PROPOSED RULEMAKING

ENVIRONMENTAL QUALITY BOARD

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

Radiological Health

The Environmental Quality Board (Board) proposes to amend Chapters 215—221, 223—228, 230 and 240. The primary purpose of the proposed amendments is to correct cross references that were rendered inaccurate by changes made in previous rulemakings where the sections linked by reference were not open to amendment. The regulations are also being generally updated and clarified as necessary.

This proposal was adopted by the Board at its meeting of July 15, 2003.

A. *Effective Date*

These proposed amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final-form rulemaking.

B. *Contact Persons*

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C. *Statutory Authority*

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

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

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

D. *Background and Purpose*

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

As a result of the revisions, many sections in Article V (relating to radiological health) now reference code that no longer exists. Those references show as "reserved." These proposed amendments only replace the orphaned references with the corresponding regulations incorporated by reference and impose no new requirements. Other amendments address the recent changes to NRC regulations that are incorporated by reference, most notably the comprehensive revision to 10 CFR Part 35 (relating to the medical use of by-product material). Licensees of this Commonwealth are already subject to these requirements by virtue of their radioactive material licenses and incorporation by reference of 10 CFR. Several amendments clarify the wording of existing regulations and their requirements, in most part involving radiation-producing machines. The existing regulations in § 216.6(c) (relating to assembly, transfer and disposal obligations) require persons involved in certain commercial and service activities involving radiation-producing machines to register their activities with the Department. There is a new § 216.2a (relating to the registration of radiation-producing machine service providers) along with the provision for registration fees and reporting requirements. Overall, the proposed amendments are necessary to improve the clarity, coherency and effectiveness of the regulations and restore linkages between sections that were broken in separate limited rulemakings.

As required by section 301(c)(14) of the act (35 P. S. § 7110.301), the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the proposed amendments and to advise the Department prior to submittal to the Board. On October 24, 2002, and November 20, 2002, the RPAC met and reviewed the proposed amendments. Most of the committee's discussion and input on this matter centered around how best to re-word parts of the regulations to improve clarity. This involved definitions such as "stray radiation," the use of impersonal pronouns such as the substitution of "individual" for "person" where actions are performed and the general use of words in syntax and context such as replacing "initial" with "prior to first use." Many of the comments are appropriate and incorporated in the proposed Annex A. The RPAC, by letter dated December 18, 2002 from the Chairman, recommended that the amendments to the radiological health regulations be sent to the Board as proposed rulemaking.

E. *Summary of Regulatory Requirements*

Unless otherwise specified, the proposed amendments reflect, and are not more stringent than Federal requirements in areas of Federal jurisdiction such as the use of byproduct material, the control of which would be assumed by the Commonwealth after attaining agreement state status. Other proposed regulations address areas where there is no Federal jurisdiction such as the use of radiation-producing machines and naturally occurring or accelerator-produced radioactive material (NARM) but the regulations attempt to assure application of a consistent regulatory structure for similar hazards through incorporation by reference of radiation protection standards that are common to both. Incorporation by reference increases

the ability of the regulatory community to participate in rulemaking, once at the Federal level and again when published in the *Pennsylvania Bulletin* as proposed rulemaking or by appeal to the Department. The Department may also issue Fact Sheets or Guidance on the regulations. The Department uses its website to help disseminate relevant information.

The significant parts of the proposed rulemaking are summarized as follows.

Chapter 215. General Provisions.

§ 215.1. Purpose and scope.

Subsection (e) lists which NRC regulations in 10 CFR are incorporated by reference. References to NRC sections 150.20(a)(1), 150.20(a)(2) and 150.20(b) are replaced by a reference to section 150.20.

Subsection (e)(4) lists which NRC regulations governing general licenses in 10 CFR Part 31 are not incorporated by reference. The reference excluding NRC section 31.3 dealing with a general license for certain devices distributed nationally is being deleted. The NRC now requires that the regulation be adopted for compatibility to become an Agreement State.

