Regulatory Analysis Form

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(1) **Agency**

ENVIRONMENTAL PROTECTION

(2) **I.D. Number (Governor's Office Use)**

7 – 350

IRRC Number: 2138

(3) **Short Title**

RADIOLOGICAL HEALTH

(4) **PA Code Cite**	(5) **Agency Contacts & Telephone Numbers**
25 Pa. Code 215,217,219,220,224,225,226,230, 232	Primary Contact: Sharon F. Trostle, 783-1303 Secondary Contact: Barbara Sexton, 783-1303

(6) **Type of Rulemaking (Check One)**	(7) **Is a 120-Day Emergency Certification Attached?**
____Proposed Rulemaking __X__Final Order Adopting Regulation ____Final Order, Proposed Rulemaking Omitted	__X__No ____Yes: By the Attorney General ____Yes: By the Governor

(8) **Briefly explain the regulation in clear and non-technical language.**

The purpose of this amendment is to revise and update existing radioactive material regulations. They will also become compatible with regulations of the U.S. Nuclear Regulatory Commission (NRC) as a necessary step in Pennsylvania's acquisition of Agreement State status from the NRC.

The nine chapters involving radioactive material are being revised through incorporation by reference of those NRC regulations that are necessary for compatibility with the NRC regulations.

The amendments to Chapter 225 also update the regulations for industrial radiography that utilizes radiation producing machines as well as radioactive materials.

(9) **State the statutory authority for the regulation and any relevant state or federal court decisions.**

1. Radiation Protection Act, act of July 10, 1984 (P.L. 688, No. 147), 35 P.S. Sec. 7110.101, et seq.
2. Section 1920-A of the Administrative Code, April 9, 1929 (P.L. 177, No. 175), as amended, 71 P.S. Sec. 510-20.

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(10) **Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.**

No. However compatibility of State and NRC regulations is a requirement for Agreement State status.

(11) **Explain the compelling public interest that justifies the regulation. What is the problem it addresses?**

The regulations dealing with radioactive materials have not been updated since November 18, 1995.

The changes are necessary to adapt to emerging technology and maintain a regulatory basis that promotes development, safe use and commerce in radioactive materials.

It is also a necessary prerequisite to Pennsylvania acquiring Agreement State status with the NRC, whereby the acquisition and the use of all radiation sources, as well as the potential future licensing of any low-level radioactive waste site, will be consolidated under state control.

(12) **State the public health, safety, environmental or general welfare risks associated with non-regulation.**

Non-regulation would result in no protection for the citizens of Pennsylvania against radiation hazards.

(13) **Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)**

Updating current radiological health regulations and eliminating inconsistent and obsolete standards will benefit both individuals working with radiation sources and the general public by the reduction of unnecessary radiation exposure and replicative administrative effort.

The regulated community that is currently subject to the NRC, or jointly to the NRC and the state, would benefit if Pennsylvania becomes an Agreement State. Licensing and control would be consolidated into a single agency, the Commonwealth. For current NRC licensees, (who outnumber state licensees approximately 2 to 1), licensing fees would be reduced overall. Redundant licenses and inspections would be eliminated for more than two hundred persons who now hold both NRC and state licenses for the same operations.

(14) **Describe who will be adversely affected by the regulation. (Quantify the adverse effect as completely as possible and approximate the number of people who will be adversely affected.)**

No one will be adversely affected by the regulation.

(15) **List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)**

Those persons to be affected by the regulation include any individual, corporation, institution, group or agency that uses naturally occurring and accelerator produced radioactive materials.

There are approximately 450 current licensees who will be required to comply with this regulation.

(16) **Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who where involved, if applicable.**

The proposed regulations and draft final regulations were reviewed and endorsed by the Radiation Protection Advisory Committee (RPAC). The RPAC includes representatives from the PA Dental Society, the PA Medical Society, the PA Chiropractic Association, the PA Podiatric Society, the PA Veterinary Society, the PA Osteopathic Society, the Pennsylvania Society of Radiologic Technologists, the Western Pennsylvania Chapter of the Health Physics Society, the Susquehanna Valley Chapter of the Health Physics Society, the Delaware Valley Society for Radiation Safety, the Penn-Ohio Chapter of the American Association of Physicists in Medicine, the Delaware Valley Chapter of the American Association of Physicists in Medicine, and others.

The draft final regulation was published in the *Pennsylvania Bulletin* on August 26, 2000 with a 30-day comment period ending September 25, 2000.

(17) **Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.**

No additional legal, accounting or consulting procedures will be required. There are no additional compliance costs resulting from incorporation by reference of current NRC regulations because current regulations were patterned after past NRC regulations. There will be approximately 30% cost savings for all PA NRC licensees when we become an Agreement State.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There are no costs for local governments to comply with these regulations.

(19) **Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting or consulting procedures which may be required.**

There are no costs for the state government to comply with these regulations.

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(20) **In the table below, provide an estimate of the fiscal savings and cost associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.**

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community	None	None	None	*	*	*
Local Government	None	None	None	*	*	*
State Government	None	None	None	*	*	*
Total Savings	None	None	None	*	*	*
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs	None	None	None	None	None	None
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses	None	None	None	None	None	None

(20a) **Explain how the cost estimates listed above were derived.**

* The savings would start when Pennsylvania becomes an Agreement State. At that time all holders of NRC licenses would become Pennsylvania licensees and subject to lower license fees. The exact savings is difficult to quantify because of the complexity of the NRC fee structure, which for some licensees is up to ten times higher than the comparable state fees. For those holding both state and NRC licenses, there would also be savings from having one license, one set of regulations and one inspecting agency only instead of two of each.

The estimated time for the agreement is the fall of 2002.

(20b) **Provide the past three year expenditure history for programs affected by the regulation.**

Program	FY-3	FY-2	FY-1	Current FY
RAM Lic/Inspect	$ 216.402	$ 313,041	$ 245,770	$ 18,407 (1st.Qtr)
X-ray reg/insp.	$1,403,178	$1,613,178	$1,584,093	$342,295 (1st Qtr)

(21) **Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.**

There are no adverse effects and costs. The benefit of the prevention of unnecessary radiation exposure to the public and radiation workers cannot be quantified.

(22) **Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.**

There are no equivalent nonregulatory alternatives. Additionally, to not update the regulations would prevent the deletion or replacement of technically obsolete regulations.

(23) **Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.**

The only alternative regulatory scheme is to copy the model federal code into Pennsylvania code. This is redundant, subject to unexpected error in translation and is not a permanent solution. Incorporation by reference will automatically keep these regulations up to date and compatible with the referenced federal regulations. A similar approach has been adopted by other Department programs with respect to EPA regulations.

(24) **Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.**

Except for § 219.7, relating to criteria for license termination under restricted conditions, and the parts of the regulations that cover the possession and use of radiation-producing machines, which are not regulated by the federal government, the provisions of these regulations are not more stringent than the federal standards. § 219.7 provides that a licensee would have to demonstrate that the license termination plan was effective in meeting requirements of 10 CFR 20.140 for a period of five years before license termination.

(25) **How does the regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?**

The regulations are based on the NRC Regulations. About two thirds of the states have adopted NRC compatible regulations and the existing PA regulations are derived from earlier NRC regulations.. Therefore this will not put Pennsylvania at a competitive disadvantage. The state of Ohio has just adopted NRC regulations by reference, and has recently become an Agreement State.

(26) **Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.**

No

(27) **Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.**

No

(28) **Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.**

No significant change in existing reporting, record keeping, or other paperwork requirements will be incurred as a result of the proposed regulations. NRC forms will be adopted as PA forms.

(29) **Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses and farmers.**

No special provisions needed to be developed.

(30) **What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?**

This final rulemaking will become effective upon publication in the Pennsylvania Bulletin. It is anticipated that the final rulemaking will be published some time during the Summer of 2001.

Existing NRC licenses in PA will not be affected until Agreement State status is published in the *Federal Register*. At this time, the NRC licenses will be transferred to PA and become PA licenses. Any changes will occur at the anniversary date of the licenses which is spread out over 5-10 years.

(31) **Provide the schedule for continual review of the regulation.**

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

DL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2138

DO NOT WRITE IN THIS SPACE

›py below is hereby approved as to ; and legality. Attorney General (DEPUTY ATTORNEY GENERAL) DATE OF APPROVAL heck if applicable opy not approved. Objections ttached.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by: DEPARTMENT OF ENVIRONMENTAL PROTECTION ENVIRONMENTAL QUALITY BOARD (AGENCY) DOCUMENT/FISCAL NOTE NO. 7-350 DATE OF ADOPTION: BY: David E. Hess TITLE: DAVID E. HESS, CHAIRMAN (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	Copy below is hereby approved as to form and legality, Executive or Independent Agencies. BY: 6/20/01 DATE OF APPROVAL (Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title) ☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

ORDER ADOPTING REGULATIONS

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Radiological Health

25 Pa. Code,

Chapters 215, 217, 219, 220, 224, 225, 226, 230, and 232

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

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

Radiological Health

ORDER

The Environmental Quality Board (Board) by this order amends 25 PA Code, Chapters 215, 217, 219, 220, 224--226 and 230, and adds new Chapter 232. The amendments update the standards for protection against radiation to meet compatibility requirements for the Commonwealth to become an agreement state with the U. S. Nuclear Regulatory Commission.

This order was adopted by the Board at its regular meeting on June 19, 2001.

A. *Effective Date*

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

B. *Contact Persons*

For further information, the contact persons are Louis Ray Urciuolo, Chief, Licensing Section, Bureau of Radiation Protection, 13th Floor, Rachel Carson State Office Building, P. O. Box 8469, Harrisburg, PA 17105-8469, (717) 787-3720; and Marylou Barton, Assistant Counsel, Bureau of Regulatory Counsel, Rachel Carson State Office Building, 9th Floor, 400 Market Street, P. O. Box 8464, Harrisburg, PA 17105-8464, (717) 787-7060. This proposal is also available electronically through the DEP website (www.dep.state.pa.us).

C. *Statutory Authority*

This final rulemaking is being made under the authority of Sections 301 and 302 of the Radiation Protection Act (Act) (35 P. S. §§ 7110.301 and 7110.302), which, respectively, direct the Department to develop and conduct comprehensive programs for the registration, licensing, control, management, regulation and inspection of radiation sources and radiation source users, and delegate to the Board the power to adopt the regulations of the Department to implement the Act.

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

D. *Background and Summary*

In 1995, the Board updated its radiological health regulations to provide for compatibility with other states and to serve as a basis for the Commonwealth to assume authority from the 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 amendments are necessary for the Commonwealth to acquire agreement state status from the NRC. Under section 201 of the Act (35 P. S. § 7110.201), the Governor is authorized to enter into agreements with the NRC transferring regulatory authority to the Commonwealth for radiation protection. Presently, the Commonwealth is responsible for the regulation of naturally occurring and accelerator-produced radioactive material (NARM) and radiation producing equipment. Under the Atomic Energy Act of 1954 (42 U.S.C.A. § 2021), the NRC is authorized to enter into an agreement with the Governor to discontinue NRC regulatory authority with respect to most by-product materials, source materials and special nuclear materials in amounts insufficient to form a critical mass.

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

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

A description of the amendments is provided as follows:

Chapter 215. General Provisions

Section 215.1 (relating to purpose and scope) is expanded to clarify the scope of incorporation by reference and list any exceptions. Subsections (e) and (f) provide notification that this does not relieve a person from complying with Pennsylvania law nor does it expand the scope of authority already granted the Department under statute. Locations are listed in new subsection 215.1(g) for the purchase of copies of the *Code of Federal Regulations* (Title 10 Chapter I) to be incorporated by reference. An electronic version is also available on the United States

Government Printing Office world wide web site at http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199910. New subsection 215.1(h) describes the relationship between certain commonly used terms of the Department and NRC.

