation.

[(c)] (d) The licensee or registrant shall maintain employe training records for **[5] 3** years following termination of employment or until the Department authorizes their disposal.

(e) The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

§ 226.22. Operating and emergency procedures.

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(1) Handling and use of radiation sources to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Chapter 219 (relating to standards for protection against radiation) **including handling and use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate.**

(2) **[Radiation surveying] Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required under § 226.41 (relating to radiation surveys and contamination control).**

* * * * *

(5) Transportation of radiation sources **to field stations or temporary jobsites, packaging of radiation sources for transport in vehicles, placarding of vehicles when needed and physically securing radiation sources in transport vehicles during transportation to prevent accidental loss, tampering or unauthorized removal.**

* * * * *

(8) Maintaining records**, including those generated by logging personnel at temporary jobsites**.

(9) Inspecting and maintaining **sealed sources,** source holders, logging tools, source handling tools, storage containers, transport containers**, [and]** injection tools **and uranium sinker bars, as required under § 226.19 (relating to inspection and maintenance)**.

* * * * *

(11) Procedures to be used for picking up, receiving and opening packages containing radioactive material**, under § 219.162 (relating to procedures for receiving and opening packages)**.

(12) Use of remote handling tools for handling sealed sources and radioactive tracers (except low activity calibration sources).

(13) Minimizing personnel exposure, including exposures from inhalation or ingestion of licensed tracer materials.

(14) Decontamination of the environment, equipment and personnel when using tracers.

(15) Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required by § 216.13 (relating to radiation survey instruments).

(16) Identifying and reporting to the Department defects and noncompliance as required by this article.

§ 226.23. Personnel monitoring.

(a) **[No] A** licensee or registrant may **not** permit an individual to act as a logging supervisor or to assist in the handling of radiation sources unless the individual wears either a film badge or a thermoluminescent dosimeter (TLD). The film badge or TLD shall be assigned to and worn by only one individual. **A film badge shall be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD shall be promptly processed.**

* * * * *

PRECAUTIONARY PROCEDURES IN **WELL** LOGGING **[AND SUBSURFACE TRACER]** OPERATIONS

§ 226.31. Security.

(a) During a **well** logging **[or tracer application] operation**, the logging supervisor or other designated employe shall maintain direct surveillance of the operation to protect against unauthorized and unnecessary entry into a restricted area.

(b) A logging supervisor shall be physically present at a temporary jobsite whenever radiation sources are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite to obtain assistance, such as if a source becomes lodged in a well or if a medical emergency arises.

§ 226.33. Subsurface tracer studies **and use of sealed sources in wells without surface casings.**

(a) Protective gloves and other appropriate protective clothing and equipment shall be used by personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion, inhalation or contamination **[of] by** radioactive material **of personnel, field stations and temporary jobsites**.

(b) **[No] A** licensee may **not** inject radioactive material into **[potable] fresh water** aquifers without prior written authorization from the Department and other responsible State or Federal **[agency] agencies.**

(c) The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure shall be approved by the Department under the conditions of the license or by the NRC or an agreement state.

§ 226.34. Particle accelerators.

(a) [No] 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 **§ 219.51 (relating to dose limits for individual members of the public) [§§ 219.11 and 219.21 (relating to radiation dose to individuals and maximum permissible levels of radiation from external sources) protection programs; as applicable,]** 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).

RADIATION SURVEYS AND RECORDS

§ 226.41. Radiation surveys **and contamination control.**

(a) Radiation surveys shall be made and recorded for an area where radioactive materials are **used and** stored.

* * * * *

(e) **[Records required under subsections (a)—(d) shall include the dates, the identification of individuals making the survey, the survey instrumentation used and an exact description of the location of the survey. Records of these surveys shall be maintained for 5 years after completion of the survey or until the Department authorizes their disposal] If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.**

(f) If the licensee detects evidence that a sealed source has ruptured or that radioactive materials have caused contamination, the licensee shall immediately initiate the emergency procedures required under § 226.22 (relating to operating and emergency procedures).

(g) If contamination results from the use of radioactive material in well logging operations, the licensee shall decontaminate all work areas, equipment and unrestricted areas. At a minimum, the decontamination efforts shall achieve the requirements of § 219.51 (relating to dose limits for individual members of the public).

(h) During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

(i) Records required under subsections (a)—(g) shall include the dates, the identification of individuals making the survey, the survey instrumentation used and an exact description of the location of the survey. Records of these surveys shall be maintained for 3 years after completion of the survey or until the Department authorizes their disposal.

§ 226.42. Documents and records required at field stations.

A licensee or registrant shall maintain, for inspection by the Department, the following documents and records for the specific devices and sources used at the field station:

* * * * *

(6) **[Quarterly] Physical** inventories required under § 226.15 (relating to **[quarterly] physical** inventory).

* * * * *

(10) Training records required under § 226.21 (relating to training requirements).

§ 226.43. Documents and records required at temporary jobsites.

A licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the Department:

(1) Operating and emergency procedures **required under § 226.22 (relating to operating and emergency procedures)**.

(2) Survey records required under § 226.41 (relating to radiation surveys **and contamination control**) for the period of operation at the site.

* * * * *

(5) The shipping papers for the transportation of radioactive materials required under Chapter 230 (relating to packaging and transportation of radioactive material).

NOTIFICATION

§ 226.51. Notification of incidents, abandonment and lost sources.

* * * * *

(b) The licensee shall immediately notify the Department by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground **[potable] fresh** water source. The notice shall designate the well location and shall describe the **[magniture] magnitude** and extent of loss of radioactive material, **[access] assess** the consequences of the loss and explain efforts planned or being taken to mitigate these consequences.

(c) If a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations**, as required under § 226.41 (relating to radiation surveys and contamination control)**.

(2) Notify the Department immediately by telephone if radioactive contamination is detected at the surface or if the source appears to be damaged**, as required under § 226.41**.

* * * * *

(e) If a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque **[—an example of a suggested plaque is shown in Appendix B—]** for posting the well or well-bore. The plaque shall:

* * * * *

(2) Contain the following information engraved on its face:

* * * * *

(viii) An appropriate warning, depending on the specific circumstances of the abandonment. Appropriate warnings may include:

* * * * *

(C) "Do not re-enter the hole," followed by the words "before contacting the Pennsylvania Department of Environmental **[Resources] Protection**."

(3) Be at least 7 inches (17cm) square and 1/8-inch (3mm) thick.

[APPENDIX B] (Reserved)

(*Editor's Note*: As part of this proposal, the Board is proposing to delete Appendix B (relating to example of plaque for identifying wells containing radioactive material abandoned downhole) which appears at 25 Pa. Code page 226-15, serial page (203991).)

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE AND DEFINITIONS

§ 230.2. Definitions.

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

* * * * *

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

* * * * *

[*Closed transport vehicle*—A transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be temporary or permanent, but shall limit access from the top, sides and ends. In the case of packaged materials, the enclosure may be of the see-through type.]

***Containment system*—The assembly of components of the packaging intended to retain the radioactive material during transport.**

***Conveyance*—Any of the following:**

(i) For transport by public highway or rail, transport vehicle or large freight container.

(ii) For transport by water, vessel or hold, compartment or defined deck area of a vessel including transport vehicle on board the vessel.

(iii) For transport by air, any aircraft.

Exclusive use—The sole use of a conveyance by a single consignor and for which initial, intermediate and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. **[The term is used interchangeably with the terms "sole use" or "full load" in other regulations, such as 49 CFR (relating to transportation).] The consignor and the carrier shall ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor shall issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.**

Fissile material—**[Special nuclear material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium] Plutonium**-238, plutonium-239, plutonium-241, uranium-233**, [and]** uranium-235 **or a combination of these radionuclides.** The term does not include **unirradiated** natural **uranium [or] and** depleted uranium**, and natural uranium or depleted uranium that has been irradiated in thermal reactors only.** Department jurisdiction extends only to special nuclear material in quantities not sufficient to form a critical mass as defined in Chapter 215 (relating to general provisions).

[(i) *Fissile Class I*—A package which may be transported in unlimited numbers and in any arrangement, and which requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

(ii) *Fissile Class II*—A package which may be transported together with other packages in any

arrangement but, for criticality control, in numbers which do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

Fissile material package—A fissile material packaging together with its fissile contents as presented for transport.]

* * * * *

Low specific activity material—[Includes one or more of the following:

(i) Uranium or thorium ores and physical or chemical concentrates of those ores.

(ii) Unirradiated natural or depleted uranium or unirradiated natural thorium.

(iii) Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries (185 MBq) per milliliter.

(iv) Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration per gram of contents does not exceed one of the following:

(A) 0.0001 millicurie (3.7 kBq) of radionuclides for which the A_2 quantity in Appendix A of this part is not more than 0.05 curie (1.85 GBq).

(B) 0.005 millicurie (185 kBq) of radionuclides for which the A_2 quantity in Appendix A of this part is more than 0.05 curie (1.85 GBq) but not more than 1 curie (37 GBq).

(C) 0.3 millicurie (11.1 MBq) of radionuclides for which the A_2 quantity in Appendix A of this part is more than 1 curie (37 GBq).

(v) Objects of nonradioactive material externally contaminated with radioactive material, if the radioactive material is not readily dispersible, and the surface contamination, when averaged over an area of 1 square meter, does not exceed 0.0001 millicurie per square centimeter (3.7 kBq/cm^2) of radionuclides for which the A_2 quantity in Appendix A is not more than 0.05 curie (1.85 GBq) or 0.001 millicurie per square centimeter (37 kBq/cm^2) for other radionuclides.] Radioactive material with limited specific activity that satisfies the descriptions and limits as follows. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. LSA material shall be in one of three groups:

(i) LSA-I is any of the following:

(A) Ores containing only naturally occurring radionuclides, (for example, uranium, thorium) and uranium or thorium concentrates of these ores.