Subsection (e)(8) lists which NRC regulations governing medical use of radioactive material in 10 CFR Part 35 are not incorporated by reference. In a revision to 10 CFR Part 35 effective October 24, 2002, the previous sections 35.990 and 35.991 relating to violations and civil penalties respectively were renumbered to 35.4001 and 35.4002 in the revised CFR. The same changes have been made in subsection (e)(8) to avoid pointing to a nonexistent reserved reference.

Subsection (e)(11) lists which NRC regulations governing the licensing of source material in 10 CFR Part 40 are not incorporated by reference. Reference to NRC section 40.33 has been added to the list of regulations that are not incorporated by reference because that section deals with the authorization of licenses for uranium enrichment facilities. The NRC does not relinquish that authority to the states.

Subsection (e)(13) lists those NRC regulations governing the packaging and transportation of radioactive material in 10 CFR Part 71 that are not incorporated by reference. The reference to exclude NRC section 71.47 dealing with external radiation standards for packages is being deleted. The NRC now requires the regulation be adopted for compatibility to become an Agreement State. A reference to NRC section 71.61 dealing with irradiated nuclear fuel shipments has been added to the list to be excluded from incorporation by reference because the NRC does not relinquish that authority to the states. The reference to exclude NRC subsection 71.83 dealing with assumptions of properties in fissile packages is being deleted. The NRC no longer reserves this authority and allows states to regulate small quantities of fissile material. Adoption of this NRC regulation is now required for compatibility to become an Agreement State.

§ 215.2. Definitions.

License—The current definition of "license" in this section is for the possession and use of radioactive material. However, there are license requirements in Chapter 228 for accelerators that are not covered under this definition or any other because an accelerator is not radioactive material. An accelerator is a type of radiation-producing machine. The current definition has been modified. "Radiation sources" replaces "radioactive material." This accommodates accelerators and any other radiation sources that may be authorized for licensure under future rulemaking.

Major X-ray system component—A new term is defined. It is based on components identified in the United States Food and Drug Administration regulations 21 CFR Chapter I, Subchapter J, Radiological Health, Part 1020 Performance Standards for Electronic Products: General. It is used in conjunction with new § 216.2b, to identify which components fall under the new reporting and recordkeeping requirements for registered radiation-producing machine service providers.

Qualified expert—Similar terms exist under the definitions in §§ 215.2, 221.2 and 228.2. The term may be applicable to any chapter so the definition will be removed from §§ 221.2 and 228.2 and combined into the definition in § 215.2.

Radiological physicist—A radiological physicist is a type of qualified expert. The term is being deleted and references to it will be added to the revised definition of "qualified expert."

§ 215.12. Inspections and investigations.

In addition to inspections, the Department may also conduct investigations. "Investigations" has also been added to the title of this section.

Subsection (a) dealing with the maintenance of records requires that records be available for inspection by the Department. The requirement has been clarified to specify that these records be available at the permanent sites or facilities of use identified in a license or registration. Radioactive material licenses in particular, may authorize use at multiple sites anywhere in this Commonwealth. Those licenses have fees determined by the number of noncontiguous sites covered under the licenses. The intent of this requirement is that compliance records be available locally for reference during an inspection.

Subsection (c) dealing with inspections by the Department has been expanded for clarity to reference investigations. This is consistent with other references to inspections such as Chapter 220 (relating to notices, instructions and reports to workers; inspections and investigations). The scope of this subsection is also clarified to cover inspection and investigation of regulated activities as necessary to demonstrate compliance with the act or this article. References to inspection periods have been removed as the frequency of inspection, as just stated, is determined by the Department "as necessary" to ensure compliance. This provides the flexibility necessary for the Department to carry out its obligations. Agreements may be entered into with Federal agencies that dictate certain inspection periods. For example, to conform to Agreement State standards, radioactive material licenses would have a range of routine inspection periods from 1 to 5 years. This does not signal a shift in policy. The routine inspection period for the majority of regulated activities is still anticipated to be four years. Compliance history has not indicated a class of regulated activity that requires a routine inspection period more frequent than annual.