Section 215.2 (relating to definitions) The following definitions were deleted because they are incorporated by reference: "ALARA," "A_1," "A_2," "absorbed dose," "agreement state," "airborne radioactive material," "airborne radioactivity area," "background radiation," "becquerel," "byproduct material," "calendar quarter," "collective dose," "committed dose equivalent," "committed effective dose equivalent," "controlled area," "curie," "deep dose equivalent," "depleted uranium," "dose," "dose equivalent," "dose limits," "effective dose equivalent," "embryo/fetus," "exposure," "exposure rate," "external dose," "extremity," "eye dose equivalent," "generally applicable environmental radiation standards," "gray," "high radiation area," "individual monitoring," "individual monitoring devices," "internal dose," "licensed material," "lost or missing licensed or registered source of radiation," "member of the public," "minor," "misadministration", "monitoring," "normal form," "occupational dose," "personnel monitoring equipment," "prescribed dosage," "public dose," "rad," "radiation area," "radiopharmaceutical," "rem," "research and development," "restricted area," "sealed source," "SI," "shallow dose equivalent," "sievert," "site boundary," "source material," "special form," "special nuclear material," "special nuclear material in quantities not sufficient to form a critical mass," "survey," "TEDE," "unrefined and unprocessed ore," "unrestricted area," "week," "whole body," "worker", "working level," "working level month" and "year."

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

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

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

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

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

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

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

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

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

A new § 215.27 (relating to vacating premises) contains the provisions of § 219.241 (relating to vacating premises), which is relocated to this chapter. The requirement is extended to all licensees and is in addition to the decommissioning requirements of 10 CFR 30.36 that are incorporated by reference under Chapter 217.

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

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

Chapter 217. Licensing of Radioactive Material

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

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

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

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

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

Section 217.133 (relating to persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an Agreement State as published in the *Federal Register*) is the existing § 217.24, which is deleted.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sections 217.161 and 217.162 (relating to incorporation by reference; and effect of incorporation of 10 CFR Part 32) explain the incorporation by reference.

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

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

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

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

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

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

A new Subchapter J (relating to reciprocity) is the existing Subchapter F amended to incorporate 10 CFR 150.1 (relating to purpose), 10 CFR 150.2 (relating to scope), 10 CFR 150.3 (relating to definitions), 10 CFR 150.11

(relating to critical mass) and certain sections of 10 CFR 150.20 (relating to recognition of Agreement State licenses).

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

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

Chapter 219. Standards for Protection Against Radiation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chapter 224. Medical Use of Radioactive Material

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Existing Appendix A is retained.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Chapter 226. Licenses and Radiation Safety Requirements for Well Logging

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

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

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

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

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

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

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

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

Chapter 230. Packaging and Transportation of Radioactive Material

Sections 230.2, 230.11, 230.12, 230.14, 230.21--230.26, 230.41--230.46, 230.51, Appendix A and Tables I--IV are deleted because of incorporation by reference of 10 CFR Part 71.

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

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

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

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

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

Chapter 232. Licenses and Radiation Safety Requirements for Irradiators

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

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

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

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

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

The Department prepared a comment and response document that summarizes and

responds to the aforementioned comments. A copy of the comment and response document is available upon request from the contact person listed in Section B of this order.

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

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

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

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

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

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

particle beam therapy is included in addition to x-ray. For the same reasons, the proposed term "written directive for x-ray therapy" has been clarified to read "written directive for therapy using radiation-producing machines." The definition of "worker" has also been deleted in the final rule since an applicable definition of "worker" is incorporated by reference.

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

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

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

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

§§ 217.132(4), 217.142(4), 217.172(4), 217.182(4), 217.202(4) and 224.11(3) change "the definition of *licensed material*" to "a reference to *byproduct material*" as an editorial correction since the corresponding Parts of the CFR refer to *byproduct material* rather than *licensed material*. Similarly, "The definition of *licensed material* includes NARM" has been deleted from §§ 217.152(4) and 217.162(4) as the phrase "licensed material" is not found in the corresponding parts of the CFR.

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

§ 217.191 (relating to transfer of material) has been amended at final rulemaking. The existing text is replaced by incorporation by reference of 10 CFR 30.41 because the CFR is equivalent. Three concerns were raised to items in this section. One objection related to the provision for verification of a licensee's authority to receive material by using data supplied from parties other than the Department or the licensee. Another commentator felt even more strongly that direct contact with the licensee should be the only form of permissible verification. The Department disagrees with the first two comments because

they were based on the misconception that the transferor was accountable for not allowing the transferee's inventory to exceed the transferee's license possession limits. The transferor need only verify that the material to be transferred does not exceed the limits listed in the transferee's license. The transferee is responsible for ensuring that current inventory (which may fluctuate on a day-to-day basis) never exceeds the license limits. The third concern questioned what constituted "verbal" certification. These regulations are not new, and the requirements are not being altered. They are currently in force and are identical to the CFR. They have been in place for a sufficient time for the Department to note that there is no indication that the regulated community has a problem understanding or complying with the regulations, and no significant problems have arisen that could be attributed to defects in the regulations. No one has approached the Department as yet to compile a third-party verification service. If this did happen, it would have to be approved by the Department. Verbal certification has no special legal definition and must be followed up in writing anyway. In summary the Department has not changed the existing requirements. However, the text of these requirements is now 10 CFR 30.41, incorporated by reference.

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

§ 219.3 (definitions) is retained at final rulemaking for the purpose of the new definition, "medical reportable event for radiation-producing machine therapy." The new definition is the renamed successor to the definition of "misadministration" for events not involving radioactive material. Several additional concerns were raised regarding the definition. These concerns involved clarity of scope, interpretation and limits. The resolution of these issues resulted in a significant rewrite of the proposed regulation. The proposed regulation closely followed the anticipated form of the NRC's new definition of medical event, with the exception of being slanted toward invasive therapy. The final rule is closer to the traditional form of the Council of Radiation Control Directors Suggested State Regulations for teletherapy. The result is a rule that better addresses the comments

and provides more flexibility to the regulated community. The rule was simplified by removing such issues as wrong site, errors of precision, wrong beam energy, wrong mode or wedge factor. The criteria is that controllable exposures to areas inside or outside the treatment volume do not exceed a certain percentage of the prescription regardless of the cause. The percentage is based upon the total dose and, as suggested by a commentator, the weekly dose rather than an individual dose fraction.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

F. *Benefits Costs and Compliance*

Executive Order 1996-1 requires a cost/benefit analysis of the 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 employees but will also protect the general public. The Commonwealth will also be able to continue pursuit of agreement state status with the NRC that will lead to an overall reduction in license fees for NRC licensees of this Commonwealth. The regulation will also generally reduce the records retention requirement from 5 years to 3 years for registrants and licensees of the Department.

Compliance Costs

There are no additional compliance costs because licensees either currently comply with these regulations by virtue of their NRC licenses or through licenses

issued by the Department which incorporate similar requirements by condition. There is no additional compliance cost for registrants as the generally applicable standards for radiological health already apply to them.

Compliance Assistance Plan

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

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

Paperwork Requirements

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

G. *Pollution Prevention*

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

H. *Sunset Review*

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

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Department submitted a copy of the proposed rulemaking on August 8, 2000 to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the Senate and House Environmental Resources and Energy Committees. In compliance with Section 5(b.1) of the Regulatory Review Act, the Department

also provided IRRC and the Committees with copies of the comments, as well as other documentation.

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

This final-form regulation was deemed approved by the House Environmental Resources and Energy Committee on _____ and was deemed approved by the Senate Environmental Resources Committee and Energy Committee on _____. The Commission met on _____ and approved the regulation in accordance with Section 5(c) of the Act.

J. *Findings of the Board*

The Board finds that:

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

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

(3) These regulations do not enlarge the purpose of the proposal published at *30 Pennsylvania Bulletin 4503* (August 26, 2000).

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

K. *Order of the Board*

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

(a) The regulations of the Department of Environmental Protection, *25 Pennsylvania Code,* Chapters 215, 217, 219, 220, 224, 225, 226, 230 and 232, are amended by amending the aforesaid chapters to read as set forth in Annex A, with ellipses referring to the existing test of the regulations.

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

(c) The Chairman shall submit this order and Annex A to the Independent Regulatory Review Commission and the Senate and House Environmental Resource and Energy Committees as required by law.

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

(e) This order shall take effect immediately.

BY:

DAVID E. HESS

Chairman

Environmental Quality Board

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 215. GENERAL PROVISIONS

GENERAL PROVISIONS

§ 215.1. Purpose and scope.

* * * * *

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

(Editor's Note: § 215.1(d) is not changed but is printed to improve clarity of the remainder of the rulemaking.)

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and §§150.1 150.2, 150.3, 150.11, 150.20(a)(1), 150.20(a)(2) AND 150.20(b) of the CFR is incorporated by reference WITH THE EXCEPTIONS SET FORTH BELOW. Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101--7130.905).

(1) §§19.4, 19.5, 19.8, 19.30, 19.40 ARE NOT INCORPORATED.

(2) §§20.1006, 20.1009, 20.2206(a)(1), 20.2206(a)(3), 20.2206(a)(4), 20.2206(a)(5), 20.2401, AND 20.2402 ARE NOT INCORPORATED.

(3) §§30.5, 30.6, 30.8, 30.21(c), 30.34(d), 30.34(e)(1), 30.34(e)(3), 30.41(a)(6), 30.55, 30.63, AND 30.64 ARE NOT INCORPORATED

(4) §§31.3, 31.4 AND 31.14 ARE NOT INCORPORATED

(5) §§32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, AND

32.40 ARE NOT INCORPORATED.

(6) §§33.8, 33.21 AND 33.22 ARE NOT INCORPORATED.

(7) §§34.5, 34.8, 34.121 AND 34.123 ARE NOT INCORPORATED.

(8) §§35.8, 35.990, AND 35.991 ARE NOT INCORPORATED.

(9) §§36.5, 36.8, 36.91 AND 36.93 ARE NOT INCORPORATED.

(10) §§39.5, 39.8, 39.101 AND 39.103 ARE NOT INCORPORATED.

(11) §§40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k), 40.31(i), 40.32(d), 40.32(e), 40.32(g), 40.38, 40.41(d), 40.41(e)(1), 40.41(e)(3), 40.41(g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 AND 40.82 ARE NOT INCORPORATED.

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

(13) §§71.2, 71.6, 71.13(c), 71.13(d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.47, 71.51, 71.52, 71.53, 71.55, 71.59, 71.63, 71.64, 7.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.83, 71.99 AND 71.100 ARE NOT INCORPORATED.

(f) If a provision of the CFR incorporated by reference in this article includes a section which is inconsistent with the *Pennsylvania Code*, the *Pennsylvania Code* controls to the extent Federal law does not preempt Commonwealth law. If a provision of the CFR incorporated by reference in

this article is beyond the scope of authority granted the Department under statute, or is in excess of the statutory authority, the provisions shall be and remain effective only to the extent authorized by the Pennsylvania law.

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

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

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

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

(h) TO RECONCILE DIFFERENCES BETWEEN THIS CHAPTER AND THE INCORPORATED SECTIONS OF FEDERAL REGULATIONS AND TO EFFECTUATE THEIR JOINT ENFORCEMENT, THE FOLLOWING WORDS AND PHRASES SHALL BE SUBSTITUTED FOR THE LANGUAGE OF THE FEDERAL REGULATIONS AS FOLLOWS:

(1) A REFERENCE TO "NRC" OR "COMMISSION" MEANS DEPARTMENT.

(2) A REFERENCE TO "NRC OR AGREEMENT STATE" MEANS DEPARTMENT, NRC OR AGREEMENT STATE.

(3) THE DEFINITION OF "SEALED SOURCE" INCLUDES NARM.

(4) A REFERENCE TO "BYPRODUCT MATERIAL" INCLUDES NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

§ 215.2. Definitions.

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

this article, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

[*ALARA--As low as is reasonably achievable*--Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this article as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

A_1 [~~1~~]--The maximum activity of special form radioactive material permitted in a Type A package.

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

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

* * * * *

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

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

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

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

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

***Background radiation*--Radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the**

environment from the testing of nuclear explosive devices. The term does not include sources of radiation from radioactive materials regulated by the Department.

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

* * * * *

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

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

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

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

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

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

***Committed effective dose equivalent (HE,50)*--The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues (HE,50 = □wT,HT,50).**

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

***Curie (Ci)*--The special unit or quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7 x 1010 transformations per second (tps).**

***Deep dose equivalent (Hd), which applies to external whole body exposure*--The dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm2).**

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

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

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

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

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

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

* * * * *

[*Exposure*--The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen (R). See § 215.3 (relating to units of exposure and dose) for the SI equivalent.

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

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

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

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

* * * * *

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

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

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

* * * * *

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

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

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

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

* * * * *

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

* * * * *

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

* * * * *

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

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

***Minor*--An individual under 18 years of age.]**

(Editor's note: The following definition for Misadministration (Medical Event) from x-ray is deleted in entirety from § 215.2 in the final rulemaking.)