(B) Solid unirradiated natural uranium or depleted uranium or natural thorium or their solid or liquid compounds or mixtures.

(C) Radioactive material, other than fissile material, for which the A_2 value is unlimited.

(D) Mill tailings, contaminated earth, concrete, rubble, other debris and activated material in which the radioactive material is essentially uniformly distributed, and the average specific activity does not exceed 10^{-6} A_2/g.

(ii) LSA-II is any of the following:

(A) Water with tritium concentration up to 0.8 TBq/liter (20.0 ci/liter).

(B) Material in which the radioactive material is distributed throughout, and the average specific activity does not exceed 10^{-4} A^2/g for solids and gases, and 10^{-5} A_2/g for liquids.

(iii) LSA-III solids (for example, consolidated wastes, activated materials) in which all of the following are met:

(A) The radioactive material is distributed throughout a solid or a collection of solid objects or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, and so forth).

(B) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatvely insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days, would not exceed 0.1 A_2.

(C) The average specific activity of the solid does not exceed 2,000 A_2/g.

Low toxicity alpha emitters—Natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical contrates or tailings; or alpha emitters with a half-life of less than 10 days.

Maximum normal operating pressure—The maximum gauge pressure that would develop in the containment system in 1 year under the heat condition specified in 10 CFR 71.71(c)(1) (relating to normal conditions of transport) in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

Natural thorium—Thorium with the naturally occurring distribution of thorium isotopes—essentially 100 weight percent thorium-232.

* * * * *

Surface contaminated object—A solid object that itself is not classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO shall be in one of two groups with surface activity not exceding the following limits:

(i) SCO-1—A solid object to which all of the following conditions apply:

(a) The nonfixed contamination on the accessible surface averaged over 300 cm^2—or the area of the surface if less than 300 cm^2—does not exceed 4 Bq/cm^2 (10^{-4} µC/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} µCi/cm^2) for all other alpha emitters.

(B) The fixed contamination on the accessible surface averaged over 300 cm^2—or the area of the surface if less than 300 cm^2—does not exceed 4 x 10^4 Bq/cm^2 (1µCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 4 x $10^3$3 Bq/cm^2 (0.1 µCi/cm^2) for all other alpha emitters.

(c) The nonfixed contamination plus the fixed contamination on the accessible surface averaged over 300 cm^2—or the area of the surface if less than 300 cm^2—does not exceed does not exceed 4 x 10^4

Bq/cm^2 (1 µCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 4 x 10^3 Bq/cm^2 (0.1 µCi/cm^2) for all other alpha emitters.

(ii) SCO-2—A solid object on which the limits FRO SCO-1 are exceeded and on which:

(a) The nonfixed contamination on the accessible surface averaged over 300 cm^2—or the area of the surface if less than 300 cm^2—does not exceed 400 Bq/cm^2 (10^{-2} µCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 40 Bq/cm^2 (10^{-3} µCi/cm^2) for all other alpha emitters.

(B) The fixed contamination on the accessible surface averaged over 300 cm^2—or the area of the surface if less than 300 cm^2—does not exceed 8 x 10^5 Bq/cm^2 (20 µCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 µCi/cm^2) for all other alpha emitters.

(c) The nonfixed contamination plus the fixed contamination on the accessible surface averaged over 300 cm^2—or the area of the surface if less than 300 cm^2—does not exceed 8 x 10^5 Bq/cm^2 (20 µCi/cm^2) for beta and gamma and low toxicity alpha emitters, or 8 x 10^4 Bq/cm^2 (2 µCi/cm^2) for all other alpha emitters.

* * * * *

Transport index—The dimensionless number, rounded up to the **[first decimal place] next tenth**, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. **For nonfissile material packages, the transport index is the number expressing the maximum radiation level in mrem per hour at 1 meter from the external surface of the package or the maximum radiation level in millisievert per hour at 1 meter from the external surface of the package multiplied by 100.**

* * * * *

***Uranium (natural, depleted, enriched)*—One of the following:**

(i) *Natural uranium*—Uranium with the naturally occurring distribution of uranium isotopes—approximately 0.711 weight percent uranium-235, and the remainder by weight essentially.

(ii) *Depleted uranium*—Urainium containing less uranium-235 than the naturally occurring distribution of isotopes.

(iii) *Enriched uranium*—Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

Subchapter B. GENERAL

§ 230.12. Exemptions.

* * * * *

(c) With the exception of §§ 230.13 and 230.42 (relating to transportation of licensed material; and preliminary determinations), a licensee is exempt from this chapter, with respect to shipment or carriage of one or more of the following:

* * * * *

(3) A package in which only the radioactive material is LSA material or SCO, if the external level at 3 meters from the unshielded material or objects does not exceed 10 mSv/hr (1 rem/hr).

(d) A licensee is exempt from the requirements of this chapter, other than §§ 230.13 and 230.44 (relating to transportation of licensed material; and air transport of plutonium), with respect to shipment or carriage of LSA material in group LSA-1, or SCO in group SCO-1.

Subchapter C. USE OF APPROVED PACKAGES

(*Editor's Note*: The Department is proposing to delete §§ 230.25 and 230.26 (relating to Type A Fissile Class II package; and restricted, Fissile Class II package) as they currently appear in the *Pennsylvania Code* at pages 230-9—230-11 (serial pages (204181)—(204183).

§ 230.25. (Reserved).

§ 230.26. (Reserved).

Subchapter D. OPERATING CONTROLS AND PROCEDURES

§ 230.41. **[Fissile material: assumptions as to unknown properties] Applicability of operating controls and procedures.**

[When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation or other pertinent property of fissile material in a package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that would cause the maximum nuclear reactivity.] A licensee subject to this chapter, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with this subchapter, Subchapter B and Subchapter E (relating to general; and quality assurances).

§ 230.42. Preliminary determinations.

Prior to the first use of packaging for the shipment of radioactive material the licensee shall do the following:

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(2) Test the containment system at an internal pressure at least 50% higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure, **[where] if** the maximum normal operating pressure will exceed **[34.3] 35** kilopascal (5 psi) gauge.

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§ 230.48. Opening instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use under § 219.162(e) (relating to procedures for receiving and opening packages).

APPENDIX A

DETERMINATION OF A_1 AND A_2

[I. Single Radionuclides.

1. For a single radionuclide of known identity, the values of A_1 and A_2 are taken from Table I if listed there. The values A_1 and A_2 in Table I are also applicable for the radionuclide contained in (alpha,n) or (gamma,n) neutron sources.

2. For any single radionuclide whose identity is known but which is not listed in Table I, the value of A_1 and A_2 are determined according to the following procedure:

(a) If the radionuclide emits only one type of radiation A_1 is determined according to the appropriate formula in paragraphs (1) through (4). For radionuclides emitting different kinds of radiation, A_1 is the most restrictive value of those determined for each kind of radiation. However, in either case, A_1 is restricted to a maximum of 1,000 curies (37 TBq). If a parent nuclide decays into a shorter lived daughter with a half-life not greater than 10 days, A_1 is calculated for both the parent and the daughter, and the more limiting of the two values is assigned to the parent nuclide.

(1) For gamma emitters, A_1 is determined by the expression:

$$A_1 = 9 \text{ curies}/\gamma$$

where γ is the gamma-ray constant, corresponding to the dose in roentgens per curie-hour at 1 meter, and the number 9 results from the choice of 1 rem per hour at a distance of 3 meters as the reference dose-equivalent rate.

(2) For x-ray emitters, A_1 is determined by the atomic number of the nuclide:

$$\text{for } Z \leq 55, A_1 = 1{,}000 \text{ Ci (37 TBq); and}$$

$$\text{for } Z > 55, A_1 = 200 \text{ Ci (7.4 TBq)}$$

where Z is the atomic number of the nuclide.

(3) For beta emitters, A_1 is determined by the maximum beta energy (E_{max}) according to Table II; and

(4) For alpha emitters, A_1 is determined by the expression:

$$A_1 = 1{,}000\ A_3$$

where A_3 is the value listed in Table III;

(b) A_2 is the more restrictive of the following two values:

(1) The corresponding A_1; and

(2) The value A_3 obtained from Table III.

3. For any single radionuclide whose identity is unknown, the value of A_1 is taken to be 2 Ci (74 GBq) and the value of A_2 is taken to be 0.002 Ci (74 MBq). However, if the atomic number of the radionuclide is known to be less than 82, the value of A_1 is taken to be 10 Ci (370 GBq) and the value of A_2 is taken to be 0.4 Ci (14.8 GBq).] Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these regulations are given in Table A-1. The curie (Ci) values specified are obtained by converting from the terabecquerel (TBq) figure. The curie values are expressed to three significant figures to assure that the difference in the TBq and Ci quantities is 1/10 of 1% or less. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. [Mixtures of Radionuclides, Including Radioactive Decay Chains.

1. For mixed fission products, the activity limit may be assumed if a detailed analysis of the mixture is not carried out,

A_1 = 10 Ci (370 GBq)

A_2 = 0.4 Ci (14.8 GBq)

2. A single radioactive decay chain is considered to be a single radionuclide when the radionuclides are present in their naturally occurring proportions and no daughter nuclide has a half-life either longer than 10 days or longer than that of the parent nuclide. The activity to be taken into account and the A_1 or A_2 value from Table I to be applied are those corresponding to the parent nuclide of that chain. When calculating A_1 or A_2 values, radiation emitted by daughters must be considered. However, in the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days or greater than that of the parent nuclide, the parent and daughter nuclides are considered to be mixtures of different nuclides.