Subsection (d) dealing with the right to conduct follow-up inspections has been expanded to include investigations to be consistent with subsection (c).

§ 215.14. Availability of records for public inspection.

In paragraph (2), the reference to inspection records not pertaining to safety or health is removed. Inspection records do not contain the information referred to. In any

case, all access to department inspection records is subject to the act of June 21, 1957 (P. L. 390, No. 212), Right to Know Law (65 P. S. §§66.1—66.4) as implemented through Departmental policy.

§ 215.24. Human use.

Subsections (b) and (c) dealing with auxiliary personnel have been added. Rather than repeat this requirement throughout Article V, the same references to auxiliary personnel in §§ 221.11(a), 224.21 and 228.35(g) were removed and consolidated in this chapter of general provisions.

Subsection (d) is new. The status of uncertified individuals in clinical training programs not covered under subsection (b) or (c) who use radiation sources on humans in the course of their training has never been clearly addressed in the regulations. This new regulation gives legitimacy to such individuals, subject to approval by the Department of the clinical training program.

§ 215.28. Improper use of a monitoring device.

Monitoring devices are relied upon to determine the radiation exposure of record. The data they provide has health and compliance consequences. The intent of this regulation is to prohibit actions that would result in misleading exposure data. This prohibition has been expanded to include the failure to use, or the improper use of a monitoring device by an individual. To reflect these changes, the heading of this section has been made more general and changed from "Deliberate exposure of a monitoring device" to "Improper use of a monitoring device."

§ 215.32. Exemption qualifications.

The exemptions listed in this section are applicable to activities covered under Chapter 240 (relating to radon certification); therefore, Chapter 240 has been added to the scope of this section.

Chapter 216. Registration of radiation-producing machines and service providers.

Engaging in certain commercial activities involving radiation-producing machines requires registration with the Department. The heading of this chapter is modified to include reference to radiation-producing machine service providers.

§ 216.1. Purpose and scope.

The existing regulation has become subsection (a) and modified to include reference to radiation-producing machine service providers. To avoid potential misunderstanding, new subsection (b) is a reminder that accelerators are not subject to registration.

§ 216.2. Registration of radiation-producing machines.

The heading of this section has been changed from "Registration" to clarify that it applies to radiation-producing machines only.

§ 216.2a. Registration of radiation-producing machine service providers.

This is a new section. The requirements for assemblers previously in § 216.6(c) have been moved here and expanded upon. The process of registration is now described, including a requirement for annual renewal. There is a new provision requiring the payment of fees to recover costs of registration and the issuance of a registration certificate. There is a new 60 day grandfather clause for persons already subject to the regulation since prior registration is now required and the previous regulation did not specify whether registration of services was required before or after engaging in that activity.

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

This is a new section that describes reporting and recordkeeping requirements for persons providing radiation-producing machine services. It expands upon the requirements for assemblers previously found in § 216.6(a). For certified X-ray equipment, this requirement is satisfied by submittal of the information required in United States Food and Drug Administration (FDA) assembler's Form 2579. For noncertified equipment not subject to Federal reporting, submittal of the equivalent information is required. The new definition of "major X-ray system component" is used here to limit the scope of reporting. This regulation provides for the Department to be informed of new installations or significant changes in existing installations in a timely manner (15 days) by the service provider so that the necessity for follow-up inspection can be determined and to help ensure the proper recording of registration and inventory and submission of any fees that may be due within the 30 day period specified in § 216.2. New § 216.2b(c) specifies the time period that service provider records shall be kept available for inspection. New § 216.2b(d) is provided to help ensure that knowledge of unregistered X-ray equipment will be reported to the Department.

§ 216.3. Exemptions.