[~~*Misadministration (medical event) from X-ray*--The administration to a human being [of:], except for administrations resulting from the direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:~~]

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

(A) Involving the wrong patient or wrong pharmaceutical.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(B) Involving a sealed source that is leaking.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[~~An administration of a dose to the wrong individual.~~

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

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

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

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

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

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

* * * * *

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

* * * * *

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

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

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

* * * * *

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

(i) In a written directive.

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

Prescribed dose for ~~[X-ray]~~ therapy ***USING RADIATION-PRODUCING MACHINES*****--[One of the following:**

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

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

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

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

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

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

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

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

* * * * *

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

* * * * *

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

* * * * *

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

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

(i) Theoretical analysis, exploration or experimentation.

(ii) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. The term does not

include the internal or external administration of radiation or radioactive material to human beings.

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

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

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

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

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

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

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

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

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

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

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

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

constructed after June 30, 1985 shall meet the requirements of this subparagraph.

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

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

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

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

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

* * * * *

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

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

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

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

~~[*Worker*--an individual engaged in work under a license or registration issued by the department and controlled by a licensee or registrant. the term does not include the licensee or registrant.]~~

* * * * *

[*Working level (WL)*--A combination of radon-222 daughters in one liter of air which will result in the ultimate emission of 1.3 x 105 million electron volts of alpha particle energy.

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

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

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

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

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

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

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

(vi) For other brachytherapy the following apply:

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

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

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

[(viii)] **(ii)** For X-ray, **ELECTRON OR OTHER [~~and~~] PARTICLE BEAM [~~electron beam~~)]** therapy at energies of 1 MeV and above: the total dose, dose per fraction, treatment site, field size, beam type and energy, applicator, use of beam blocking or shaping devices, treatment geometry and overall treatment period.

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

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

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

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

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

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

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

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

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

TABLE I
QUALITY FACTORS AND
ABSORBED DOSE EQUIVALENCIES

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

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

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

TABLE II

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

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

7	7	24E+6	24E+8
10	6.5	24E+6	24E+8
14	7.5	17E+6	17E+8
20	8	16E+6	16E+8
40	7	14E+6	14E+8
60	5.5	16E+6	16E+8
1E+2	4	20E+6	20E+8
2E+2	3.5	19E+6	19E+8
3E+2	3.5	16E+6	16E+8
4E+2	3.5	14E+6	14E+8

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

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

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

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

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

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

§ 215.5. Effect of Incorporation of the CFR.

(a) *Title and name changes.* To reconcile differences between this chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations as follows:

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

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

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

(c) NOTIFICATIONS, REPORTS AND CORRESPONDENCE

REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.11. Records.

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

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

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

§ 215.12. Inspections.

* * * * *

(c) *Inspections by the Department.*

(1) The Department, its [~~employes~~] **EMPLOYEES** and agents may conduct inspections of the facilities of registrants of radiation-producing machines and licensees of radioactive material at the following frequencies:

(i) For major medical facilities, including hospitals, at least once every **[2]** 3 years **for X-ray operations.**

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

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

* * * * *

§ 215.15. Additional requirements

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

PROHIBITIONS AND RESTRICTIONS

§ 215.25. Deliberate misconduct.

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

§ 215.26. [~~Employe~~] EMPLOYEE protection.

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

§ 215.27. Vacating premises.

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

§ 215.28. [~~Deceptive~~] DELIBERATE exposure of a monitoring device.

THE DELIBERATE EXPOSURE [~~Exposure~~] of [a] AN INDIVIDUAL [~~personnel~~] monitoring device or area monitoring device to [~~deceptively~~] FALSELY indicate the dose delivered to an individual is prohibited.

EXEMPTIONS

§ 215.32. Exemption qualifications.

The following sources, uses and types of users are exempt from Chapters 216--**[230]** 232:

* * * * *

CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 217.1. Purpose and scope.

* * * * *

(b) A licensee is subject to Chapters 215, **[219], 218--220 and 230 [(relating to general provisions; standards for protection against radiation, and notices, instructions and reports to workers; inspections]** (RELATING TO GENERAL PROVISIONS; FEES; STANDARDS FOR PROTECTION AGAINST RADIATION, AND NOTICES, INSTRUCTIONS AND

REPORTS TO WORKERS; AND TRANSPORTATION OF RADIOACTIVE MATERIAL). A licensee engaged in industrial **uses and** radiographic operations is subject to Chapter 225 (relating to radiation safety requirements for industrial radiographic operations). A licensee using radioactive material for human use is subject to Chapter 224 (relating to medical use of radioactive material). A licensee using sealed sources in well logging is subject to Chapter 226 (relating to **licenses and** radiation safety requirements for **[wireline service operations and subsurface tracer studies] well logging). A licensee using sealed sources in irradiators is subject to Chapter 232 (relating to licenses and radiation safety requirements for irradiators). A licensee for the disposal of low-level radioactive wastes received from other persons is subject to Chapter 236 (relating to low-level radioactive waste management and disposal).**

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

(Editor's Note: § 217.1(c) is not changed but is printed to improve clarity of the remainder of the rulemaking.)

§ 217.2. Address **for communications.**

An application for a license, license renewal and license amendments and other communications under this chapter shall be addressed to the Bureau of Radiation Protection, Department of Environmental **[Resources] Protection,** Post Office Box **[2063] 8469,** Harrisburg, Pennsylvania **[17120]-17105-8469.**

(*Editor's Note*: As part of this rulemaking, the Department is deleting existing text of §§ 217.11--217.18, 217.21--217.24, 217.31, 217.32, 217.41--217.49, 217.51--217.57, 217.65, 217.71--217.74, 217.81--217.93, 217.101, 217.121 and 217.122 and Appendices A, B and D which appear at 25 Pa. Code pages 217-2--217-76, serial pages (203810)--(203832), (249215)--(249244) and (203863)--(203884). The existing subchapters are renamed and the following regulations are new and printed in regular type to enhance readability.)

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

Sec.

217.131. Incorporation by reference.
217.132. Effect of incorporation of 10 CFR Part 30.
217.133. Persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register*.

217.134. Filing application for specific licenses.
217.135. Renewal of licenses.
217.136. Exempt concentrations.
217.137. Exempt quantities.

§ 217.131. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 30.5 (relating to interpretations), 10 CFR 30.6 (relating to communications), 10 CFR 30.8 (relating to information collection requirements: OMB approval), 10 CFR 30.63 (relating to violations) and 10 CFR 30.64 (relating to criminal penalties)~~] **10 CFR §§ 30.5, 30.6, 30.8, 30.21(c), 30.34(d), 30.34(e)(1), 30.34(e)(3), 30.41(a)(6), 30.55, 30.63, AND 30.64** are not incorporated by reference.

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

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

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

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

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

(4) [~~The definition of "licensed material"~~] **A REFERENCE TO "BYPRODUCT MATERIAL"** includes NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

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

On the date the Commonwealth becomes an agreement state as published in the *Federal Register*, a person who possesses a general or specific license issued by

the NRC for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass, is deemed to possess a like license issued under this chapter and the act. The license shall expire either 90 days after receipt from the Department of a notice of expiration of the license, or on the date of expiration specified in the NRC license, whichever is earlier.

§ 217.134. Filing application for specific licenses.

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

§ 217.135. Renewal of licenses.

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

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

§ 217.136. Exempt concentrations.

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

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

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

TABLE 1

EXEMPT CONCENTRATIONS

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

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

Actinium (89)	Ac-228		9E-04
Cadmium (48)	Cd-109		2E-03
Cesium (55)	Cs-129		3E-03
Europium (63)	Eu-154		2E-04
Gallium (31)	Ga-67		2E-03
Germanium (32)	Ge-68		9E-03
Gold (79)	Au-195		1E-02
Indium (49)	In-111		1E-03
Iodine (53)	I-123		3E-04
	I-124		4E-06
	I-125		2E-06
Lead (82)	Pb-212		2E-04
Phosphorus (15)	P-33		3E-04
Potassium (19)	K-43		2E-04
Protactinium (91)	Pa-230		2E-03
Radium(88)	Ra-223		7E-06
	Ra-224		2E-05
	Ra-228		3E-07
Radon (86)	Rn-220	1E-07	
	Rn-222	3E-08	
Sodium (11)	Na-22		4E-04
Technetium (43)	Tc-97m		4E-03
Xenon (54)	Xe-127	4E-06	
Yttrium (39)	Y-88		8E-04

§ 217.137. Exempt quantities.

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

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

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

TABLE 2

EXEMPT QUANTITIES

Radioactive Material	Microcuries

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

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

Sec.

217.141. Incorporation by reference.
217.142. Effect of incorporation of 10 CFR Part 31.
217.143. Certain measuring, gauging or controlling devices.
217.144. Incidental radioactive material produced by a particle accelerator.

§ 217.141. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, ~~[10 CFR 31.4 (relating to information collection requirements: OMB approval), 10 CFR 31.13 (relating to violations) and 10 CFR 31.14 (relating to criminal penalties)]~~ 10 CFR §§ 31.3, 31.4 AND 31.14 are not incorporated by reference.

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

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

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

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

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

(4) ~~[The definition of "licensed material"]~~ A REFERENCE TO "BYPRODUCT MATERIAL" includes NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

§ 217.143. Certain measuring, gauging or controlling devices.

In addition to the parts of ~~[10 CFR 30.5 (relating to interpretations)]~~ 10 CFR 31.5 (RELATING TO CERTAIN MEASURING, GAUGING, OR CONTROLLING DEVICES) incorporated by reference, general licensees SUBJECT TO REGISTRATION UNDER 10 CFR 31.5(c)(13)(i) OR POSSESSING GENERAL LICENSED DEVICES CONTAINING 370 MBq (10 mCi) OR MORE OF ACCERERATOR-PRODUCED MATERIAL, AS DETERMINED ON THE DATE OF MANUFACTURE, OR 3.7 MBq (0.1 mCi) OR MORE OF RADIUM-226 shall also comply with the following:

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

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

(ii) Furnish a report to the Department annually showing to the extent practicable, the make, model, serial number, isotope, source activity and location of each device. The report shall list an individual to contact regarding questions about this report.

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

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

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

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

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

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

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

(B) The name of the assigned user.

(C) Locations and dates of use.

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

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

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

transfer of radioactive material; and packaging and transportation of radioactive material). A licensee may dispose of this radioactive material only with Department approval.

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

Sec.

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

§ 217.151. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 32.8 (relating to information collection requirements; OMB approval) is~~] 10 CFR §§ 32.8, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.22, 32.23, 32.25, 32.26, 32.27, 32.28, 32.29, AND 32.40 are not incorporated by reference.

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

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

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

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

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

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

~~(5)~~] A reference to byproduct material includes NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC

LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

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

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

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

In addition to the incorporation by reference of requirements in 10 CFR 32.57 (relating to calibration sources containing americium-241) applicants using plutonium and radium-226 in the manufacture of calibration or reference sources shall comply with 10 CFR 32.57.

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

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

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

Subchapter E. [Reserved]

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

Sec.

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

§ 217.161. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 33.8 (relating to information collection requirements: OMB approval), 10 CFR 33.21 (relating to violations) and 10 CFR 33.22 (relating to criminal penalties)~~] 10 CFR §§ 33.8, 33.21 AND 33.22 are not incorporated by reference.

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

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

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

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

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

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

~~(5)~~] A reference to byproduct material includes NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

§ 217.163. Types of specific licenses of broad scope.

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

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

(2) A Type B specific license of broad scope is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of a chemical or physical form of radioactive material specified in Table 3, for an authorized purpose. The possession limit for a Type B broad license, if only one radionuclide

is possessed thereunder, is the quantity specified for that radionuclide in Column I, Table 3. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Column I, Table 3, for that radionuclide; the sum of the ratios for radionuclides possessed under the license may not exceed unity.

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

TABLE 3

LIMITS FOR BROAD LICENSES

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

Subchapter G. LICENSING OF SOURCE MATERIAL

Sec.

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

§ 217.171. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 40.5 (relating to communications), 10 CFR 40.6 (relating to interpretations), 10 CFR 40.8 (relating to information collection requirements: OMB approval), 10 CFR Part 40.81 (relating to violations) and 10 CFR Part 40.82 (relating to criminal penalties)~~] 10 CFR §§ 40.6, 40.8, 40.12(b), 40.23, 40.27, 40.28, 40.31(k), 40.31(i), 40.32(d), 40.32(e), 40.32(g), 40.38, 40.41(d), 40.41(e)(1),

40.41(e)(3), 40.41(g), 40.51(b)(6), 40.64, 40.66, 40.67, 40.81 AND 40.82 are not incorporated by reference.