3. In the case of a mixture of different radionuclides, where the identity and activity of each radionuclide are known, the permissible activity of each radionuclide R_1, R_2 . . . R_n is such that $F_1 + F_2 + \ldots F_n$ is not greater than unity, where:

F_1 = Total activity of $R_1/A_i(R_1)$

F_2 = Total activity of $R_2/A_i(R_2)$

F_n = Total activity of $R_n/A_i(R_n)$ and

A_i (R_1, R_2 . . . R_n) is the value of A_1 or A_2 as appropriate for the nuclide R_1, R_2 . . . R_n.

4. When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the formula given in paragraph 3. is applied to establish the values of A_1 or A_2 as appropriate. All the radionuclides whose individual activities are not known (their total activity will, however, be known) are classed in a single group and the most restrictive value of A_1 and A_2 applicable to any one of them is used as the value of A_1 or A_2 in the denominator of the fraction.

5. Where the identity of each radionuclide is known but the individual activity of none of the radionuclides is known, the most restrictive value of A_1 or A_2 applicable to any one of the radionuclides present is adopted as the applicable value.

6. When the identity of none of the nuclides is known, the value of A_1 is taken to be 2 Ci (74 GBq) and the value of A_2 is taken to be 0.002 Ci (74 MBq). However, if alpha emitters are known to be absent, the value of A_2 is taken to be 0.4 Ci (14.8 GBq).] For individual radionuclides whose identities are known, but which are not listed in Table A-1, the determination of the values of A_1 and A_2 requires Department approval, except that the values of A_1 and A_2 in Table A-2 may be used without Department approval.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which no daughter nuclides a half-life either longer than 10 days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied

shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than 10 days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package:

$$\Sigma_I \, B(i)/A_1(i) \text{ less than or equal to } 1$$

(b) For normal form radioactive material, the maximum quantity transported in a Type A package:

$$\Sigma_I \, B(i)/A_2(i) \text{ less than or equal to } 1$$

where B(i) is the activity of radionuclide I and $A_1(i)$ and $A_2(i)$ are the A_1 and A_2 values for radionuclide I, respectively.

Alternatively, an A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = 1/(\Sigma_I \, F(i)/A_1(i))$$

where F(i) is the fraction of activity of nuclide I in the mixture and $A_1(i)$ is the appropriate A_1 value for nuclide I.

An A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = 1/(\Sigma_I \, F(i)/A_2(i)$$

where F(i) is the fraction of activity of nuclide I in the mixture and $A_2(i)$ is the appropriate A_2 value for nuclide I.

V. When the identity of each radionuclide is known, but the individual activities of some radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

(*Editor's Note*: The Department is proposing to delete Tables I—IV as they currently appear in the *Pennsylvania Code* pages 230-21—230-30 (serial pages (204193)—(204202)) and replace them with new Tables A-1 and A-2).

TABLE A-1

A_1 and A_2 Values for Radionuclides

(See Footnotes at End of Table)

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 X 10^{-2} or 0.06, 6E+2 represents 6 X 10^{2} or 600, and 6E+0 represents 6 X 10^{0} or 6.

Symbol of radionuclide	*Element and atomic number*	*A_1 (TBq)*	*A_1 (Ci)*	*A_2 (TBq)*	*A_2 (Ci)*	*Specific activity (TBq/g)*	*Specific activity (Ci/g)*
Ac-225	Actinium (89)	0.6	16.2	1E-2	0.270	2.1E+3	5.8E+4
Ac-227		40	1080	2E-5	5.41E-4	2.7	7.2E+1
Ac-228		0.6	16.2	0.4	10.8	8.4E+4	2.2E+6
Ag-105	Silver (47)	2	54.1	2	54.1	1.1E+3	3.0E+4
Ag-108m		0.6	16.2	0.6	16.2	9.7E-1	2.6E1
Ag-110m		0.4	10.8	0.4	10.8	1.8E+2	4.7E+3
Ag-111		0.6	16.2	0.5	13.5	5.8E+3	1.9E+5
Al-26	Aluminum (13)	0.4	10.8	0.4	10.8	7.0E-4	1.9E-2
Am-241	Americium (95)	2	54.1	2E-4	5.41E-3	1.3E-1	3.4
Am-242m		2	54.1	2E-4	5.41E-3	3.6E-1	1.0E+1
Am-243		2	54.1	2E-4	5.41E-3	7.4E-3	2.0E-1
Ar-37	Argon (18)	40	1080	40	1080	3.7E+3	9.9e+4
Ar-39		20	541	20	541	1.3	3.4E+1
Ar-41		0.6	16.2	0.6	16.2	1.5E+6	4.2E+7
Ar-42		0.2	5.41	0.2	5.41	9.6	2.6E+2
As-72	Arsenic (33)	0.2	5.41	0.2	5.41	6.2E+4	1.7E+6
As-73		40	1080	40	1080	8.2E+2	2.2E+4
As-74		1	27.0	0.5	13.5	3.7E+3	9.9E+4
As-76		0.2	5.41	0.2	5.41	5.8E+4	1.6E+6
As-77		20	541	0.5	13.5	3.9E+4	1.0E+6
At-211	Astatine (85)	30	811	2	54.1	7.6E+4	2.1E+6
Au-193	Gold (79)	6	162	6	162	3.4E+4	9.2E+5
Au-194		1	27.0	1	27.0	1.5E+4	4.1E+5
Au-195		10	270	10	270	1.4E+2	3.7E+3
Au-196		2	54.1	2	54.1	4.0E+3	1.1E+5
Au-198		3	81.1	0.5	13.5	9.0E+3	2.4E+5
Au-199		10	270	0.9	24.3	7.7E+3	2.1E+5
Ba-131	Barium (56)	2	54.1	2	54.1	3.1E+3	8.4E+4
Ba-133m		10	270	0.9	24.3	2.2E+4	6.1E+5
Ba-140		0.4	10.8	0.4	10.8	2.7E+3	7.3E+4
Be-7	Beryllium (4)	20	541	20	541	1.3E+4	3.5E+5

Symbol of radionuclide	*Element and atomic number*	A_1 *(TBq)*	A_1 *(Ci)*	A_2 *(TBq)*	A_2 *(Ci)*	*Specific activity (TBq/g)*	*(Ci/g)*
Be-10		20	541	0.5	13.5	8.3E-4	2.2E-2
Bi-205	Bismuth (83)	0.6	16.2	0.6	16.2	1.5E-3	4.2E+4
Bi-206		0.3	8.11	0.3	8.11	3.8E+3	1.0E+5
Bi-207		0.7	18.9	0.7	18.9	1.9	5.2E+1
Bi-210m		0.3	8.11	3E-2	0.811	2.1E-5	5.7e-4
Bi-212		0.3	8.11	0.3	8.11	5.4E+5	1.5E+7
Bk-247	Berkelium (97)	2	54.1	2E-4	5.41E-3	3.8E-2	1.0
Bk-249		40	1080	8E-2	2.16	6.1E+1	1.6E+3
Br-76	Bromine (76)	0.3	8.11	0.3	8.11	9.4E++4	2.5E+6
Br-77		3	81.1	3	81.1	2.4E+4	7.1E+5
Br-82		0.4	10.8	0.4	10.8	4.0E+4	1.1E+6
C-11	Carbon (6)	1	27	0.5	13.5	3.1E+7	8.4E+8
C-14		40	1080	2	54.1	1.6E-1	4.5
Ca-41	Calcium (20)	40	1080	40	1080	3.1E-3	8.5E-2
Ca-45		40	1080	0.9	24.3	6.6E+2	1.8E+4
Ca-47		0.9	24.3	0.5	13.5	2.3E+4	6.1E+5
Cd-109	Cadmium (48)	40	1080	1	27	9.6E+1	2.6E+3
Cd-113m		20	541	9E-2	2.43	8.3	2.2E+2
Cd-115m		0.3	8.11	0.3	8.11	9.4E+2	2.5E+4
Cd-115		4	108	0.5	13.5	1.9E+4	5.1E+5
Ce-139	Cerium (58)	6	162	6	162	2.5E+2	6.8E+3
Ce-141		10	270	0.5	13.5	1.1E+3	2.8E+4
Ce-143		0.6	16.2	0.5	13.5	2.5E+4	6.6E+5
Ce-144		0.2	5.41	0.2	5.41	1.2E+2	3.3E+3
Cf-248	Californium (98)	30	811	3E-3	8.11E-2	5.8E+1	1.6E+3
Cf-249		2	54.1	2E-4	5.41E-3	1.5E-1	4.1
Cf-250		5	135	5E-4	1.35E-2	4.0	1.1E+2
Cf-251		2	54.1	2E-4	5.41E-3	5.9E-2	1.6
Cf-252		0.1	2.70	1E-3	2.70E-2	2.0E+1	5.4E+2
Cf-253		40	1080	6E-2	1.62	1.1E+3	2.9E+4
Cf-254		3E-1	8.11E-2	6E-4	1.62E-2	3.1E+2	8.5E+3
Cl-36	Chlorine (36)	20	541	0.5	13.5	1.2E-3	3.3E-2
Cl-38		0.2	5.41	0.2	5.41	4.9E+6	1.3E+8
Cm-240	Curium (96)	40	1080	2E-2	0.541	7.5E+2	2.0E+4
Cm-241		2	54.1	0.9	24.3	6.1E+2	1.7E+4
Cm-242		40	1080	1E-2	0.270	1.2E+2	3.3E+3
Cm-243		3	81.1	3E-4	8.11E-3	1.9	5.2E+1
Cm-244		4	108	4E-4	1.08E-2	3.0	8.1E+1
Cm-245		2	54.1	2E-4	5.41E-3	6.4E-3	1.7E-1
Cm-246		2	54.1	2E-4	5.41E-3	1.1E-2	3.1E-1
Cm-247		2	54.1	2E-4	5.41E-3	3.4E-6	9.3E-5
Cm-248		4E-2	1.08	5E-3	1.35E-3	1.6E-4	4.2E-3
Co-55	Cobalt (27)	0.5	13.5	0.5	13.5	1.1E+5	3.1E+6
Co-56		0.3	8.11	0.3	8.11	1.1E+3	3.0E+4
Co-57		8	216	8	216	3.1E+2	8.4E+3
Co-58m		40	1080	40	1080	2.2E+5	5.9E+6
Co-58		1	27.0	1	27.0	1.2E+3	3.2E+4
Co-60		0.4	10.8	0.4	10.8	4.2E+1	1.1E+3
Cr-51	Chromium (24)	30	811	30	811	3.4E+3	9.2E+4
Cs-129	Cesium (55)	4	108	4	108	2.8E+4	7.6E+5
Cs-131		40	1080	40	1080	3.8E+3	1.0E+5
Cs-132		1	27.0	1	27.0	5.7E+3	1.5E+5
Cs-134m		40	1080	9	243	3.0E+5	8.0E+6
Cs-134		0.6	16.2	0.5	13.5	4.8E+1	1.3E+3
Cs-135		40	1080	0.9	24.3	4.3E-5	1.2E-2
Cs-136		0.5	13.5	0.5	13.5	2.7E+3	7.3E+4
Cs-137		2	54.1	0.5	13.5	3.2	8.7E+1
Cu-64	Copper (29)	5	135	0.9	24.3	1.4E+5	3.9E+6
Cu-67		9	243	0.9	24.3	2.8E+4	7.6E+5
Dy-159	Dysprosium (66)	20	541	20	541	2.1E+2	5.7E+3
Dy-165		0.6	16.2	0.5	13.5	3.0E+5	8.2E+6
Dy-166		0.3	8.11	0.3	8.11	8.6E+3	2.3E+5
Er-169	Erbium (68)	40	1080	0.9	24.3	3.1E+3	8.3E+4
Er-171		0.6	16.2	0.5	13.5	9.0E+4	2.4E+6
Es-253	Einsteinium (99)(a)	200	5400	2E-2	5.41E-1		
Es-254		30	811	3E-3	8.11E-2		
Es-254m		0.6	16.2	0.4	10.8		