"Radiation machines" in paragraph (2) is changed to "radiation-producing machines" for clarity. The reference to "storage incidental thereto" is removed to avoid confusion. The wording is clarified to show that the exemption from registration is intended to apply to carriers that are in possession of X-ray machines belonging to another while the machines are in transit. It is not intended to remove the registration requirement for machines while they are still owned by, in the possession of or under the control of a person who would otherwise be required to maintain a registration, even if the machines are being shipped. For example, a nonfunctioning portable X-ray machine that is in transit from a repair facility when re-registration is due is still considered to be subject to re-registration. But a registrant's X-ray machine while in transport by a party other than the registrant for the purpose of being permanently transferred to another person is no longer subject to registration by the originator, provided the transfer is culminated.

In paragraph (4) the exemption of accelerators from registration is repeated for clarity as well as the admonition that registration of service providers for accelerators is not exempt.

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

Subsection (c)(1) is updated to include the reference to the new certificate of registration of radiation-producing machine services under § 216.2a. Failure to renew a certificate of registration for radiation-producing machine services requires the registrant to cease all services subject to registration.

Subsection (c)(2) is clarified by specifying only radiation-producing machines "subject to registration under § 216.2" are applicable to the requirements in the subsection. The reference to § 216.6 has also been updated to show that "assembly" has been removed from the section title assembly, transfer and disposal obligations, as discussed previously under new § 216.2b.

§ 216.6. Transfer and disposal obligations.

Reference to assembly, installation and all of subsection (c) (relating to registration of service activities) have been removed from this section and treated elsewhere in this chapter as previously discussed. Transfer and disposal related obligations remain. Subsection (a) is a safety net provision to require that persons report the transfer of radiation-producing machines not otherwise reported under the service provider reporting provisions of § 216.2b. The general reference to "equipment" has been removed and the existing requirement has been enhanced to include reporting the transfer of any major X-ray system components because that could signal the need for registration or inspection related activities. The existing reporting period of 90 days has been reduced to 30 days to allow for a more timely follow-up by the Department if it is warranted.

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

Currently, registration and registration fees are waived for persons who bring radiation-producing machines into the Commonwealth for temporary use (not more than 180 days per calendar year). In light of the term "temporary" and in the absence of a fee to cover related activities by the Department, it is appropriate to reduce the temporary period in the Commonwealth to 60 days per year (approximately one day per week). Furthermore, the time period to register with the Department following 60 days in this Commonwealth is shortened from 30 days to 15 days.

Chapter 217. Licensing of radioactive material.

§ 217.136. Exempt concentrations.

Reference to the isotope Cadmium-109 in Table 1 Exempt Concentrations is deleted. The quantity for this isotope is already incorporated by reference in 10 CFR Part 20.

§ 217.141. Incorporation by reference.

Subsection (b) repeats the information in § 215.1(e)(4) for convenience. In § 215.1(e)(4), NRC section 10 CFR 31.3 was removed from the list of sections in 10 CFR Part 31 that are not incorporated by reference for reasons already discussed. Reference to NRC section 10 CFR 31.3 is removed from subsection (b) for the same reasons.

§ 217.143. Certain measuring, gauging or controlling devices.

Devices in this category are eligible for the simpler regulatory structure of the general license in this section. License fees are correspondingly lower than the class of specific licenses to which these devices would otherwise be subject. The threshold for admittance into this category for accelerator-produced material is being lowered from 10 millicuries (mCi) to 1 mCi. This will allow the inclusion of a group of X-ray fluorescence (XRF) devices that are currently specifically licensed, but suitable for general license. It will provide for consistency with the NRC who generally license certain XRF devices under their jurisdiction. Many of the XRF licensees are also sole proprietors for whom the higher fees associated with a specific license represent a significant business cost.

§ 217.171. Incorporation by reference.

Subsection (b) repeats the information in § 215.1(e)(11) for convenience. In § 215.1(e)(11), NRC section 10 CFR 40.33 was added to the list of sections in 10 CFR Part 40 that are not incorporated by reference for reasons already discussed. Reference to NRC section 10 CFR 40.33 is added to subsection (b) for the same reasons.