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

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

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

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

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

(4) [~~The definition of "licensed material"~~] A REFERENCE TO "BYPRODUCT MATERIAL" includes NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

Subchapter H. LICENSING OF SPECIAL NUCLEAR MATERIAL

Sec.

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

§ 217.181. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 70.5 (relating to communications), 10 CFR 70.6 (relating to interpretations), 10 CFR 70.8 (relating to information collection requirements: OMB approval), 10 CFR 70.71 (relating to violations) and 10 CFR 70.72 (relating to criminal penalties)~~] 10 CFR §§ 70.1(c), 70.1(d), 70.1(e), 70.5, 70.6, 70.8, 70.13, 70.13a, 70.20a, 70.20b, 70.21(a)(1), 70.21(c), 70.21(f), 70.21(g), 70.21(h), 70.22(b), 70.22(c), 70.22(f), 70.22(g), 70.22(h), 70.22(i), 70.22(j), 70.22(k), 70.22(l), 70.22(m), §70.22(n), 70.23(a)(6), 70.23(a)(7), 70.23(a)(8), 70.23(a)(9), 70.23(a)(10), 70.23(a)(11), 70.23(a)(12), 70.23(b), 70.23a, 70.24, 70.25(a),

70.31(c), 70.31(d), 70.31(e), 70.32(a)(1), 70.32(a)(4), 70.32(a)(5), 70.32(a)(6), 70.32(a)(7), 70.32(b)(1), 70.32(b)(3), 70.32(b)(4), 70.32(c), 70.32(d), 70.32(e), 70.32(f), 70.32(g), 70.32(h), 70.32(i), 70.32(j), 70.32(k), 70.37, 70.40, 70.42(b)(6), 70.44, 70.51(c), 70.51(d), 70.51(e), 70.52, 70.53, 70.54, 70.55(c)(1), 70.55(c)(2), 70.55(c)(3), 70.56(c), 70.56(d), 70.57, 70.58, 70.59, 70.62, 70.71, AND 70.72 are not incorporated by reference.

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

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

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

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

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

(4) [~~The definition of "licensed material"~~] A REFERENCE TO "BYPRODUCT MATERIAL" includes NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

Subchapter I. TRANSFER OF RADIOACTIVE MATERIAL

Sec.

217.191. Transfer of material.

§ 217.191. Transfer of material.

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

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

~~(2) The United States Department of Energy.~~

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

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

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

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

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

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

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

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

~~(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the NRC, the licensing agency of an agreement state or a licensing state as to the identity of licensees and the scope and expiration dates of licenses.~~

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

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

THE REQUIREMENTS OF 10 CFR 30.41 (RELATING TO TRANSFER OF BYPRODUCT MATERIAL) SHALL ALSO APPLY TO NARM.

Subchapter J. RECIPROCITY

Sec.

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

§ 217.201. Incorporation by reference.

Except as provided in this subchapter, the requirements of **10 CFR 150.1 (RELATING TO PURPOSE),** 10 CFR 150.2 (relating to scope), **10 CFR 150.3 (RELATING TO DEFINITIONS),** 10 CFR 150.11 (relating to critical mass) and 10 CFR 150.20 **(a) (1), 150.20 (a) (2) AND 150.20 (b)** (relating to recognition of Agreement State licenses) are incorporated by reference.

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

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

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

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

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

(4) **[~~The definition of "licensed material"~~]** **A REFERENCE TO "BYPRODUCT MATERIAL"** includes NARM.

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

§ 217.203. Reciprocity of licenses of naturally occurring and accelerator-produced radioactive material.

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

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

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

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

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

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

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

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

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

(1) The person files a report with the Department within 30 days after the end of a calendar quarter in which a device is transferred to or installed in this Commonwealth. The report shall identify the general licensee to whom the device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device.

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

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

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

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

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

(*Editors Note*: As part of this rulemaking, the Department is deleting §§ 219.4, 219.21, 219.31--219.38, 219.52, 219.71--219.73, 219.91--219.93, 219.111--219.113, 219.151--219.158, 219.161, 219.162, 219.181--219.186, 219.201--219.211, 219.223--219.226, 219.241, Appendix A, Appendix B and Appendix C which appear at 25 Code pages 219-1--219-138, serial pages (252831), (252832), (204035)--(204038), (249251), (249252), (204041), (204042), (249253), (249254), (204045)--(204048), (249255), (249256), (204051)--(204054), (249257), (249258), (204057)--(204062), (249259), (249260), (204065)--(204070), (249261)--(249267), (204077)--(204080), (249269)--(249270) and (204083)--(204170). §§ 219.3 (Definitions) is amended to delete all existing definitions, reword the initial sentence, and add a new definition for "medical reportable event for radiation-producing machine therapy." The existing text of § 219.51 (relating to Dose limits for individual members of the public) is deleted and replaced with new wording. The existing text of §§ 219.61, 219.131, 219.132, 219.159, 219.160, 219.221, and 219.222 has been deleted and 10 CFR requirements incorporated as

noted together with Pennsylvania-specific text to include radiation-producing machines. § 219.229 is new.)

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

§ 219.3. DEFINITIONS.

The following [~~words and~~] term[~~s~~], when used this subchapter, [~~have~~] **HAS** the following meaning[s], unless the context clearly indicates otherwise:

MEDICAL REPORTABLE EVENT FOR RADIATION-PRODUCING MACHINE THERAPY – **THE ADMINISTRATION TO A HUMAN BEING, EXCEPT FOR AN ADMINISTRATION RESULTING FROM A DIRECT INTERVENTION OF A PATIENT THAT COULD NOT HAVE BEEN REASONABLY PREVENTED BY THE LICENSEE OR REGISTRANT, THAT RESULTS IN ONE OF THE FOLLOWING:**

(i) **AN ADMINISTRATION OF A THERAPEUTIC RADIATION DOSE TO THE WRONG INDIVIDUAL.**

(ii) **AN ADMINISTRATION OF A DOSE FOR THERAPY WHEN THE RESULT IS AN INCREASE IN THE TOTAL EXPECTED DOSES INSIDE OR OUTSIDE OF THE INTENDED TREATMENT VOLUME FOR ORGANS, TISSUE OR SKIN THAT EXCEEDS 20% OF THE TOTAL PRESCRIBED DOSE FOR THE INTENDED TARGET VOLUME.**

(iii) **A TOTAL DOSE DELIVERED TO THE TREATMENT SITE IDENTIFIED IN A WRITTEN DIRECTIVE FOR THERAPY THAT DIFFERS FROM THE TOTAL PRESCRIBED DOSE BY MORE THAN 20%, OR FOR A FRACTIONATED DOSE, WHEN THE WEEKLY ADMINISTERED DOSE DIFFERS FROM THE WEEKLY PRESCRIBED DOSE BY MORE THAN 30 PERCENT.**

§ 219.5. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 20.1006 (relating to interpretations), 10 CFR 20.1009 (relating to information collection requirements: OMB approval), 10 CFR 20.2401 (relating to violations) and 10 CFR 20.2402 (relating to criminal penalties)~~] **§§ 20.1006,**

20.1009, 20.2206(a)(1), 20.2206(a)(3), 20.2206(a)(4), 20.2206(a)(5), 20.2401, AND 20.2402 are not incorporated by reference.

§ 219.6. Effect of incorporation of 10 CFR Part 20.

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 20 (relating to standards for protection against radiation), the following words and phrases shall be substituted for the language in 10 CFR Part 20 as follows:

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

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

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

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

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

(6) A reference to "Department" in **[~~this chapter~~]** **10 CFR** means the United States Department of Energy.

(7) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

§ 219.7. EFFECT OF INCORPORATION OF 10 CFR 20.1403 "*CRITERIA FOR LICENSE TERMINATION UNDER RESTRICTED CONDITIONS*"

THE DEPARTMENT SHALL NOT TERMINATE A LICENSE UNDER THE CONDITIONS OF RESTRICTED RELEASE AS PROVIDED FOR IN 10 CFR 20.1403 UNTIL A LICENSE TERMINATION PLAN (LTP), APPROVED BY THE DEPARTMENT, HAS BEEN IN EFFECT FOR A PERIOD OF TIME SUFFICIENT TO DEMONSTRATE TO THE DEPARTMENT THAT CONTINUED IMPLEMENTATION OF THE PLAN WILL BE EFFECTIVE IN MAINTAINING COMPLIANCE WITH THE REQUIRED CONDITIONS OF THE PLAN. THE DEPARTMENT MAY CHOOSE TO IMPLEMENT THE LICENSE TERMINATION PROCESS IN ONE OR MORE OF THE FOLLOWING STEPS:

(1) THE LICENSE IS AMENDED TO AUTHORIZE ACTIVITIES NECESSARY TO BEGIN DECOMMISSIONING UNDER THE LTP.

(2) AFTER DECOMMISSIONING ACTIVITIES ARE COMPLETE AND THE PROVISIONS OF 10 CFR 20.1403 ARE IN EFFECT UNDER THE LTP, THE

LICENSE MAY BE AMENDED TO END AUTHORIZATION OF LICENSED ACTIVITIES. HOWEVER, THE LICENSE SHALL REMAIN IN EFFECT FOR A PERIOD OF UP TO FIVE YEARS BEING LIMITED TO OWNERSHIP / POSSESSION OF THE DECOMMISSIONED MATERIAL.

(3) AT THE END OF THE PERIOD PRESCRIBED IN PARAGRAPH (2), THE DEPARTMENT SHALL MAKE A DETERMINATION OF THE EFFECTIVENESS OF THE LTP AS ENACTED. IF THE LTP HAS DEMONSTRATED THE ABILITY TO MAINTAIN COMPLIANCE WITH 10 CFR 20.1403, THE LICENSE SHALL BE TERMINATED SUBJECT TO THE REVISITATION PROVISION OF 10 CFR 20.1401(C) REGARDING NEW EVIDENCE OF A SIGNIFICANT THREAT TO HEALTH AND SAFETY. OTHERWISE, THE LICENSEE SHALL BE DIRECTED BY THE DEPARTMENT TO TAKE CORRECTIVE ACTIONS AS NECESSARY TO CONFORM TO 10 CFR 20.1403 AND THE PROCESS SHALL REVERT BACK TO PARAGRAPH (2).

(Editors note: Sections 219.21 and 219.31-219.38 are deleted and are not printed here).

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

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

In addition to incorporation by reference of 10 CFR Part 20 Subpart D (relating to dose limits for individual members of the public), registrants who met the previous limit (5 mSv or 0.5 REM in 1 year) for locations having existing radiation-producing machines or equipment or other registered radiation sources will not be required to retrofit installations existing before November 18, 1995. The Department does not require the retrofitting of shielding for the replacement of equipment in the facility as long as the equipment is being replaced with similar equipment.

(Editor's note: Section 219.52 is deleted and is not reprinted here.)

Subchapter E. TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

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

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

* * * * *

(Editor's note: Sections 219.71-219.73, 219.91-219.93 and 219.111-219.113 are deleted and are not reprinted here.)

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

§ 219.131. Security of stored sources of radiation.

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

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

In addition to incorporation by reference of 10 CFR Part 20 (relating to standards for protection against radiation), the licensee or registrant shall maintain control of radiation producing machines that are not in storage.

Subchapter J. PRECAUTIONARY PROCEDURES

§ 219.159. Posting of radiation-producing machines.

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

"CAUTION--RADIATION
THIS EQUIPMENT PRODUCES RADIATION
WHEN ENERGIZED."

§ 219.160. Exceptions to posting requirements.

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

(Editor's note: Sections 219.161 and 219.162, 219.181-219.186 and 219.201-219.211 are deleted and are not reprinted here.)

Subchapter M. REPORTS

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

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

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

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

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

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

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

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

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

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

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

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

§ 219.222. Notification of incidents AND REPORTABLE EVENTS.

In addition to incorporation by reference of the requirements in **10 CFR 20.2202 (RELATING TO NOTIFICATION OF INCIDENTS) AND 20.2203 (RELATING TO REPORTS OF EXPOSURES, RADIATION LEVELS AND**

CONCENTRATIONS OF RADIOACTIVE MATERIAL EXCEEDING THE CONSTRAINTS OR LIMITS), those notification requirements, **AS WELL AS WRITTEN 30-DAY REPORTS PURSUANT TO 10 CFR 20.2203(a)**, also apply to radiation-producing machines and NARM.