Symbol of radionuclide	*Element and atomic number*	A_1 *(TBq)*	A_1 *(Ci)*	A_2 *(TBq)*	A_2 *(Ci)*	*Specific activity (TBq/g)*	*Specific activity (Ci/g)*
Es-255							
Eu-147	Europium (63)	2	54.1	2	54.1	1.4E+3	3.7E+4
Eu-148		0.5	13.5	0.5	13.5	6.0E+2	1.6E+4
Eu-149		20	541	20	541	3.5E+2	9.4E+3
Eu-150		0.7	18.9	0.7	18.9	6.1E+4	1.6E+6
Eu-152m		0.6	16.2	0.5	13.5	8.2E+4	2.2E+6
Eu-152		0.9	24.3	0.9	24.3	6.5	1.8E+2
Eu-154		0.8	21.6	0.5	13.5	9.8	2.6E+2
Eu-155		20	541	2	54.1	1.8E+1	4.9E+2
Eu-156		0.6	16.2	0.5	13.5	2.0E+3	5.5E+4
F-18	Fluorine (9)	1	27.0	0.5	13.5	3.5E+6	9.5E+7
Fe-52	Iron (26)	0.2	5.41	0.2	5.41	2.7E+5	7.3E+6
Fe-55		40	1080	40	1080	8.8E+1	2.4E+3
Fe-59		0.8	21.6	0.8	21.6	1.8E+3	5.0E+4
Fe-60		40	1080	0.2	5.41	7.4E-4	2.0E-2
Fm-255	Fermium (100)(b)	40	1080	0.8	21.6		
Fm-257		10	270	8E-3	21.6E-1		
Ga-67	Gallium(31)	6	162	6	162	2.2E+4	6.0E+5
Ga-68		0.3	8.11	0.3	8.11	1.5E+6	4.1E+7
Ga-72		0.4	10.8	0.4	10.8	1.1E+5	3.1E+6
Gd-146	Gadolinium (64)	0.4	10.8	0.4	10.8	6.9E+2	1.9E+4
Gd-148		3	81.1	3E-4	8.11E-3	1.2	3.2E+1
Gd-153		10	270	5	135	1.3E+2	3.5E+3
Gd-159		4	108	0.5	13.5	3.9E+4	1.1E+6
Ge-68	Germanium (32)	0.3	8.11	0.3	8.11	2.6E+2	7.1E+3
Ge-71		40	1080	40	1080	5.8E+3	1.6E+5
Ge-77		0.3	8.11	0.3	8.11	1.3E+5	3.6E+6
H-3	Hydrogen (1)	See T-Tritium					
Hf-172	Hafnium (72)	0.5	13.5	0.3	8.11	4.1E+1	1.1E+3
Hf-175		3	81.1	3	81.1	3.9E+2	1.1E+4
Hf-181		2	54.1	0.9	24.3	6.3E+2	1.7E+4
Hf-182		4	108	3E-2	0.811	8.1E-6	2.2E-4
Hg-194	Mercury (80)	1	27.0	1	27.0	1.3E-1	3.5
Hg-195m		5	135	5	135	1.5E+4	4.0E+5
Hg-197m		10	270	0.9	24.3	2.5E+4	6.7E+5
Hg-197		10	270	10	270	9.2E+3	2.5E+5
Hg-203		4	108	0.9	24.3	5.1E+2	1.4E+4
Ho-163	Holmium (67)	40	1080	40	1080	2.7	7.6E-1
Ho-166m		0.6	16.2	0.3	8.11	6.6E-2	1.8
Ho-166		0.3	8.11	0.3	8.11	2.6E+4	7.0E+5
I-123	Iodine (53)	6	162	6	162	7.1E+4	1.9E+6
I-124		0.9	24.3	0.9	24.3	9.3E+3	2.5E+5
I-125		20	541	2	54.1	6.4E+2	1.7E+4
I-126		2	54.1	0.9	24.3	2.9E+3	8.0E+4
I-129		Unlimited		Unlimited		6.5E-6	1.8E-4
I-131		3	81.1	0.5	13.5	4.6E+3	1.2E+5
I-132		0.4	10.8	0.4	10.8	3.8E+5	1.0E+7
I-133		0.6	16.2	0.5	13.5	4.2E+4	1.1E+6
I-134		0.3	8.11	0.3	8.11	9.9E+5	2.7E+7
I-135		0.6	16.2	0.5	13.5	1.3E+5	3.5E+6
In-111	Indium (49)	2	54.1	2	54.1	1.5E+4	4.2E+5
In-113m		4	108	4	108	6.2E+5	1.7E+7
In-114m		0.3	8.11	0.3	8.11	8.6E+2	2.3E+4
In-115m		6	162	0.9	24.3	2.2E+5	6.1E+6
Ir-189	Iridium (77)	10	270	10	270	1.9E+3	5.2E+4
Ir-190		0.7	18.9	0.7	18.9	2.3E+3	6.2E+4
Ir-192		1	27.0	0.5	13.5	3.4E+2	9.2E+3
Ir-193m		10	270	10	270	2.4E+3	6.4E+4
Ir-194		0.2	5.41	0.2	5.41	3.1E+4	8.4E+5
K-40	Potassium (19)	0.6	16.2	0.6	16.2	2.4E-7	6.4E-6
K-42		0.2	5.41	0.2	5.41	2.2E+5	6.0E+6
K-43		1.0	27.0	0.5	13.5	1.2E+5	3.3E+6
Kr-81	Krypton (39)	40	1080	40	1080	7.8E-4	2.1E-2
Kr-85m		6	162	6	162	3.0E+5	8.2E+6
Kr-85		20	541	10	270	1.5E+1	3.9E+2
Kr-87		0.2	5.41	0.2	5.41	1.0E+6	2.8E+7
La-137	Lanthanum (57)	40	1080	2	54.1	1.6E-3	4.4E-2