§ 217.201. Incorporation by reference.

This section repeats the information in § 215.1(e) regarding incorporation by reference of 10 CFR Part 150 for convenience. In § 215.1(e), the references to various subsections of NRC section 10 CFR 150.20 were replaced with a reference to section 150.20 in its entirety as being equivalent. The same change has been made in this section.

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

In this section the title of 10 CFR Part 150 was misquoted. The word "authorization" was replaced by the words "authority in."

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

Sections 217.201 and 217.202 currently provide for reciprocal recognition of Agreement State licensees use of NARM in this Commonwealth for up to 180 days per calendar year and Agreement State byproduct, source and special nuclear material when the Commonwealth becomes an Agreement State. Section 217.203 currently provides for the same recognition for NARM used by nonagreement states. But there is no provision for recognition of NRC licensees who operate in the Commonwealth on a temporary basis when the Commonwealth becomes an Agreement State. Without reciprocity, those NRC licensees would have to secure a specific license from the Department. They would not be treated on an equal basis with similar agreement state licenses. To avoid this potential situation, the reciprocity provisions of § 217.203 are expanded to include byproduct, source and special nuclear material in quantities not sufficient to form a critical mass. References to holders of an NRC license have been added. The reference to a "licensing state" has been replaced by "state" as licensing state has a strict meaning regarding certification that the licensing programs in many competent nonagreement states do not technically have.

Subsection (a) has an added reminder that Commonwealth authority does not extend into areas of exclusive Federal jurisdictions.

Reciprocity is considered to be a type of general license. As such, new subsection (e) is a reminder that implementation of the requirements for byproduct, source and special nuclear material is subject to the safe harbor provisions of § 217.133 on the day the Commonwealth becomes an Agreement State.

Chapter 218. Fees.

§ 218.1. Purpose and scope.

Subsection (a) is expanded to clarify the criteria the Department uses to determine the scope of registration or licensing of radiation-producing machines. Radiation-producing machines have always been registered under the facility in which they were located. In some cases, for the convenience of the Department, radiation-producing machines in the same building, at the same address or in a contiguous group of buildings under the same administrative control have been treated as a single registration. The Department determines the appropriate manner of registration. Subsequently, when the Department announced its intention to discontinue the registration of accelerators and license them instead, the intent was the same. Accelerators that were previously covered under the same registration number would be under the same license.

Subsection (b)(1) is updated to show the applicability of the new category of "radiation-producing machine services" in Chapter 216.

§ 218.11. Registration, renewal of registration and license fees.

Subsection (a) is clarified to show its applicability to "X-ray" tubes or other "radiation generating devices" such as electron microscopes that are regulated. Similar wording is added to the header of column three in the fee table.

Subsection (b) reference to § 216.2 is updated to show the new title of that section is "registration of radiation-producing machines."

Subsection (d) is clarified to show that the fees for accelerators are "annual." Under subparagraphs (i) and (ii), "site" is replaced by "facility" on the basis of the preceding discussion in § 218.1. The phrase "of the same general type" is deleted for simplification. The term was undefined and confusing. The way fees are assessed has not changed. The intent of "of the same general type" was to refer to one of the three categories of accelerators in the regulation, not the brand, the use or whether it's a linear accelerator or a cyclotron. In (iii), the Professional Fee Hourly Rate applicable to Department personnel time spent in licensing, inspection and the like is now specified here and the reference to Appendix A is removed because the Fee Category PF in Appendix A is being deleted. Another change to subparagraph (iii) is the specification of the minimum annual fee for accelerators above 50 MeV. It is equal to the next lower fee category, "accelerators below 50 MeV, other than ion implantation." This clarifies what initial fee is required under subsection (e) to be remitted as required by subsection (f) when applying for a license in the category "greater than 50 MeV." It also avoids the potential for the licensee of an accelerator greater than 50 MeV to pay less than would be payed for an accelerator below 50 MeV in any given year. It should be noted that as of yet there are no licensable accelerators above 50 MeV in this Commonwealth.