§219.228. Reports of [~~misadministrations from X-ray~~] MEDICAL REPORTABLE EVENTS FOR RADIATION- PRODUCING MACHINE THERAPY.

(a) For a **[~~misadministration from X-ray,~~]** **MEDICAL REPORTABLE EVENT FOR RADIATION-PRODUCING MACHINE THERAPY,** the licensee or registrant shall do the following:

(1) Notify the Department by telephone no later than 24 hours after discovery of the **[~~misadministration~~]** **EVENT.**

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

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

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

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

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

(b) The licensee or registrant shall retain a record of each [~~misadministration~~] **MEDICAL REPORTABLE EVENT FOR RADIATION-PRODUCING MACHINE THERAPY** for 5 years. The record shall contain the names of the individuals involved (including the prescribing physician, allied health personnel, the patient and the patient's referring physician), the patient's Social Security number or identification number if one has been assigned, a brief description of the [~~misadministration~~] **EVENT,** why it occurred, the effect on the patient, what improvements are needed to prevent recurrence and the actions taken to prevent recurrence.

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

§ 219.229 OTHER MEDICAL REPORTS .

WITHIN 30 DAYS OF THE DISCOVERY OF EITHER ACTUAL OR SUSPECTED ACUTE OR LONG-TERM FUNCTIONAL DAMAGE TO TISSUE OF A PATIENT EXPOSED TO THERAPEUTIC OR DIAGNOSTIC RADIATION FROM A RADIATION-PRODUCING MACHINE, THE REGISTRANT OR LICENSEE SHALL DOCUMENT THEIR FINDING AND PROVIDE A REPORT TO THE DEPARTMENT AND PROVIDE A CLINICAL SUMMARY TO THE PRESCRIBING PHYSICIAN AND THE PATIENT. THE REPORT SHALL BE RETAINED FOR AT LEAST 5 YEARS. EXEMPT FROM THIS REPORTING REQUIREMENT ARE ANY EVENTS ALREADY REPORTED PURSUANT TO SECTION 219.228 (RELATING TO NOTIFICATION OF INCIDENTS AND REPORTABLE EVENTS)AND ANY FUNCTIONAL DAMAGE TO PATIENT TISSUE THAT WAS AN EXPECTED OUTCOME WHEN THE CAUSATIVE PROCEDURES WERE PRESCRIBED.

(Editor's Note: Subchapter N, Additional Requirements, is deleted. Section 219.241 was renumbered as new Section 215.27 and amended.)

(Editor's Note: Appendices A, B and C are deleted and are not reprinted here.*)*

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

§ 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.

* * * * *

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

§ 220.9. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 19.4 (relating to interpretations), 10 CFR 19.5 (relating to communications), 10 CFR 19.8 (relating to information collection requirements: OMB approval), 10 CFR 19.30 (relating to violations) and 10 CFR 19.40 (relating to criminal penalties)~~] 10 CFR §§ 19.4, 19.5, 19.8, 19.30, AND 19.40 are not incorporated by reference.

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

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

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

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

(3) A REFERENCE TO "LICENSE", "LICENSES", "LICENSED", AND "LICENSED RADIOACTIVE MATERIAL ALSO INCLUDE REGISTRATION, REGISTRANT, REGISTERED, AND REGISTERED SOURCE OF RADIATION, RESPECTIVELY.

(4) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

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

Subchapter A. GENERAL

§ 224.10. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, ~~[10 CFR 35.8 (relating to information collection requirements: OMB approval), 10 CFR 35.990 relating to violations) and 10 CFR 35.991 (relating to criminal penalties)]~~ 10 CFR §§ 35.8, 35.990, AND 35.991 are not incorporated by reference.

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

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

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

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

(3) ~~[The definition of "licensed material"]~~ A REFERENCE TO "BYPRODUCT MATERIAL" includes NARM.

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

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

(6) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

Subchapter B. OTHER REQUIREMENTS

§ 224.21. Supervision.

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

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

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

§ 224.22. Authorization for calibration and reference sources.

Notwithstanding the incorporation by reference of 10 CFR Part 35, a licensee authorized for medical use radioactive materials may receive, possess and use sealed sources of radioactive material up to ~~[27 mCi (1,000 MBq)]~~ **1,110 MBq (30 mCi)** apiece for check, calibration and reference use.

§ 224.23. Decay-in-storage.

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

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

(*Editor's Note*: As part of this rulemaking, the Department is deleting the text of §§ 225.2, 225.11--225.18, 225.21--225.23, 225.31--225.33, 225.41--225.44 and 225.51--225.53 which appears at 25 Pa. Code pages 225-3--225-18, serial pages (203957)--(203972). Appendix A is retained.)

Subchapter A. GENERAL PROVISIONS

Sec.

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

§ 225.1. Purpose and scope.

(a) This chapter establishes radiation safety requirements for persons utilizing radiation sources for industrial radiography. Licensees and registrants who use radiation sources for industrial radiography shall comply with this chapter. The

requirements of this chapter are in addition to and not in substitution for other applicable requirements in this article, **in particular, the requirements and provisions of Chapters 215, 217--220, 228 and 230.**

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

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

(Editor's note: The following text is new and printed in regular type to enhance readability.)

§ 225.2a. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, **[~~10 CFR 34.5 (relating to interpretations), 10 CFR 34.8 (relating to information collection requirements: OMB approval), 10 CFR 34.121 (relating to violations) and 10 CFR 34.123 (relating to criminal penalties)~~]** **10 CFR §§ 34.5, 34.8, 34.121 AND 34.123** are not incorporated by reference.

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

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

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

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

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

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

(5) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

§ 225.4a. Radiation safety program.

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

§ 225.5a. Reciprocity.

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

§ 225.6a. Prohibitions.

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

Subchapter B. RADIATION-PRODUCING MACHINES

GENERAL ADMINISTRATIVE REQUIREMENTS

Sec.

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

GENERAL TECHNICAL REQUIREMENTS

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

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

225.91. Radiation survey meter requirements.
225.92. Radiation survey meter calibration requirements.

225.93. Personnel monitoring control.

RADIATION-PRODUCING MACHINE REQUIREMENTS

225.101. Cabinet X-ray systems and baggage/package X-ray systems.
225.102. Shielded room X-ray radiography.
225.103. Temporary job site radiography.
225.104. X-ray detection systems for explosives, weapons and illegal items.

§ 225.71. Definitions.

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

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

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

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

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

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

***DIRECT READING DOSIMETER (DRD)*—AS USED IN THIS SUBCHAPTER, MEANS AN "INDIVIDUAL MONITORING DEVICE" (SEE 10 CFR 20.1003 *DEFINITIONS*) THAT DOES NOT REQUIRE ADDITIONAL PROCESSING TO MEASURE AN INDIVIDUAL'S DOSE. THIS ALSO INCLUDES THE DIRECT READING PERSONNEL (INDIVIDUAL) MONITORING DEVICES KNOWN AS POCKET DOSIMETER, POCKET IONIZATION CHAMBER AND ELECTRONIC PERSONAL DOSIMETER (EPD).**

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

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

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

(i) Physically present at the site.

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

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

***PERSONNEL DOSIMETER*—AS USED IN THIS SUBCHAPTER, MEANS ANY OF THE "INDIVIDUAL MONITORING DEVICES" (SEE 10 CFR 20.1003 *DEFINITIONS*) THAT MUST BE PROCESSED AND EVALUATED TO GENERATE A PERMANENT RECORD OF AN INDIVIDUAL'S DOSE, FOR EXAMPLE A FILM BADGE, THERMOLUMINESCENT DOSIMETER (TLD), OR OPTICALLY STIMULATED LUMINESCENT DOSIMETER (OSLD).**

RSO--Radiation Safety Officer--An individual who ensures that, in the daily operation of the registrant's or licensee's radiation safety program, activities are being performed in accordance with approved procedures and are in compliance with Department requirements. ~~[An RSO shall have the authority to suspend or terminate radiographic operations].~~

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

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

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

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

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

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

§ 225.72. Duties of personnel.

(a) The RSO shall assure that the radiation safety program of the registrant or licensee is implemented and suspend or terminate operations that are not being

conducted in accordance with approved procedures or the Department's requirements.

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

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

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

§ 225.73. Training of personnel.

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

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

§ 225.74. Training and testing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 225.76. Reporting requirements.

(a) In addition to the reporting requirements in **[~~Chapter 219 (relating to standards for protection against radiation)~~]** **SECTION 219.221 (RELATING TO REPORTS OF STOLEN, LOST OR MISSING LICENSED OR REGISTERED SOURCES OF RADIATION) AND SECTION 219.222 (RELATING TO NOTIFICATION OF INCIDENTS AND REPORTABLE EVENTS)**, each registrant or licensee shall provide to the Department, within 30

days of its occurrence, a written report on any of the following incidents involving machines or equipment used in radiographic operations:

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

(2) An interlock failure during shielded room radiography.

(b) The registrant **OR LICENSEE** shall include the following information in each report submitted under subsection (a):

(1) A description of the equipment problem.

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

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

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

(5) Actions taken to reestablish normal operations.

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

(7) The names and qualifications of personnel involved.

(c) Reports of overexposures, required under 10 CFR 20.2202 (relating to notification of incidents) or of excessive exposures, required under 10 CFR 20.2203 (relating to reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits) which involve the failure of safety components of radiography equipment shall also include, **TO THE EXTENT KNOWN,** the information specified under subsection (b). **COMPLETE INFORMATION REQUIRED IN SUBSECTION (b) SHALL BE AVAILABLE IN THE 30-DAY FOLLOWUP REPORT RULE UNDER 10 CFR 20.2203 (a).**

GENERAL TECHNICAL REQUIREMENTS

§ 225.81. Permanent radiographic installations.

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

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

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

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

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

§ 225.82. Operating requirements.

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

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

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

(1) The appropriate barrier ropes and warning signs.

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

(3) ~~[A current whole body individual monitoring device, for example, a "film badge" or "TLD" for]~~ **FOR** each worker **REQUIRING MONITORING, AN INDIVIDUAL PERSONNEL DOSIMETER THAT IS PROCESSED AND EVALUATED BY A NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM (NVLAP) PROCESSOR.**

(4) An operable, calibrated ~~[pocket ionization chamber, that is, a "pocket dosimeter"]~~ **DIRECT READING DOSIMETER** with a range of zero to 51.6 μC/kg (200 milliroentgen) for each worker **REQUIRING MONITORING.**

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

§ 225.83. Records required at temporary job sites.

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

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

(2) Operating and emergency procedures.

(3) Relevant regulations of the Department.

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

(5) Daily ~~[pocket ionization chamber]~~ **DIRECT READING DOSIMETER** records for the period of operation at the site.

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

§ 225.84. Operating and emergency procedures.

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

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

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

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

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

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

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

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

(8) Maintenance of records required by the Department.

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

§ 225.85. Surveys and survey records.

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

(b) Records of the surveys required by subsection (a) shall be maintained (for inspection by the Department) for 3 years. If the survey has been used to determine an individual's exposure, the records of the survey shall be maintained until the Department [~~authorizes their disposition~~] TERMINATES THE REGISTRATION OR LICENSE.

§ 225.86. Utilization logs.

A registrant or licensee shall maintain current logs, which shall be kept available for inspection by the Department for 3 years from the date of the event, showing for each radiation-producing machine, the following applicable information:

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

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

(3) The locations and dates of use.

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

§ 225.87. Security.

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

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

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

§ 225.88. Posting.

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

RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

§ 225.91. Radiation survey meter requirements.

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

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

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

§ 225.92. Radiation survey meter calibration requirements.

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

(b) Each radiation instrument shall be calibrated:

(1) At energies appropriate for use.

(2) At intervals not to exceed 6 months.

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

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

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

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

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

§ 225.93. Personnel monitoring control.

(a) The registrant **OR LICENSEE** may not permit an individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each individual wears a direct reading **[~~pocket~~]** dosimeter and [**~~either a film badge, thermoluminescent dosimeter (TLD), optically stimulated luminescent dosimeter (OSLD) or other Department approved personnel monitoring device~~]** **A PERSONNEL DOSIMETER THAT IS PROCESSED AND EVALUATED BY A NVLAP PROCESSOR.**

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

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

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

(b) Film badges shall be replaced at intervals not to exceed 1 month. **[~~TLDs and OSLDs~~]** **OTHER PERSONNEL DOSIMETERS PROCESSED AND EVALUATED BY AN ACCREDITED NVLAP PROCESSOR** shall be replaced at intervals not to exceed 3 months.