Symbol of radionuclide	*Element and atomic number*	A_1 *(TBq)*	A_1 *(Ci)*	A_2 *(TBq)*	A_2 *(Ci)*	*Specific activity (TBq/g)*	*Specific activity (Ci/g)*
La-140		0.4	10.8	0.4	10.8	2.1E+4	5.6E+5
Lu-172	Lutetium (71)	0.5	13.5	0.5	13.5	4.2E+3	1.1E+5
Lu-173		8	216	8	216	5.6E+1	1.5E+3
Lu-174m		20	541	8	216	2.0E+2	5.3E+3
Lu-174		8	216	4	108	2.3E+1	6.2E+2
Lu-177		30	811	0.9	24.3	4.1E+3	1.1E+5
MFP		For mixed fisson products,use formulas for mixtures in Table A-2					
Mg-28	Magnesium (12)	0.2	54.1	0.2	54.1	2.0E+5	5.4E+6
Mn-52	Manganese (25)						
Mn-53		Unlimited		Unlimited		6.8E-5	1.8E-3
Mn-54		1	27.0	1	27.0	2.9E+2	7.7E+3
Mn-56		0.2	5.41	0.2	5.41	8.0E+5	2.2E+7
Mo-93	Molybdenum (42)	40	1080	7	189	4.1E-2	1.1
Mo-99		0.6	16.2	0.5	13.5(c)	1.8E+4	4.8E+5
N-13	Nitrogen (7)	0.6	16.2	0.5	13.5	5.4E+7	1.5E+9
Na-22	Sodium (22)	0.5	13.5	0.5	13.5	2.3E+2	6.3E+3
Na-24		0.2	5.41	0.2	5.41	3.2E+5	8.7E+6
Nb-92m	Niobium (41)	0.7	18.9	0.7	18.9	5.3E+3	1.4E+5
Nb-93m		40	1080	6	162	8.8	2.4E+2
Nb-94		0.6	16.2	0.6	16.2	6.9E-3	1.9E-1
Nb-95		1	27.0	1	27.0	1.5E+3	3.9E+4
Nb-97		0.6	16.2	0.5	13.5	9.9E+5	2.7E+7
Nd-147	Neodymium (60)	4	108	0.5	13.5	3.0E+3	8.1E+4
Nd-149		0.6	16.2	0.5	13.5	4.5E+5	1.2E+7
Ni-59	Nickel(28)	40	1080	40	1080	3.0E-3	8.0E-2
Ni-63		40	1080	30	811	2.1	5.7E+1
Ni-65		0.3	8.11	0.3	8.11	7.1E+5	1.9E+7
Np-235	Neptunium(93)	40	1080	40	1080	5.2E+1	1.4E+3
Np-236		7	189	1E-3	2.70E-2	4.7E-4	1.3E-2
Np-237		2	54.1	2E-4	5.41E-3	2.5E-5	7.1E-4
Np-239		6	162	0.5	13.5	8.6E+3	2.3E+5
Os-185	Osmium(76)	1	27.0	1	27.0	2.8E+2	7.5E+3
Os-191m		40	1080	40	1080	4.6E+4	1.3E+6
Os-191		10	270	0.9	24.3	1.6E+3	4.4E+4
Os-193		0.6	16.2	0.5	13.5	2.0E+4	5.3E+5
Os-194		0.2	5.41	0.2	5.41	1.1E+1	3.1E+2
P-32	Phosphorus(15)	0.3	8.11	0.3	8.11	1.1E+4	2.9E+5
P-33		40	1080	0.9	24.3	5.8E+3	1.6E+5
Pa-230	Protactinium (91)	2	54.1	0.1	2.70	1.2E+3	3.3E+4
Pa-231		0.6	16.2	6E-5	1.62E-3	1.7E-3	4.7E-2
Pa-233		5	135	0.9	24.3	7.7E+2	2.1E+4
Pb-201	Lead(82)	1	27.0	1	27.0	6.2E+4	1.7E+6
Pb-202		40	1080	2	54.1	1.4E-4	3.4E-3
Pb-203		3	81.1	3	81.1	1.1E+4	3.0E+5
Pb-205		Unlimited		Unlimited		4.5E-6	1.2E-4
Pb-210		0.6	16.2	9E-3	0.243	2.8	7.6E+1
Pb-212		0.3	8.11	0.3	8.11	5.1E+4	1.4E+6
Pd-103	Palladium(46)	40	1080	40	1080	2.8E+3	7.5E+4
Pd-107		Unlimited		Unlimited		1.9E-5	5.1E-4
Pd-109		0.6	16.2	0.5	13.5	7.9E+4	2.1E+6
Pm-143	Promethium(61)	3	81.1	3	81.1	1.3E+2	3.4E+3
Pm-144		0.6	16.2	0.6	16.2	9.2E+1	2.5E+3
Pm-145		30	811	7	189	5.2	1.4E+2
Pm-147		40	1080	0.9	24.3	3.4E+1	9.3E+2
Pm-148m		0.5	13.5	0.5	13.5	7.9E+2	2.1E+4
Pm-149		0.6	16.2	0.5	13.5	1.5E+4	4.0E+5
Pm-151		3	81.1	0.5	13.5	2.7E+4	7.3E+5
Po-208	Polonium(84)	40	1080	2E-2	0.541	2.2E+1	5.9E+2
Po-209		40	1080	2E-2	0.541	6.2E-1	1.7E+1
Po-210		40	1080	2E-2	0.541	1.7E+2	4.5E+3
Pr-142	Praseodymium(59)	0.2	5.41	0.2	5.41	4.3E+4	1.2E+6
Pr-143		4	108	0.5	13.5	2.5E+3	6.7E+4
Pt-188	Platinum(78)	0.6	16.2	0.6	16.2	2.5E+3	6.8E+4
Pt-191		3	81.1	3	81.1	8.7E+3	2.4E+5
Pt-191m		40	1080	9	243	5.8E+3	1.6E+5
Pt-193		40	1080	40	1080	1.4	3.7E+1
Pt-195m		10	270	2	54.1	6.2E+3	1.7E+5

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Pt-197m		10	270	0.9	24.3	3.7E+5	1.0E+7
Pt-197		20	541	0.5	13.5	3.2E+4	8.7E+5
Pu-236	Plutonium(94)	7	189	7E-4	1.89E-2	2.0E+1	5.3E+2
Pu-237		20	541	20	541	4.5E+2	1.2E+4
Pu-238		2	54.1	2E-4	5.41E-3	6.3E-1	1.7E+1
Pu-239		2	54.1	2E-4	5.41E-3	2.3E-3	6.2E-2
Pu-240		2	54.1	2E-4	5.41E-3	8.4E-3	2.3E-1
Pu-241		40	1080	1E-2	0.270	3.8	1.0E+2
Pu-242		2	54.1	2E-4	5.41E-3	1.5E-4	3.9E-3
Pu-244		0.3	8.11	2E-4	5.41E-3	6.7E-7	1.8E-5
Ra-223	Radium(88)	0.6	16.2	3E-2	0.811	1.9E+3	5.1E+4
Ra-224		0.3	8.11	6E-2	1.62	5.9E+3	1.6E+5
Ra-225		0.6	16.2	2E-2	0.541	1.5E+3	3.9E+4
Ra-226		0.3	8.11	2E-2	0.541	3.7E-2	1.0
Ra-228		0.6	16.2	4E-2	1.08	1.0E+1	2.7E+2
Rb-81	Rubidium(37)	2	54.1	0.9	24.3	3.1E+5	8.4E+6
Rb-83		2	54.1	2	54.1	6.8E+2	1.8E+4
Rb-84		1	27.0	0.9	24.3	1.8E+3	4.7E+4
Rb-86		0.3	8.11	0.3	8.11	3.0E+3	8.1E+4
Rb-87			Unlimited		Unimited	3.2E-9	8.6E-8
Rb(natural)			Unlimited		Unlimited	6.7E+6	1.8E+8
Re-183	Rhenium(75)	5	135	5	135	3.8E+2	1.0E+4
Re-184m		3	81.1	3	81.1	1.6E+2	4.3E+3
Re-184		1	27.0	1	27.0	6.9E+2	1.9E+4
Re-186		4	108	0.5	13.5	6.9E+3	1.9E+5
Re-187			Unlimited		Unlimited	1.4E-9	3.8E-8
Re-188		0.2	5.41	0.2	5.41	3.6E+4	9.8E+5
Re-189		4	108	0.5	13.5	2.5E+4	6.8E+5
Re(natural)			Unlimited		Unlimited		2.4E-8
Rh-99	Rhodium(45)	2	54.1	2	54.1	3.0E+3	8.2E+4
Rh-101		4	108	4	108	4.1E+1	1.1E+3
Rh-102m		2	54.1	0.9	24.3	2.3E+2	6.2E+3
Rh-102		0.5	13.5	0.5	13.5	4.5E+1	1.2E+3
Rh-103m		40	1080	40	1080	1.2E+6	3.3E+7
Rh-105		10	270	0.9	24.3	3.1E+4	8.4E+5
Rn-222	Radon(86)	0.2	5.41	4E-3	0.108	5.7E+3	1.5E+5
Ru-97	Ruthenium(44)	4	108	4	108	1.7E+4	4.6E+5
Ru-103		2	54.1	0.9	24.3	1.2E+3	3.2E+4
Ru-105		0.6	16.2	0.5	13.5	2.5E+5	6.7E+6
Ru-106		0.2	5.41	0.2	5.41	1.2E+2	3.3E+4
S-35	Sulfur(16)	40	1080	2	54.1	1.6E+3	4.3E+4
Sb-122	Antimony(51)	0.3	8.11	0.3	8.11	1.5E+4	4.0E+5
Sb-124		0.6	16.2	0.5	13.5	6.5E+2	1.7E+4
Sb-125		2	54.1	0.9	24.3	3.9E+1	1.0E+3
Sb-126		0.4	10.8	0.4	10.8	3.1E+3	8.4E+4
Sc-44	Scandium(21)	0.5	13.5	0.5	13.5	6.7E+5	1.8E+7
Sc-46		0.5	13.5	0.5	13.5	1.3E+3	3.4E+4
Sc-47		9	243	0.9	24.3	3.1E+4	8.3E+5
Sc-48		0.3	8.11	0.3	8.11	5.5E+4	1.5E+6
Se-75	Selenium(34)	3	81.1	3	81.1	5.4E+2	1.5E+4
Se-79		40	1080	2	54.1	2.6E-3	7.0E-2
Si-31	Silicon(14)	0.6	16.2	0.5	13.5	1.4E+6	3.9E+7
Si-32		40	1080	0.2	5.41	3.9	1.1E+2
Sm-145	Samarium(62)	20	541	20	541	9.8E+1	2.6E+3
Sm-147			Unlimited		Unlimited	8.5E-1	2.3E+1
Sm-151		40	1080	4	108	9.7E-1	2.6E+1
Sm-153		4	108	0.5	13.5	1.6E+4	4.4E+5
Sn-113	Tin(50)	4	108	4	108	3.7E+2	1.0E+4
Sn-117m		9	162	2	54.1	3.0E+3	8.2E+4
Sn-119m		40	1080	40	1080	1.4E+2	3.7E+3
Sn-121m		40	1080	0.9	24.3	2.0	5.4E+1
Sn-123		0.6	16.2	0.5	13.5	3.0E+2	8.2E+3
Sn-125		0.2	5.41	0.2	5.41	4.0E+3	1.1E+5
Sn-126		0.3	8.11	0.3	8.11	1.0E-3	2.8E-2
Sr-82	Strontium(38)	0.2	5.41	0.2	5.41	2.3E+3	6.2E+4
Sr-85m		5	135	5	135	1.2E+6	3.3E+7
Sr-85		2	54.1	2	54.1	8.8E+2	2.4E+4