Wording is added to subsection (e) to exclude full cost recovery licenses in Appendix A from the requirement to submit a specified fee with the submittal of a license application. Otherwise, the provisions of subsection (f) would make a full cost recovery license application invalid if there is no accompanying fee.

Subsection (h) is new. It provides for recovery of the costs of registration of radiation-producing machine service providers under new § 216.2a. No fees had been collected previously under the activities of § 216.6(c) that formed the basis for new § 216.2a.

Appendix A. Fees for radioactive material licenses.

The header of the third column was changed to "Annual Fee." The words "Proposed Pa" are removed and new footnote 7 is referenced. Once the fees were passed, they were no longer proposed. Footnote 7 clarifies that reduced fees under Small Business Categories 1 and 2 are not consistent with the intent of full cost recovery and the requirement to post financial assurance for major licenses. Abbreviations in the descriptions are spelled out for clarity. The description of Category 14 is reworded for clarity to better match the description of its corresponding NRC fee category.

There is a new fee category, 3Q, for generally licensed devices under § 217.143. The NRC added this category to provide for more rigorous tracking of the most significant types of generally licensed devices that the NRC had difficulty accounting for. The annual fee for 3Q has been set at 70 % of the current NRC fee according to the provisions of the formula in footnote 3. Note that the formula includes a prorated portion of the NRC application fee to account for the difference that the Commonwealth uses a simplified annual single fee system with no separate application fees. In this category license, the NRC fee schedule has no annual fee, only an application fee, but the applicant must reapply yearly instead of once every 10 years, so the NRC license application fee used in the formula was not modified by the 10 year 0.1 proration factor. The licensee community will benefit from specifying a fee for the 3Q category because the fee will be fixed. The NRC has scheduled an increase in this fee. Without a fixed fee, the fee as currently determined by formula will rise.

Licenses subject to "Full Cost" recovery now display an asterisk in the fee column to reference a new footnote. The new asterisk footnote clarifies the meaning of "Full Cost."

Fee category 8A1 currently applies only to NRC licenses for materials used by Civil Defense. It was originally intended to be identical to category 8A2 for NARM licenses to provide reduced fees for certain minor NRC licenses when the Commonwealth becomes an Agreement State.

Fee category 8A1 and 8A2 have been modified to limit the duration of storage-only licenses to 2 years. It is required under incorporation by reference of 10 CFR 30.36(d)(3) for a licensee who has ceased all licensed activity other than secured storage of licensed material for 2 years to begin decommissioning and termination of the license.

In the table of Fee Categories in Appendix A, PF (Professional Fee) has been removed. PF is not actually a license category. Professional fees for full cost recovery licenses are discussed under the new footnote referenced by an asterisk on "Full Cost" licenses. The Professional Fee Hourly Rate previously specified under PF has been moved to the footnoted asterisk.

Footnote 1 has been clarified to show how fees for radioactive material licenses with more than four noncontiguous sites will be determined. The base fee is increased by 25% for each additional non-contiguous site above four. Note the maximum fee will be subject to the NRC fee limitation in footnote 4.

Chapter 219. Standards for protection against radiation.

§ 219.3. Definitions.

A grammar correction has been made by inserting the word "in" between the words "used this."

In the definition of "medical reportable event for radiation-producing machine therapy" under subparagraph (iii), an additional condition of "outside the prescribed dose range" has been added. This recognizes that a therapy treatment plan may specify a dose range instead of a dose. It is consistent with the requirements for the use of radioactive material in therapy in 10 CFR 35.3045(a)(1)(ii).