(c) **[~~Pocket~~]** **DIRECT READING** dosimeters shall meet the criteria as in ANSI N13.5-1972, "performance specifications for direct reading and indirect reading pocket dosimeters for X- and gamma-radiation" published in 1972, exclusive of subsequent amendments or additions.

(d) The use of direct reading **[~~pocket~~]** dosimeters is subject to the following requirements:

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

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

(3) Direct reading **[~~pocket~~]** dosimeters **[~~and electronic personal dosimeters~~]** shall be checked for correct response to radiation at periods not to exceed 1 year. A dosimeter may not be used for personnel monitoring unless the response is accurate within +/- **[~~30%~~]** **20%** of the true radiation exposure. Records of dosimeter response checks shall be maintained for inspection by the Department for 3 years.

(4) If an individual's direct reading **[~~pocket or electronic personal~~]** dosimeter indicates exposure that is "off-scale" beyond the range it can measure, industrial

radiographic operations by that individual shall cease immediately and the individual's [~~film badge, TLD or OSLD~~] PERSONNEL DOSIMETER shall be sent immediately for processing. The individual may not use any sources of radiation until the individual's radiation dose has been determined.

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

RADIATION-PRODUCING MACHINE REQUIREMENTS

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

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

(b) [~~It may not be possible to energize a~~] A cabinet X-ray system SHALL NOT BE ENERGIZED unless all openings are securely closed and [~~the openings meet the requirements of~~] EXPOSURE TO RADIATION FROM THE SYSTEM DOES NOT EXCEED THE LIMITS IN [~~10 CFR 20.1201 (relating to occupational dose limits for adults)~~.] 10 CFR 20.1301 (RELATING TO DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC). Each access door to the cabinet shall have an interlock that terminates the exposure whenever the door is opened. The enclosure shall be shielded so that every location on the exterior meets the conditions for an unrestricted area.

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

(d) The registrant shall evaluate the cabinet X-ray system to assure compliance with [~~10 CFR 20.1201~~] 10 CFR 20.1301 (RELATING TO DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC) and 21 CFR 1020.40 if the system is a certified cabinet X-ray system. Records of these evaluations shall be maintained for inspection by the Department while the system is in the possession of the registrant or until the evaluation is replaced by an update following modifications.

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

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

§ 225.102. Shielded room X-ray radiography.

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

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

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

§ 225.103. Temporary job site radiography.

(a) The operator shall conduct a physical radiation survey to determine that the radiation source is 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 3 years.

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

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

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

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

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

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

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

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

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

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

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

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

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

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

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

(3) To the extent practicable, the X-ray system (X-ray tube, imaging system and the object being irradiated) shall be completely enclosed so that every location on the exterior meets conditions for an unrestricted area and the only access to the room or enclosure is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

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

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

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

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

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

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

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

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

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

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

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

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

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

(Editor's Note: As part of this rulemaking, the Department is deleting the text of §§ 226.1, 226.3, 226.11--226.51 and Appendices A and B which appear at 25

Pa. Code pages 226-1--226-15, serial pages (203978)--(203991). The following text is new and printed in regular type to enhance readability.)

GENERAL

§ 226.1. Purpose and scope.

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

(Editor's Note: Section 226.3 is deleted and is not reprinted here.)

§ 226.3a. Abandonment of a sealed source.

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

§ 226.4. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, ~~[10 CFR 39.5 (relating to interpretations), 10 CFR 39.8 (relating to information collection requirements: OMB approval), 10 CFR 39.101 (relating to violations) and 10 CFR 36.103 (relating to criminal penalties)]~~ **10 CFR §§ 39.5, 39.8, 39.101 AND 39.103** are not incorporated by reference.

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

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

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

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

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

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

(5) **NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR**

SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

PARTICLE ACCELERATORS

§ 226.61. Particle accelerators.

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

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

(*Editor's Note*: As part of this rulemaking, the Department is deleting the existing text of §§ 230.2, 230.11, 230.12, 230.14, 230.21--230.26, 230.41--230.46, 230.51, Appendix A and Tables I--IV which appear at 25 Pa. Code pages 230-1--230-30, serial pages (204173)--(204176), (245185), (245186), (204179)--(204202). The following text is new and has been printed in regular type to enhance readability.)

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE

§ 230.3. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 71.2 (relating to interpretations), 10 CFR 71.6 (relating to information collection requirements: OMB approval), 10 CFR 71.99 (relating to violations) and 10 CFR 71.100 (relating to criminal penalties)~~] **10 CFR §§ 71.2, 71.6, 71.13(c), 71.13(d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.47, 71.51, 71.52, 71.53, 71.55, 71.59, 71.63, 71.64, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.83, 71.99 AND 71.100** are not incorporated by reference.

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

To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material),

the following words and phrases shall be substituted for the language in 10 CFR Part 71 as follows:

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

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

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

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

(5) **NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.**

§ 230.5. Communications.

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

Subchapter B. GENERAL

(Editor's Note: Sections 230.11, 230.12, 230.14, 230.21-230.26, 230.41-230.46, 230.51, Appendix A and Tables I-IV are deleted and are not reprinted here. The existing text of §§ 230.13 and 230.47 is deleted and replaced with the text that follows.)

§ 230.13. Transportation of licensed material.

In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), if 67 Pa. Code **[~~Chapter~~]** **CHAPTERS** 403 (relating to hazardous materials transportation)**, 229 (RELATING TO INTERSTATE MOTOR CARRIER SAFETY REQUIREMENTS) AND 231 (RELATING TO INTRASTATE MOTOR CARRIER REQUIREMENTS)** or the regulations of the United States Department of Transportation **49 CFR PARTS 171 TO 180 AND 388 TO 397** are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

Subchapter D. OPERATING CONTROLS AND PROCEDURES

§ 230.47. Advance notification of transport of nuclear waste.

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

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

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

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

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

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

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

CHAPTER 232. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Sec.

232.1. Purpose and scope.
232.2. Incorporation by reference.

232.3. Effect of incorporation of 10 CFR Part 36.

§ 232.1. Purpose and scope.

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

(b) The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements in this article, in particular, the requirements and provisions of Chapters 215, 217--220 and 230.

§ 232.2. Incorporation by reference.

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

(b) Notwithstanding the requirements incorporated by reference, [~~10 CFR 36.5 (relating to interpretations), 10 CFR 36.8 (relating to information collection requirements: OMB approval), 10 CFR Part 36.91 (relating to violations) and 10 CFR Part 36.93 (relating to criminal penalties)~~] §§ 36.5, 36.8, 36.91 AND 36.93 are not incorporated by reference.

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

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

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

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

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

(4) NOTIFICATIONS, REPORTS AND CORRESPONDENCE REFERENCED IN THE INCORPORATED PARTS OF 10 CFR SHALL BE DIRECTED TO THE DEPARTMENT AND, FOR NRC LICENSES, TO THE NRC UNTIL AGREEMENT STATE STATUS IS IN EFFECT.

RADIOLOGICAL HEALTH AMENDMENTS
25 PA CODE CHS 215, 217, 219, 220, 224, 225, 226, 230 AND 232

ENVIRONMENTAL QUALITY BOARD REGULATION NO. 7-350

COMMENT AND RESPONSE DOCUMENT

Proposed Rulemaking (#7-350): Article V , Radiological Health, 25 PA Code Chapters 215, 217, 219, 220, 224, 225, 226, 230 and 232

This is a list of corporations, organizations and interested individuals from whom the Environmental Quality Board has received comments regarding the above referenced regulation.

ID	Name/Address	Zip	Submitted 1 pg Summary	Provided Testimony	Req Final Rulemaking
1	John A. Labrecque Michael J. Nanney II-VI Incorporated 375 Saxonburg Blvd. Saxonburg, PA	16056			
2	Michael A. Vince, Ph.D. Chief Medical Physicist & Radiation Safety Officer Altoona Hospital Center for Cancer Care 620 Howard Avenue Altoona, PA	16601-4899			
3	Eric Boeldt Radiation Safety Oficer Penn State University 6 Eisenhower Parking Deck University Park, PA	16802			
4	Michael Sheetz, M.S. CHP Senior Health Physicist Niversity of Pittsburgh G-7 Parran Hall Pittsburgh, PA	15261			
5	Jerry Rosen University of Pittsburgh Graduate School of Public Health Rm. G7 Pittsburgh, PA	15261			

ID	Name/Address	Zip	Submitted 1 pg Summary	Provided Testimony	Req Final Rulemaking
6	Robert E. Nyce Executive Director Independent Regulatory Review Commission 14th Floor, Harristown #2 333 Market Street Harrisburg, PA	17120			

COMMENT AND RESPONSES

Section 215.1 Purpose and Scope

1. Comment: "These subsections do not provide sufficient notice as to the requirements with which regulated parties must comply...there should be a citation to specific provisions of ...Title 10 that are incorporated by reference. In the alternative...provide that Title 10 is incorporated by reference with the exception of specific provisions that are not incorporated by reference. Additionally, the regulation should specifically reference the provisions of any other laws of the Commonwealth and any other provisions of the *Pennsylvania Code*, besides Article V, that apply". (6)

   Another commentator voiced a similar concern. "A clear and bolded statement regarding incorporation by reference should be included at the start of each chapter as appropriate." (5)

   Response: A list of each of the sections of the NRC regulations being incorporated by reference is impractical. Instead, the federal regulations are incorporated in their entirety and any sections not incorporated are listed. The language of incorporation by reference appears at the beginning of each Chapter or Subpart as necessary to identify the corresponding NRC regulations that are replacing or augmenting those Pennsylvania regulations. A suggestion to show a complete list of the incorporation of NRC regulations and exceptions at the beginning of Article V has been incorporated into the final rulemaking. Subsection 215.1(e) has been expanded to identify all of the exceptions to incorporation of 10 CFR. For convenience of the reader, the applicable NRC regulations and exceptions will continue to be identified at the beginning of the individual chapters or subparts of Article V.

   The equivalent Pennsylvania references to be universally substituted for words and phrases used throughout 10 CFR are identified in a new subsection (h).

   Existing references to other Commonwealth Laws and Pennsylvania Code described in 215.24, 221.11(a)(2), 226.51(d)(1) and 230.13(b) remain intact.

215.2 Definitions: Misadministration (medical event) from X-Ray

Three sets of comments were made regarding this definition. Two of the commentators expressed their position as isolated issues. (5,6) One commentator addressed the definition as a whole and provided a rewrite. (4) The individual issues are presented first.

2. Comment: "... the federal regulations contain a definition of misadministration... substantively different from the definition proposed... The regulation should also clarify whether the federal definition of misadministration is incorporated by reference." (6)

   Another commentator wrote "Replace the word Misadministration with Medical Event" (5)

   Response: To avoid confusion, "Misadministration (medical event) from X-Ray" has been renamed "Medical Reportable Event for Radiation Producing Machine Therapy" and moved to section 219.3 (relating to definitions). As such it is not connected to the definition of "Misadministration" in 10 CFR 35.2 (relating to definitions), which will be applicable only to administrations using radioactive material. These are separate definitions because the two modalities involved are similar but not identical. The 10 CFR 35.2 definition of misadministration is incorporated by reference through section 215.2 (relating to definitions) because of the need for compatibility with the NRC.

3. Comment: "... the provisions of the proposed definition identify the events that must be reported pursuant to section 219.228 relating to reports of misadministration from x-ray ... it would improve clarity to move the provisions of this definition to section 219.228..." (6)

   Response: The definition has been moved to section 219.3 (relating to definitions).

4. Comment: "... the commentators suggested adding words such as therapeutic or therapy and diagnosis to the description... The types of doses covered by this definition of misadministration are unclear. Does this term apply to doses for both therapy and diagnosis?" (6)

   Also, regarding subparagraph (i) another commentator offered "Either strike item (1) "An administration of a dose to the wrong individual" or change it to "An administration of a therapeutic dose to the wrong individual". (5)

Additionally, it was suggested that a minimum threshold dose be exceeded before applying the definition to situations involving delivery of a therapeutic exposure to the wrong individual. (4)

Response: The referral to dose under subparagraph (i) in the proposed definition has been clarified in the new definition to refer to "therapeutic radiation dose" in the final regulation. The mistaken exposure of the wrong individual to a therapeutic dose is too important to strike or ignore at any level. At the least, it suggests serious weakness in the licensee's or registrant radiation safety program.