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Sr-87m		3	81.1	3	81.	4.8E+5	1.3E+7
Sr-89		0.6	16.2	0.5	13.5	1.1E+3	2.9E+4
Sr-90		0.2	5.41	0.1	2.70	5.1	1.4E+2
Sr-91		0.3	8.11	0.3	8.11	1.3E+5	3.6E+6
Sr-92		0.8	21.6	0.5	13.5	4.7E+5	1.3E+7
T	Tritium(1)	40	1080	40	1080	3.6E+2	9.7E+3
Ta-178	Tantalum(73)	1	27.0	1	27.0	4.2E+6	1.1E+8
Ta-179		30	811	30	811	4.1E+1	1.1E+3
Ta-182		0.8	21.6	0.5	13.5	2.3E+2	6.2E+3
Tb-157	Terbium(65)	40	1080	10	270	5.6E-1	1.5E+1
Tb-158		1	27.0	0.7	18.9	5.6E-1	1.5E+1
Tb-160		0.9	24.3	0.5	13.5	4.2E+2	1.1E+4
Tc-95m	Technetium(43)	2	54.1	2	54.1	8.3E+2	2.2E+4
Tc-96m		0.4	10.8	0.4	10.8	1.4E+6	3.8E+7
Tc-96		0.4	10.8	0.4	10.8	1.2E+4	3.2E+5
Tc-97m		40	1080	40	1080	5.6E+2	1.5E+4
Tc-97			Unlimited		Unlimited	5.2E-5	1.4E-3
Tc-98		0.7	18.9	0.7	18.9	3.2E-5	8.7E-4
Tc-99m		8	216	8	216	1.9E+5	5.3E+6
Tc-99		40	1080	0.9	24.3	6.3E-4	1.7E-2
Te-118	Tellurium(52)	0.2	5.41	0.2	5.41	6.8E+3	1.8E+5
Te-121m		5	135	5	135	2.6E+2	7.0E+3
Te-121		2	54.1	2	54.1	2.4E+3	6.4E+4
Te-123m		7	189	7	189	3.3E+2	8.9E+3
Te-125m		30	811	9	243	6.7E+2	1.8E+4
Te-127m		20	541	0.5	13.5	3.5E+2	9.4E+3
Te-127		20	541	0.5	13.5	9.8E+4	2.6E+6
Te-129m		0.6	16.2	0.5	13.5	1.1E+3	3.0E+4
Te-129		0.6	16.2	0.5	13.5	7.7E+5	2.1E+7
Te-131m		0.7	18.9	0.5	13.5	3.0E+4	8.0E+5
Te-132		0.4	10.8	0.4	10.8	1.1E+4	3.0E+5
Th-227	Thorium(90)	9	243	1E-2	0.270	1.1E+3	3.1E+4
Th-228		0.3	8.11	4E-4	1.08E-2	3.0E+1	8.2E+2
Th-229		0.3	8.11	3E-5	8.11E-4	7.9E-3	2.1E-1
Th-230		2	54.1	2E-4	5.41E-3	7.6E-4	2.1E-2
Th-231		40	1080	0.9	24.3	2.0E+4	5.3E+5
Th-232			Unlimited		Unlimited	4.0E-9	1.1E-7
Th-234		0.2	5.41	0.2	5.41	8.6E+2	2.3E+4
Th(natural)			Unlimited		Unlimited	8.1E-9	2.2E-7
Ti-44	Titanium(22)	0.5	13.5	0.2	5.41	6.4	1.7E+2
Tl-200	Thallium(81)	0.8	21.6	0.8	21.6	2.2E+4	6.0E+5
Tl-201		10	270	10	270	7.9E+3	2.1E+5
Tl-202		2	54.1	2	54.1	2.0E+3	5.3E+4
Tl-204		4	108	0.5	13.5	1.7E+1	4.6E+2
Tm-167	Thulium(69)	7	189	7	189	3.1E+3	8.5E+4
Tm-168		0.8	21.6	0.8	21.6	3.1E+2	8.3E+3
Tm-170		4	108	0.5	13.5	2.2E+2	6.0E+3
Tm-171		40	1080	10	270	4.0E+1	1.1E+3
U-230	Uranium(92)	40	1080	1E-2	0.270	1.0E+3	2.7E+4
U-232		3	81.1	3E-4	8.11E-3	8.3E-1	2.2E+1
U-233		10	270	1E-3	2.70E-2	3.6E-4	9.7E-3
U-234		10	270	1E-3	2.70E-2	2.3E-4	6.2E-3
U-235			Unlimited		Unlimited	8.0E-8	2.2E-6
U-236		10	270	1E-3	2.7E-2	2.4E-6	6.5E-5
U-238			Unlimited		Unlimited	1.2E-8	3.4E-7
U(natural)			Unlimited		Unlimited	2.6E-8	7.1E-7
U(enriched 5% or less)			Unlimited		Unlimited		(See Table A-e)
U(enriched more than 5%)		10	270	1E-3	2.7E-2		(See Table A-3)
U(depleted)			Unlimited		Unlimited		(See Table A-3)
V-48	Vanadium(23)	0.3	8.11	0.3	8.11	6.3E+3	1.7E+5
V-49		40	1080	40	1080	3.0E+2	8.1E+3
W-178	Tungsten(74)	1	27.0	1	27.0	1.3E+3	3.4E+4
W-181		30	811	30	811	2.2E+2	6.0E+3

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W-185		40	1080	0.9	24.3	3.5E+2	9.4E+3
W-187		2	54.1	0.5	13.5	2.6E+4	7.0E+5
W-188		0.2	5.41	0.2	5.41	3.7E+2	1.0E+4
Xe-122	Xenon(54)	0.2	5.41	0.2	5.41	4.8E+4	1.3E+6
Xe-123		0.2	5.41	0.2	5.41	4.4E+5	1.2E+7
Xe-127		4	108	4	108	1.0E+3	2.8E+4
Xe-131m		40	1080	40	1080	3.1E+3	8.4E+4
Xe-133		20	541	20	541	6.9E+3	1.9E+5
Xe-135		4	108	4	108	9.5E+4	2.6E+6
Y-87	Yttrium(39)	2	54.1	2	54.1	1.7E+4	4.5E+5
Y-88		0.4	10.8	0.4	10.8	5.2E+2	1.4E+4
Y-90		0.2	5.41	0.2	5.41	2.0E+4	5.4E+5
Y-91m		2	54.1	2	54.1	1.5E+6	4.2E+7
Y-91		0.3	8.11	0.3	8.11	9.1E+2	2.5E+4
Y-92		0.2	5.41	0.2	5.41	3.6E+5	9.6E+6
Y-93		0.2	5.41	0.2	5.41	1.2E+5	3.3E+6
Yb-169	Ytterbium(70)	3	81.1	3	81.1	8.9E+2	2.4E+4
Yb-175		30	811	0.9	24.3	6.6E+3	1.8E+5
Zn-65	Zinc(30)	2	54.1	2	54.1	3.0E+2	8.2E+3
Zn-69m		2	54.1	0.5	13.5	1.2E+5	3.3E+6
Zn-69		4	108	0.5	13.5	1.8E+6	4.9E+7
Zr-88	Zirconium(40)	3	81.1	3	81.1	6.6E+2	1.8E+4
Zr-93		40	1080	0.2	5.41	9.3E-5	2.5E-3
Zr-95		1	27.0	0.9	24.3	7.9E+2	2.1E+4
Zr-97		0.3	8.11	0.3	8.11	7.1E+4	1.9E+6

(a) International shipments of Einsteinium require multilateral approval of A_1 and A_2 values.

(b) International shipments of Fermium require multilateral approval of A_1 and A_2 values.

(c) 20 Ci for Mo-99 for domestic use.

TABLE A-2

GENERAL VALUES FOR A_1 AND A_2

Contents	*A_1*		*A_2*	
	(TBq)	*(Ci)*	*(TBq)*	*(Ci)*
Only beta- or gamma-emitting nuclides are known to be present	0.20	5.00	0.02	0.5
Alpha-emitting nuclides are known to be present, or no relevant data are available	0.10	2.70	$2x10^{-5}$	$5.41x10^{-4}$

CHAPTER 232. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Subch.
- A. GENERAL PROVISIONS
- B. SPECIFIC LICENSING REQUIREMENTS
- C. DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS
- D. OPERATION OF IRRADIATORS
- E. RECORDS

Subchapter A. GENERAL PROVISIONS

Sec.
- 232.1 Purpose and scope.
- 232.2 Definitions.

§ 232.1. Purpose and scope.

(a) This chapter contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This chapter also contains radiation safety requirements for operating irradiators. The requirements of this chapter are in addition to other requirements of this article. Nothing in this chapter relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use and building code requirements for industrial facilities.

(b) The regulations in this chapter apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 Grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this chapter.

(c) The regulations in this chapter do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging or open-field (agricultural) irradiations.

§ 232.2. Definitions.

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

Annually—One of the following:

(i) At intervals not to exceed 1 year.

(ii) Once per year, at about the same time each year—plus or minus 1 month.

Doubly encapsulated sealed source—A sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator—A facility that uses radioactive sealed sources for the irradiation of objects or materials and in

which radiation dose rates exceeding 5 Grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator operator—An individual who has successfully completed the training and testing described in § 232.51 (relating to training) and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator—An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator—An irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator—An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator—An irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system—A system for moving the product to be irradiated to, from and within the area where irradiation takes place.

Radiation room—A shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Radiation safety officer—An individual with responsibility for the overall radiation safety program at the facility.