5. Comment: "... Subparagraph (ii) defines misadministration as a dose that results in or is likely to result in functional damage to tissue. What is functional damage and how is it determined? Who determines whether functional damage has occurred? The subparagraph includes an exception for situations when damage is an expected outcome of the prescribed procedure or it cannot be avoided without compromising the efficacy of the procedure. Who makes the determination that these exceptions apply and when to file a report? The regulation should identify who is responsible for determining when an accident needs to be reported and who is responsible for the actual report." (6)

Another commentator questioned the use of functional damage as a criteria. "Strike item (ii) – the statement is so subjective as to make it unlikely that any event would ever be reported." (5).

Response: Reference to "functional damage" whether due to therapeutic or diagnostic doses has been removed from the definition but retained as a reporting requirement under new section 219.229 (relating to other medical reports). This will flag therapeutic or diagnostic occurrences of excessive exposure that may produce demonstrable deleterious effects but do not qualify as Medical Reportable Events for Radiation Producing Machine Therapy. However, any functional damage to patient tissue that was an expected outcome when the causative procedure was prescribed is exempted.

The reporting requirement refers to information possessed by the licensee or registrant. It is unnecessary to specify who will determine that a report is required or who will report it. That is the responsibility of the registrant or licensee as well as compliance with all other regulations. Determination of functional damage to tissue and medical outcomes are clinical considerations that can only be under the purview of the treating physicians and medical physicists.

The Department does not agree that suspected functional damage is too subjective to ever be reported. Probability of causation and

likelihood of outcomes are routine considerations used in assessing clinical treatment.

6. Comment: "... what is meant by the term wrong site? Does it include partial misalignment or exposure to boundary areas of the treatment site?" (6)

Concern was echoed by other commentators that a definition of wrong site might be needed to differentiate the regulatory response between gross targeting errors outside the treatment volume and errors of precision in and overlapping the treatment volume. (4 , 5)

More flexible limits were also suggested. "If the wrong site is taken to include a partial misalignment then better wording for (iii)(b) is, [The result is an increase in the total expected dose that exceeds the larger of 20% of the expected dose or 2.5 Gy (250 rad) or is expected to cause functional damage]" (5)

Response: References to "wrong site", "wrong energy" etc. have been removed from the definition so the meaning of "wrong site" in Subparagraph (iii) will no longer be relevant. The objective is to prohibit unnecessarily damaging exposure to any area of a patient. The reason for the excessive exposure is not significant. Only the criteria for an unacceptable exposure level is retained as a bench mark for defining a Medical Reportable Event for Radiation Producing Machine Therapy. Even if an event occurs in which this level is not reached, it will still be reported under new section 219.229 (relating to other medical reports), if it causes injury to the patient.

7. Comment: "The definition for Medical Event from X-ray in Ch. 215.2 should be revised to read as follows:" (4)

"Medical Event from X-ray - The administration to a human being, except for administrations resulting from the direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

(i) An administration of a dose for diagnosis or therapy to the wrong individual that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin.

(ii) An administration of a dose for diagnosis that results in or is likely to result in acute functional damage to tissue, unless the damage is an expected outcome of the prescribed procedure or

the damage can not be avoided without compromising the efficacy of the procedure.

(iii) An administration of a dose for therapy when one of the following applies:

(1) The total dose delivered to the intended treatment site identified in a written directive differs from the prescribed dose by more than 20%.

(2) The total weekly fractionated dose delivered to the intended treatment site identified in a written directive differs from the prescribed dose, for the number of fractions to be delivered in a week, by more than 50%.

(3) A dose is delivered to the wrong anatomical site from that which was specified in the written directive (this does not include positional errors of the treatment field targeting the intended treatment site).

(iv) An administration of a dose for therapy by the wrong treatment mode (photon versus electron), wrong effective energy, wrong applicator or wrong treatment geometry which results in a dose to the skin or an organ or tissue outside of the intended treatment site and causes clinically significant functional damage to the tissue."

"The purpose of number (1) is to include diagnostic errors which exceed a certain dose limit to the patient - consistent with NRC definition. Number (2) limits the type of damage which can occur from excessive interventional procedures only to acute effects to the skin, and does not include stochastic effects. For X-ray therapy, a tolerance level of 50% for one fraction is too restrictive. It is more appropriate, from a clinical standpoint, to control the total amount of radiation delivered over a week. The 50% tolerance level on a single fraction of dose incorporated in the new 10 CFR 35 regulations is intended for HDR brachytherapy and Gamma Knife radiosurgery where the doses per fraction are in excess of 500 rads. Typical doses for external beam therapy are 150 to 250 rads per fraction.

The definition of wrong treatment site needs to be defined to address both anatomical errors (right lung versus left lung) and positional or setup errors (deviation of the treatment field orientation from that intended, but still targeting the treatment site). The former clearly qualifies as a medical event from one fraction. However, with the later, is very difficult to set a rational threshold for these types of

deviations due to the subjective nature of defining appropriate treatment fields. Therefore, such errors should only be considered a medical event if it results in clinically significant damage." (4)

Response: This commentator's wording in subparagraph (i) introduces the concept of a threshold level for reporting. However, since the new proposed definition will not include diagnostic exposures it is not expected that any exposure to the wrong individual from therapy will be small or insignificant. Therefore no minimum value is stated in final form.

In final-form, the condition for functional damage is moved to new section 219.229 (relating to other medical reports). The wording of subparagraph (ii) is similar but adds the restriction of acuteness. Long term damage is also a legitimate concern and it is also included in the final-form of the regulation.

The comment on subparagraph (iii)(2) regarding error limits for therapy fractions suggests using a weekly error limit rather than an individual fraction error limit. The Department agrees with the use of a weekly limit; however, 30% not 50% is the value traditionally associated with teletherapy. The individual fraction limit will be replaced by a weekly error limit of 30% in the final-form regulation.

The comment on subparagraph (iv) would make certain errors of energy, geometry or mode applicable only if they result in "significant functional damage." Any error under the licensee or registrant's control that results in a deleterious effect is significant. The regulation in final-form addresses that concern.

In summary to the comments regarding the definition, the regulation in final-form replaces the functionality of the existing requirements for misadministration for x-ray therapy. It defines a medical reportable event for radiation producing machine therapy only. However, the reporting requirements in the proposed regulation for therapeutic and diagnostic events of interest that did not meet the definition of "Medical Reportable Event" have also been captured by retaining the trigger of functional damage, but specifying it as a separate reporting requirement under section 219.229 (relating to other medical reports). Using the concept of functional damage makes the regulation outcome-based without locking in numbers for threshold values. The Department believes that these changes simplify the final regulation. Reference to an individual dose fraction has been deleted as unnecessarily restrictive. However, existing language pertaining to the constraints placed on weekly dose and total treatment dose are retained as they are generally accepted nationally. There are no longer separate standards for energies below 1 mev and above 1 mev or separate categories of dose fractions. The source of errors (wrong beam energy, wedge factor, etc.) is no longer specified, the trigger is the outcome

of increasing dose by more than 20 percent. The previous difficulty in reconciling wrong treatment site with alignment accuracy versus gross positional errors no longer exists.

Section 215.27. Vacating premises.

8. Comment: A commentator suggested the regulation should include criteria and standards for decontamination. (6)

   Response: No change is necessary. The situations requiring decontamination are identified in 10 CFR 30.36. The standards are incorporated by reference in 10 CFR Part 20 Subpart E. The language "When deemed necessary by the Department, the licensee shall decontaminate the premises as the Department may specify" reflects the caveat that, though there are decontamination standards, the standards are maximum limits that are also subject to the criteria of "ALARA" (as low as reasonably achievable). ALARA may vary with circumstances and is in the judgment of the Department.

   However, to add clarity as suggested to issues regarding decontamination, a new Section 219.7 (relating to incorporation of 10 CFR 20.1403 "*Criteria for license termination under restricted conditions*") has been added to clarify the process of obtaining a license termination under restricted release conditions.

Section 215.28. Deceptive exposure of a monitoring device.

9. Comment: A commentator indicated that section 215.28 is unclear, and asked that its intent be clarified. (6)

   Response: The Department agrees and has clarified this section in the final rulemaking.

Section 217.131. Incorporation by reference.

10. Comment: A commentator suggested that the specific regulations of 10 CFR Part 30 that are incorporated by reference, and when they are superceded, is vague. Subsection (b) would be unnecessary if each applicable section of Part 30 was specified. The same concerns apply to Sections 217.141, 217.151, 217.161, 217.171, 217.181, 217.201, 219.5, 220.9, 224.10, 225.2a, 226.4, 230.3, and 232.2. (6)

    Response: As noted in the Department's response to comment #1, specification of each applicable section of 10 CFR Part 30 is impractical. The scope of incorporation has been defined in the alternative by listing the exclusions to incorporation in entirety. For clarity, subsection

217.13(b) lists all the sections of 10 CFR not incorporated by reference.

Section 217.191 Transfer of Material.

11. Comment: Two commentators requested deletion of Subsection 217.191(c)(4) and Subsection 217.191(c)(1) that allow verification using other sources of information compiled from official records or from information presented by personally examining a copy of the transferee's current license. The reason was that only direct contact with the licensee could ensure that the quantity of material to be transferred would not exceed the recipient's authorized license limits when added to existing inventory (a quantity that would only be unknown by the licensee). (3,6)

Response: The comments appear to misinterpret what a transferor is required to verify in regards to the quantity of material authorized by the recipient's license. The transferor is not required to consider or verify the quantity that the recipient has already. (The recipient is responsible for controlling their inventory. The recipient, not the transferor, will be held responsible if the license possession limits are exceeded.) The transferor must verify that the material transferred does not exceed the quantity limits listed in the license document. This is why a copy of the recipient's license or an official record describing the license are listed as acceptable forms of verification. It is agreed that if the recipient has a poor procurement system, it may under certain circumstances lead to a technical violation of possession limits. The low probability of a possession limit violation and the minimal safety impact do not warrant deleting the regulation or imposing impractical burdens upon the transferor.

The Department is also not aware of whether the provision for utilizing reporting services has ever been exercised. In the history of the regulation, no one has approached the agency for access to compile this data. If a third party reporting mechanism were proposed, it would require approval by the Department.

These are not new, but existing regulations formerly located in section 217.101. Since they are a requirement for compatibility with the NRC, these provisions and those of section 217.191(c)(4) have been retained. However, the text of Subchapter I has been replaced with language incorporating 10 CFR 30.41 by reference in the final rulemaking.

12. Comment: [Regarding subsection 217.191(a)(3)], "The regulation should indicate who would be exempt [from Article V] and how an exemption is granted" (6)

Response: In the regulations, exemptions are granted without petition to certain persons meeting the specifications described in the regulations. For example, section 215.32 cites federal agencies in general and subsection 217.13(a) allows transfer of exempt quantities not for commercial distribution. Section 215.31 also permits the Department to grant exemptions by petition or by fiat such as a license condition. It is not practical to list all possible exemptions with any section. That would invite the same for all other sections of the regulations. The format has been to list exemptions of general applicability in Chapter 215. Other exemptions appear in the chapters that most closely regulate the provisions addressed by the exemption.

13. Comment: [Regarding subsection 217.191(a)(4)], "Subsection (a)(4) refers to a general license or its equivalent, or a specific license or equivalent licensing document. Are equivalent licenses issued by another jurisdiction? The final-form regulation should clarify what documents are equivalent to general or specific licenses." (6)

Response: Document naming conventions may vary among different regulatory agencies. The equivalent of a general license in these regulations may be called a registration certificate in another state. A specific license may be a permit elsewhere. In any case the licensing requirements are not necessarily identical in all jurisdictions. A regulated activity that requires a specific license in one jurisdiction may be allowed under a general license in another jurisdiction. Equivalent documents cannot be specified in advance. It is the responsibility of the transferor to ascertain whether the authorization of the transferee meets the requirements of the regulation.

14. Comment: [Regarding subsection 217.191(a)(5)], "Subsection (a)(5) refers to a person otherwise authorized by the Department in writing. The regulation should specify who would fall into this category." (6)

Response: This rule is intended for flexibility. There is no way to anticipate every person who might fall into this category. An example is Section 217.22 that requires a licensee to obtain Department approval before a license can be transferred to another entity such as expected during a corporate merger.