Sealed source—A byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Seismic area—An area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the United States Geological Survey.

Underwater irradiator—An irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

Subchapter B. SPECIFIC LICENSING REQUIREMENTS

Sec.

§ 232.11. Application for a specific license.

A person may file an application for a specific license authorizing the use of sealed sources in an irradiator as required under § 217.51 (relating to filing application for specific licenses).

§ 232.13. Specific licenses for irradiators.

The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(1) The applicant shall satisfy the general requirements specified in §§ 217.51 and 217.52 (relating to filing application for specific licenses; and general requirements for the issuance of specific licenses) and this chapter.

(2) The application shall describe the training provided to irradiator operators including:

(i) Classroom training.

(ii) On-the-job or simulator training.

(iii) Safety reviews.

(iv) The means employed by the applicant to test each operator's understanding of the Department's regulations and licensing requirements and the irradiator operating and emergency procedures.

(v) Minimum training and experience of personnel who may provide training.

(3) The application shall include an outline of the written operating and emergency procedures in § 232.53 (relating to operating and emergency procedures) that describes the radiation safety aspects of the procedures.

(4) The application shall describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and management personnel who have important radiation safety responsibilities or authorities. In particular, the application shall specify who, within the management structure, has the authority to stop unsafe operations. The application shall also describe the training and experience required for the position of radiation safety officer.

(5) The application shall include a description of the access control systems required by § 232.23 (relating to access control), the radiation monitors required by § 232.29 (relating to radiation monitors), the method of detecting leaking sources required by § 232.59 (relating to detection of leaking sources) including the sensitivity of the method and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(6) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Department. The description shall include the following:

(i) Instruments to be used.

(ii) Methods of performing the analysis.

(iii) Pertinent experience of the individual who analyzes the samples.

(7) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall be done by an organization specifically authorized by the Department, NRC or an agreement state to load or unload irradiator sources.

(8) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by § 232.61 (relating to inspection and maintenance).

§ 232.15. Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to the Department of both an application for a license for the irradiator and the fee required by Chapter 218 (relating to fees). As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of this article.

§ 232.17. Applications for exemptions.

(a) The Department may, upon application of an interested person or upon its own initiative, grant exemptions from the requirements in this chapter that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) An application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this chapter. The Department will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

§ 232.19. Request for written statements.

(a) After the filing of the original application, the Department may request further information necessary to enable the Department to determine whether the application should be granted or denied.

(b) Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Department's request, submit written statements to enable the Department to determine whether the license should be modified, suspended or revoked.

Subchapter C. DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

Sec.

§ 232.21. Performance criteria for sealed sources.

(a) *After July 1, 1993.* Sealed sources installed after July 1, 1993, shall meet the following requirements:

(1) Have a certificate of registration issued under 10 CFR 32.210 (relating to product information).

(2) Be doubly encapsulated.

(3) Use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator.

(4) Be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools.

(5) In prototype testing of the sealed source, shall have been leak tested and found leak-free after each of the tests described in subsections (b)—(g).

(b) *Temperature.* The test source shall be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(c) *Pressure.* The test source shall be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million Newtons per square meter.

(d) *Impact.* A 2-kilogram steel weight, 2.5 centimeters in diameter, shall be dropped from a height of 1 meter onto the test source.

(e) *Vibration.* The test source shall be subjected three times for 10 minutes each to vibrations sweeping from 25 hertz to 500 Hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source shall be vibrated for 30 minutes at each resonant frequency found.

(f) *Puncture.* A 50-gram weight and pin, 0.3-centimeter pin diameter, shall be dropped from a height of 1 meter onto the test source.

(g) *Bend.* If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source shall be subjected to a force of 2,000 Newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

§ 232.23. Access control.

(a) Each entrance to a radiation room at a panoramic irradiator shall have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It shall be impossible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed shall cause the sources to return promptly to their shielded position. The personnel entrance door or barrier shall have a lock that is operated by the same key used to move the sources. The doors and barriers may not prevent an individual in the radiation room from leaving.

(b) Each entrance to a radiation room at a panoramic irradiator shall have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm shall also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance promptly.

(c) A radiation monitor shall be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor shall be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures

high radiation levels, shall activate the alarm described in subsection (b). The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control shall automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms shall give individuals enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room at a panoramic irradiator shall have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(f) Each radiation room of a panoramic irradiator shall contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator shall have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators shall also have a sign stating "High radiation area," but the sign may be removed, covered or otherwise made inoperative when the sources are fully shielded.

(h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it shall be impossible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(i) Underwater irradiators shall have a personnel access barrier around the pool which shall be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There shall be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

§ 232.25. Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.00002 Sv (2 mrem) per hour at any location 30 cm or more from the wall of the room when the sources are exposed. The dose rate shall be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 0.00002 Sv (2 mrem) per hour shall be locked, roped off or posted.

(b) The radiation dose at 30 cm over the edge of the pool of a pool irradiator may not exceed 0.0002 Sv (2 mrem) per hour when the sources are in the fully shielded position.

(c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.00002 Sv (2 mrem) per hour and at 5 centimeters from the shield may not exceed 0.0002 Sv (20 mrem) per hour.

§ 232.27. Fire protection.

(a) The radiation room at a panoramic irradiator shall have heat and smoke detectors. The detectors shall activate an audible alarm. The alarm shall be capable of alerting a person who is prepared to summon assistance promptly. The sources shall automatically become fully shielded if a fire is detected.

(b) The radiation room at a panoramic irradiator shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.

§ 232.29. Radiation monitors.

(a) Irradiators with automatic product conveyor systems shall have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm shall sound and product conveyors shall stop automatically. The alarm shall be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from this paragraph.

(b) Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the pool to detect abnormal radiation levels. The monitor shall have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm shall be capable of alerting an individual who is prepared to respond promptly.

§ 232.31. Control of source movement.

(a) The mechanism that moves the sources of a panoramic irradiator shall require a key to actuate. Actuation of the mechanism shall cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room shall require the same key.

(b) The console of a panoramic irradiator shall have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit and when the sources are exposed.

(c) The control console of a panoramic irradiator shall have a control that promptly returns the sources to the shielded position.

(d) Each control for a panoramic irradiator shall be clearly marked as to its function.

§ 232.33. Irradiator pools.

(a) The licensee shall have a method to safely store the sources during repair of the pool. For licenses initially issued after July 1, 1993, irradiator pools shall meet one of the following:

(1) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool.

(2) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

(b) For licenses initially issued after July 1, 1993, irradiator pools shall have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons shall have siphon breakers to prevent the siphoning of pool water.

(c) A means shall be provided to replenish water losses from the pool.

(d) A visible indicator shall be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(e) Irradiator pools shall be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(f) A physical barrier, such as a railing or cover, shall be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection and service operations.

(g) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.00002 Sv (2 mrem) per hour.

§ 232.35. Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack shall be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

§ 232.37. Power failures.

(a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources shall automatically return to the shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

(c) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

§ 232.39. Design requirements.

Irradiators whose construction begins after July 1, 1993, shall meet the design requirements of this section.

(1) *Shielding.* For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations and entranceways to meet the radiation shielding requirements of § 232.25 (relating to shielding). If the irradiator will use more than 2×10^{17} Bq (5 MCi) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) *Foundations.* For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(3) *Pool integrity.* For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of § 232.33(b) (relating to irradiator pools), and that metal components are metallurgically compatible with other components in the pool.

(4) *Water handling system.* For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of § 232.33(e) (relating to irradiator pools). The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(5) *Radiation monitors.* For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by § 232.29(a) (relating to radiation monitors). The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under § 232.59(b) (relating to detection of leaking sources), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(6) *Source rack.* For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(7) *Access control.* For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of § 232.23 (relating to access control).

(8) *Fire protection.* For panoramic irradiators, the licensee shall verify that the number, location and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(9) *Source return.* For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

(10) *Seismic.* For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(11) *Wiring.* For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

§ 232.41. Construction monitoring and acceptance testing.

The requirements of this section shall be met for irradiators whose construction begins after July 1, 1993. The requirements shall be met prior to loading sources.

(1) *Shielding.* For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(2) *Foundations.* For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(3) *Pool integrity.* For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of § 232.33(b) (relating to irradiator pools).

(4) *Water handling system.* For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter and the water level indicators operate properly.

(5) *Radiation monitors.* For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by § 232.29(a) (relating to radiation monitors). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet § 232.59(b) (relating to detection of leaking sources). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms and interlocks required by § 232.29(b) (relating to radiation monitors).

(6) *Source rack.* For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading. Testing shall include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in § 232.35 (relating to source rack protection) are met for protection of the source rack and the mechanism that moves the rack. Testing shall include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

(7) *Access control.* For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls and interlocks work properly.

(8) *Fire protection.* For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

(9) *Source return.* For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

(10) *Computer systems.* For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

(11) *Wiring.* For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

Subchapter D. OPERATION OF IRRADIATORS

Sec.

§ 232.51. Training.

(a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall be instructed in the following:

(1) The fundamentals of radiation protection applied to irradiators including:

(i) The differences between external radiation and radioactive contamination.

(ii) Units of radiation dose.

(iii) Dose limits.

(iv) Why large radiation doses shall be avoided.

(v) How shielding and access controls prevent large doses.

(vi) How an irradiator is designed to prevent contamination.

(vii) The proper use of survey meters and personnel dosimeters.

(viii) Other radiation safety features of an irradiator, and the basic function of the irradiator).

(2) The requirements of this chapter and chapter 219 (relating to the standards for radiation protection) that are relevant to the irradiator.

(3) The operation of the irradiator.

(4) The operating and emergency procedures in § 232.53 (relating to operating and emergency procedures) that the individual is responsible for performing.

(5) Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give

each operator a brief written test on the information. Each safety review shall include, to the extent appropriate, each of the following:

(1) Changes in operating and emergency procedures since the last review, if any.

(2) Changes in regulations and license conditions since the last review, if any.

(3) Reports on recent accidents, mistakes or problems that have occurred at irradiators, if any.

(4) Relevant results of inspections of operator safety performance.

(5) Relevant results of the facility's inspection and maintenance checks.

(6) A drill to practice an emergency or abnormal event procedure.

(e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures in § 232.53 that they are expected to perform or comply with, and their proper response to alarms required in this chapter. Tests may be oral.

(g) Individuals who shall be prepared to respond to alarms required by §§ 232.23(b) and (i), 232.27(a), 232.29(a) and (b) and 232.59(b) shall be trained and tested on how to respond. Each individual shall be retested at leat once a year. Tests may be oral.

§ 232.53. Operating and emergency procedures.

(a) The licensee shall have and follow written operating procedures for the following:

(1) Operation of the irradiator, including entering and leaving the radiation room.

(2) Use of personnel dosimeters.

(3) Surveying the shielding of panoramic irradiators.

(4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas.

(5) Leak testing of sources.

(6) Inspection and maintenance checks required by § 232.61 (relating to inspection and maintenance).

(7) Loading, unloading and repositioning sources, if the operations will be performed by the licensee.

(8) Inspection of movable shielding required by § 232.23(h) (relating to access control), if applicable.

(b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for the following:

(1) Sources stuck in the unshielded position.

(2) Personnel overexposures.

(3) A radiation alarm from the product exit portal monitor or pool monitor.

(4) Detection of leaking sources, pool contamination or alarm caused by contamination of pool water.

(5) A low or high water level indicator, an abnormal water loss or leakage from the source storage pool.

(6) A prolonged loss of electrical power.

(7) A fire alarm or explosion in the radiation room.

(8) An alarm indicating unauthorized entry into the radiation room, area around pool or another alarmed area.

(9) Natural phenomena, including an earthquake, a tornado, flooding or other phenomena as appropriate for the geographical location of the facility.

(10) The jamming of automatic conveyor systems.

(c) The licensee may revise operating and emergency procedures without Department approval only if the following conditions are met:

(1) The revisions do not reduce the safety of the facility.

(2) The revisions are consistent with the outline or summary of procedures submitted with the license application.

(3) The revisions have been reviewed and approved by the radiation safety officer.

(4) The users or operators are instructed and tested on the revised procedures before they are put into use.

§ 232.55. Personnel monitoring.

(a) Irradiator operators shall wear either a film badge or a thermoluminescent (TLD) dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor shall be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges. Each film badge or TLD shall be assigned to and worn by only one individual. Film badges shall be processed at least monthly, and TLDs shall be processed at least quarterly.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation shall be done at least annually. Acceptable dosimeters shall read within ±30 % of the true radiation dose.

§ 232.57. Radiation surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator shall be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators shall be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding shall be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in § 232.25 (relating to shielding) are exceeded, the facility shall be modified to comply with § 232.25.

(c) Portable radiation survey meters shall be calibrated at least annually to an accuracy of ±20% for the gamma energy of the sources in use. The calibration shall be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters shall be of a type that does not saturate and read zero at high radiation dose rates.

(d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming shall be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations may not exceed those specified in Chapter 219, Appendix B Table 2, Column 2 or Table 3 of, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(e) Before releasing resins for unrestricted use, they shall be monitored before release in an area with a background level less than 0.0005 mSv (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used shall be capable of detecting radiation levels of 0.0005 mSv (0.05 mrem) per hour.

§ 232.59. Detection of leaking sources.

(a) Each dry-source-storage sealed source shall be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Department or an agreement state. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test shall be capable of detecting the presence of 200 Bq (0.005 µCi) of radioactive material and shall be performed by a person approved by the Department the NRC or an agreement state to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the 6 months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis shall be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels shall activate an alarm. The alarm set-point shall be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired or disposed of by a Department, the NRC or agreement state licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination shall be performed promptly. If contaminated equipment, facilities or products are found, the licensee shall arrange to have them decontaminated or disposed of by a Department, NRC or agreement state licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in 10 CFR Part 20, Appendix B, Table 2, Column 2. (See 10 CFR 30.50 (relating to reporting requirements) for reporting requirements.

§ 232.61. Inspection and maintenance.

(a) The licensee shall perform inspection and maintenance checks at the frequency specified in the license or license application that include, as a minimum, each of the following:

(1) Operability of each aspect of the access control system required by § 232.23 (relating to access control).

(2) Functioning of the source position indicator required by § 232.31(b) (relating to control of source movement).

(3) Operability of the radiation monitor for radioactive contamination in pool water required by § 232.59(b) (relating to detection of leaking sources) using a radiation check source, if applicable.

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by § 232.29(b) (relating to radiation monitors).

(5) Operability of the product exit monitor required by § 232.29(a).

(6) Operability of the emergency source return control required by § 232.31(c) (relating to control of source movement).

(7) Leak-tightness of systems through which pool water circulates (visual inspection).

(8) Operability of the heat and smoke detectors and extinguisher system required by § 232.27 (relating to fire protection)—but without turning extinguishers on.

(9) Operability of the means of pool water replenishment required by § 232.33(c) (relating to irradiator pools).

(10) Operability of the indicators of high and low pool water levels required by § 232.33(d).

(11) Operability of the intrusion alarm required by § 232.23(i) (relating to access control), if applicable.

(12) Functioning and wear of the system, mechanisms and cables used to raise and lower sources.

(13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by § 232.35 (relating to source rack protection).

(14) Amount of water added to the pool to determine if the pool is leaking.

(15) Electrical wiring on required safety systems for radiation damage.

(16) Pool water conductivity measurements and analysis as required by § 232.63(b) (relating to pool water purity).

(b) Malfunctions and defects found during inspection and maintenance checks shall be repaired without undue delay.

§ 232.63. Pool water purity.

(a) Pool water purification system shall be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters shall be calibrated at least annually.

§ 232.65. Attendance during operation.

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite as whenever:

(1) The irradiator is operated using an automatic product conveyor system.

(2) The product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in § 232.51(g) (relating to training) shall be onsite.

(c) At an underwater irradiator, an irradiator operator shall be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators. The operator shall have received the training described in § 232.51(f) and (g). Static irradiations may be performed without a person present at the facility.

§ 232.67. Entering and leaving the radiation room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(1) Visually inspect the entire radiation room to verify that no one else is in it.

(2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by § 232.29(b) (relating to radiation monitors) is operating with backup power.

§ 232.69. Irradiation of explosive or flammable materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems or cause radiation overexposures of personnel.

(b) Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Subchapter E. RECORDS

Sec.
232.81. Records and retention periods.
232.82. Reports.

§ 232.81. Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified:

(1) A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents not superseded.

(2) Records of each individual's training, tests and safety reviews provided to meet the requirements of § 232.51(a)—(d), (f) and (g) (relating to training) until 3 years after the individual terminates work.

(3) Records of the annual evaluations of the safety performance of irradiator operators required by § 232.51(e) for 3 years after the evaluation.

(4) A copy of the current operating and emergency procedures required by § 232.53 until superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by § 232.53(c)(3) retained for 3 years from the date of the change.

(5) Film badge and TLD results required by § 232.55 (relating to personnel monitoring) until the Department terminates the license.

(6) Records of radiation surveys required by § 232.57 (relating to radiation surveys) for 3 years from the date of the survey.

(7) Records of radiation survey meter calibrations required by § 232.57 and pool water conductivity meter calibrations required by § 232.63(b) (relating to pool water purity) until 3 years from the date of calibration.

(8) Records of the results of leak tests required by § 232.59(a) (relating to detection of leaking sources) and the results of contamination checks required by § 232.59(b) for 3 years from the date of each test.

(9) Records of inspection and maintenance checks required by § 232.61 (relating to inspection and maintenance) for 3 years.

(10) Records of major malfunctions, significant defects, operating difficulties or irregularities and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

(11) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by § 217.101 (relating to transfer of radioactive material).

(12) Records on the design checks required by § 232.39 (relating to design requirements) and the construction control checks as required by § 232.41 (relating to construction monitoring and acceptance testing) until the license is terminated. The records shall be signed and dated. The title or qualification of the person signing shall be included.

(13) Records related to decommissioning of the irradiator as required by § 217.58(g) (relating to financial assurance arrangements for reclaiming sites).

§ 232.83. Reports.

(a) In addition to the reporting requirements of this article, the licensee shall report the following events if not reported under other requirements of this article:

(1) Source stuck in an unshielded position.

(2) Any fire or explosion in a radiation room.

(3) Damage to the source racks.

(4) Failure of the cable or drive mechanism used to move the source racks.

(5) Inoperability of the access control system.

(6) Detection of radiation source by the product exit monitor.

(7) Detection of radioactive contamination attributable to licensed radioactive material.

(8) Structural damage to the pool liner or walls.

(9) Abnormal water loss or leakage from the source storage pool.

(10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report shall include a telephone report within 24 hours. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(1) The caller's name and call back number.

(2) A description of the event including date and time.

(3) The exact location of the event.

(4) The isotopes, quantities and chemical and physical form of the licensed material involved.

(5) Any personnel radiation exposure data available.

(c) A written follow-up report within 30 days of the initial report. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain the necessary information. The reports shall include the following:

(1) A description of the event including the probable cause and the manufacturer and model number—if applicable—of any equipment that failed or malfunctioned.

(2) The exact location of the event.

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved.

(4) The date and time of the event.

(5) Corrective actions taken or planned and the results of any evaluations or assessments.

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

[Pa.B. Doc. No. 98-287. Filed for public inspection February 13, 1998, 9:00 a.m.]