15. Comment: [Regarding subsection 217.191(c)(3)], "Subsection (c)(3) refers to oral certification. A definition of "oral certification" would improve clarity." (6)

Response: The Department believes the meaning of "oral certification" to be ordinary language and sufficiently obvious. The formality of an "oath" is not implied. The recipient transmits and attests verbally to such

information contained in the license document that the transferor is required to verify in the manner specified by the subsection. The certification is not all oral as it must be completed by a written confirmation within 10 days.

Section 220.2(a)(3) Posting of notices to workers.

16. Comment: "Although this [section 220.2(a)(3) *posting of notices to workers*] is not a change from the current regulations, posting comprehensive operating procedures for a research and development organization does not seem possible. Posting operating procedures for radioactive devices or X-ray machines... is a reasonable and useful requirement. Trying to post procedures for wet chemistry work would just be confusing... Please revise §220.2(a)(3) to [read "*The operating procedures applicable to activities under the registration.*"]. (3)

Response: The Department disagrees. The requirement applies to activities involving licensed radiation sources as well registered sources and unsealed radioactive material as well sealed sources and devices emitting radiation. The comment appears to be based upon a misunderstanding of the requirement. The procedures relative to the regulated activity are the procedures for implementing the radiation safety program. Rather than technical procedures that the commentator alludes to, these are things such as the general radiation safety manual and any specific safety procedures relevant to the posted area. It would address concerns like "personnel monitoring required beyond this point" or "verify the target room is unoccupied before energizing" etc. In any case, where a complete posting is impractical because safety concerns in the local work area are more complicated than a few simple admonitions like, "do not pipette by mouth", section 220.2(b) only requires that the posting contain a reference to the location of the pertinent documents.

Chapter 224 Medical use of radioactive material

17. Comment: There is a general objection to incorporation by reference of 10 CFR Part 35. The commentator believes the NRC regulations of Part 35 are inconsistent, contradictory and not right in general. The formation of a task force to develop independent regulations that can be crafted to eliminate perceived problems is recommended. (2)

Response: Radiation-producing machine therapy is handled separately from Chapter 224 and 10 CFR Part 35. Only those licensees who are already subject to Part 35 are affected. For them, no change is proposed at this time. It is common knowledge that the NRC has had much friction with the medical community over the years and the NRC

is currently working on a comprehensive revision to Part 35. Amendments to Chapter 224 will not be contemplated until it is apparent how the new Part 35 will look.

Section 225.71. Definitions: RSO – Radiation Safety Officer

18. Comment: "The last sentence of this definition [radiation safety officer] is substantive. Furthermore the information in this sentence is included in [Section 225.72 (relating to duties of personnel)]...For these reasons the last sentence should be deleted from the definition." (6)

    Response: The Department agrees and the sentence has been deleted.

Section 225.74. Training and testing.

19. Comment: Regarding subsection (a)(3), a commentator questioned how many hours of safety instruction are required and suggested that a minimum number of hours should be specified. (6)

    Regarding subsection (a) (4) the commentator also noted that each licensee / registrant may conduct their own testing and certification. Is there adequate assurance of safety without requiring standardized testing. (6)

    Response: With respect to subsection (a)(3), no set time or minimum time will be established because this is a performance based requirement which is satisfied by passing a written test and field examination. The degree of effort is variable depending upon the individual.

    With respect to subsection (a)(4), non-destruct testing radiography with radiation producing machines is inherently safer than with radiographic exposure devices using radioactive material. The relative relaxation in the regulations reflects this. The majority of programs utilize sources in completely shielded cabinets or rooms. Except in the case of accelerators, an evaluation of the program for safety training does not occur prior to the routine site inspections conducted by the Department. For accelerators, prior review of training is conducted as part of the licensing process. (Note: non-accelerator x-ray is an activity registered after the fact, not a licensed activity regulated before the fact.)

Section 225.76. Reporting requirements.

20. Comment: A commentator suggested that it is not clear whether notification of excessive exposure under subsection (c) is required to be followed up

by a report within 30 days as is required by the events in subsection (a) (6).

Response: Thirty-day reports under subsection (c) are required. Subsection (c) references 10 CFR 20.2203, which proscribes the thirty-day reporting requirement for events covered by 10 CFR 20.2202 and 20.2203. However, the Department agrees that references to thirty-day reporting requirements should be further clarified. Subsection (a) now references sections 219.221 and 219.222 specifically. Section 219.222 has been renamed "*Notification of Incidents and Reportable Events*" since it represents both Parts 20.2202 and 20.2203. The general reference to 10 CFR Part 20 in 219.222 has been replaced by specific references to Parts 20.2202 and 20.2203 and notes the written thirty-day reporting requirement. In regards to subsection 225.76(c), the reference to include the information in subsection 225.76 (b) will read "to the extent known". Complete information referenced in subsection 225.76 (b) may not be immediately available and will not be mandatory until the thirty-day report is due. Subsection (b) also references licensees in addition to registrants for clarity.

Section 225.82. Operating requirements.

21. Comment: A commentator asked that the terminology used throughout Subchapter B be consistent. Subsection 225.82(c)(4) and 225.84(5) refer to "pocket dosimeter" in quotes. The quotes should be removed and the term should be included in definitions. Elsewhere, it is also referred to as a "pocket ionization chamber," "direct reading personnel monitoring device," "direct reading pocket dosimeter" and a substitute for "electronic personal dosimeter". (6)

Response: This various usage of these terms mimics that employed by the NRC. There has been no confusion in the regulated community interchanging these commonly-used terms. However, for clarity, the references have been reduced to two standards. Since Subchapter B deals with radiation-producing machines and not NRC-regulated material, the two standard definitions, "direct reading dosimeter" and "personnel dosimeter" have been added to Section 225.71. For the purposes of Chapter 225, "personnel dosimeter" means any subset of "individual monitoring devices" (see 10 CFR 20.1003 *Definitions*) that must be processed and evaluated to generate a permanent record of an individual's dose. This also includes Film Badge, TLD and OSLD. "Direct reading dosimeter (DRD)" means an individual monitoring device that does not require additional processing to measure an individual's dose. This also includes direct reading personnel (individual) monitoring devices like pocket dosimeter, pocket

ionization chamber and electronic personal dosimeter. The appropriate substitutions have been made to terms in Subchapter B.

Section 225.83. Records required at temporary job sites.

22. Comment: "This section provides for the maintenance and availability for inspection of records or documents at the temporary job site. This section does address how these records are supposed to be handled after they are removed from the temporary job site. Does the record keeping requirement in Section 225.93 apply? If so, Section 225.93 should be referenced in Section 225.83 in the final-form regulation." (6)

Response: Other than to specify retention periods, it is not necessary to describe how records are to be handled after they are removed from a temporary job site. Pursuant to subsection 215.12(a), all records required under this article must be maintained and available for inspection. How this is accomplished is at the discretion of the licensee / registrant. With regard to the record keeping requirement in section 225.93, it applies to all of Chapter 225. A section of Chapter 225 is applicable to the entire chapter unless otherwise indicated such as through the use of phrases like "except for..." or "otherwise exempt from all other provisions of this chapter...". It is unnecessary to change the text of section 225.83.

Section 225.85. Surveys and survey records.

23. Comment: A commentator believes that a timetable should be specified for retention of surveys and records used to determine an individual's exposure. (6)

Response: The Department agrees. The final-form regulation has been changed to indicate the retention periods. The periods are consistent with similar regulations of the NRC. Surveys must be maintained for a period of three years unless they are used to determine personnel exposure. Then they must be maintained until termination of the registration or license.

Section 225.93. Personnel monitoring control.

24. Comment: A commentator noted that subsection (d)(1) requires dosimeters to be recharged at least daily or at the start of each work shift. Consideration should be given to deleting the phrase "at least daily". The commentator also questioned whether the term electronic "personal" dosimeter in subsection (d) is appropriate and whether the requirement should be moved to subsection (a).(6)

Response: The Department agrees with the change in subsection (d)(1). The phrase has been deleted. Also "recharged" has been changed to read "re-zeroed." The term electronic "personal" dosimeters is correct. However, the specific references to electronic personal dosimeter have been removed from subsection (d)(1)-(4) because the definition of "direct reading dosimeter" in the final rulemaking includes this term. The accuracy of DRDs in subsection (d)(3) has also been changed to 20% to conform with generally accepted standards and parallel regulations of the NRC for Industrial Radiography using radioactive sources.

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

25. Comment: A commentator believes that subsection (b) is not written as a requirement and should be rephrased for clarity. (6)

Response: Subsection (b) is a requirement and the Department has revised the first sentence accordingly. In addition, reference to 10 CFR 20.1301 rather than 10 CFR 20.1201 has been made in subsections (b) and (d).

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

26. Comment: A commentator objects to the wording of subsection (f)(2) that requires safety or warning devices to be repaired "in a timely manner." A specific time frame should be added. (6)

Response: The Department disagrees. Specifying a specific time frame such as 30 days would be unnecessarily prescriptive. It is not possible to determine the time needed to correct a malfunction that is not yet defined. More importantly, individuals operating equipment under this section do so potentially at grave risk from dangers far greater than the hazards associated with radiation from this equipment. In recognition of such overriding risks, and putting radiation risks in perspective, it is the intent of this section to apply more flexible requirements for radiation safety than are normally used for activities involving less risk.

Section 230.13. Transportation of licensed material.

27. Comment: "This section references the regulations of the NRC, Pennsylvania Department of Transportation, and U.S. Department of Transportation (USDOT). However, the section does not contain specific citations to the applicable regulations of the USDOT. In the *Pennsylvania Bulletin*, the amendment to this section changes it to one long sentence. The end of the sentence reads: ...the licensee shall conform to the standards and requirements of those **regulations** to the same

extent as if the shipment was subject to the **regulations** [emphasis added]. The intent of this section is unclear. To which rules and standards, is the term [regulations] referring?" (6)

Response: The Department agrees that the reference to "regulations" is unclear. Section 230.2 (relating to definitions) was deleted. The regulations of the U.S.DOT and PA DOT had been defined therein. The text of section 230.13 in final-form has been clarified to show the applicable references within the U.S. DOT and PA DOT regulations.

GENERAL COMMENTS

28: Comment: "At a minimum a copy of the definitions contained in 10CFR should be made available by the State to licensees and registrants who do not also hold NRC licenses. This might be accomplished by inclusion on the State's web site." (5)

Response: 215.1(g) lists hard bound sources of the incorporated regulations which includes definitions. The Department also plans to establish links in its web site to the document pages of the NRC's web site.

29. Comment: A commentator expressed general support for future Agreement State status. (1)

Response: The Department acknowledges this support. Compatible regulations are a requirement for acquiring Agreement State status.

Pennsylvania Department of Environmental Protection

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June 27, 2001

The Secretary **717-787-2814**

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, Harristown II
Harrisburg, PA 17101

RE: Final Rulemaking: Radiological Health (Chapters 215, 217, 219, 220, 224, 225, 226, 230, and 232 (#7-350)

Dear Bob:

Pursuant to Section 5.1(a) of the Regulatory Review Act, enclosed is a copy of a final-form regulation for review by the Commission. This final rulemaking was approved by the Environmental Quality Board (EQB) on June 19, 2001.

These amendments update the standards for the safe use of radioactive material for compatibility with Nuclear Regulatory Commission (NRC) regulations. The amendments are necessary for Pennsylvania to acquire Agreement State status from the NRC. Provisions of the NRC regulations pertaining to radioactive materials licenses contained in 10 CFR Parts 19-150 are incorporated by reference. The amendments also simplify provisions applicable to the possession and use of radiation-producing machines, particularly high-energy X-ray machines and particle accelerators.

The proposed rulemaking was adopted by the EQB on June 20, 2000, and published August 26 with a 30-day public comment period. Six commentators responded to the proposal. The Radiation Protection Advisory Committee (RPAC) endorsed a draft of the final rulemaking on March 1, 2001.

The Department will provide the Commission with any assistance required to facilitate a thorough review of this final-form regulation. Section 5.1(e) of the Act provides that the Commission shall, within ten days after the expiration of the committee review period, approve or disapprove the final-form regulation.

For additional information, please contact Sharon Trostle, Regulatory Coordinator, at 783-8727.

Sincerely,

David E. Hess
Secretary

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	7-350
SUBJECT:	Radiological Health
AGENCY:	DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6-27-01	Cindy Zimmerman	HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
6/27/01	P. Carrathan	SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
6/27/01	Elaine Pagan	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

June 20, 2001