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

Certain X-ray procedures result in occupational exposures to individuals that are nonuniform, usually resulting from the common practice of wearing personnel dosimeters on the outside of lead aprons. The existing regulations require an overly conservative method for recording that exposure that may give the appearance

that safety limits have been exceeded, thereby resulting in individuals curtailing participation in necessary medical procedures, or continuing and violating the regulations. Wording has been added in paragraph (8) to allow X-ray exposures to be weighted by methods approved by the Department to arrive at a more accurate determination of the total effective dose equivalent. This can reduce the current unnecessary adverse impact on the medical community. This concept is consistent with the NRC's position in Regulatory Issue Summary (RIS) 2002-06 *Evaluating Occupational Dose For Individuals Exposed To NRC-Licensed Material And Medical X-rays*. The referenced document is currently available on the NRC's website at the following address: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2002/ri02006.pdf.

§ 219.8. Requirement for a radiation safety committee.

Previously the need for a radiation safety committee was addressed through the licensing process. The NRC has recently codified this requirement in 10 CFR 35.24 (relating to authority and responsibilities for the radiation protection program). This new section clarifies how incorporation by reference of this requirement applies to registrants and licensees of radiation-producing machines and NARM.

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

Subsection (a)(2) and (3) are clarified to show that the origin of the specification for alternative intervals of sealed source leak testing is the National Sealed Source and Device Registry maintained by the NRC. Reserved references resulting from previous rulemaking are removed. The specification of a "licensing" state is removed. Use of the word "licensing" implies a certification that is unduly restrictive. The limitation of 3 years between leak test intervals is removed. A limitation on the maximum leak test interval that can be specified in the registry is not codified by the NRC. Limits are established through the licensing process for each source manufacturer.

Subsection (b)(6) is expanded to exempt any sealed source in storage from leak testing while in storage and the maximum interval of 3 years between leak tests is removed to avoid unnecessary exposure to personnel. If individual exceptions are warranted, they can be addressed through license condition on the user.

§ 219.229. Other medical reports.

The word "discovery" is replaced with "determination by a physician" to clarify who may make the determination of function damage. The word "tissue" is too generic. It is replaced by "an organ or a physiological system" for clarity.

Chapter 220. Notices, instructions and reports to workers; inspections and investigations.

§ 220.2. Posting of notices to workers.

Section (c) reference to Department Form ER-BRP-3 "Notice to Employees" has been updated to reflect the Form's new designation 2900-FM-RP0003.

Chapter 221. X-rays in the healing arts.

§ 221.2. Definitions.

"Filter," "filtration" and "half-value layer" are defined more comprehensively.

"Healing arts screening" sentence structure is rearranged to avoid misinterpretation of the definition. The phrase "for the purpose of diagnosis or treatment" in its current position at the end of the sentence might mislead one to think it describes a type of licensed practitioner (one authorized to prescribe tests) rather than a condition placed on the purpose of the test (tests that are performed as an adjunct to a patient's diagnosis or treatment by a physician for a medical condition).

"Qualified expert" is deleted since the definition was consolidated previously in § 215.2.

§ 221.11. Registrant responsibilities.

Subsection (a)(2) and (3) is deleted. The requirements were consolidated and moved to new § 215.24(b) and (c).

Subsection (b) includes a requirement for continuing education. The continuing education requirement in Appendix A (relating to determination of competence) was moved from paragraph (6) and expanded upon.

Subsection (e)(2) and (3) references to "scatter" radiation are replaced by the more appropriate term "stray" radiation. The subsection (l) requirement for a quality assurance program is expanded upon to clarify the minimum program components, the need for documentation and the associated record retention requirements.

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

Healing arts screening is an activity regulated by the Department that occurs when asypmtomatic individuals self-refer themselves for an X-ray test that has not been prescribed by a physician for the purpose of diagnosing or treating a condition. Nothing in the proposal will deny individuals access to diagnostic tests deemed necessary by a physician to diagnose or treat a patient. X-ray tests ordered, prescribed or obtained through referral of a patient under the care of a physician are not affected by this proposal.

In the section heading, "requesting approval" has replaced "proposing" to emphasize that healing arts screening is subject to approval as stated in subsection (b).

The format of the existing section is rearranged from paragraphs to subsections with the addition of new subsection (a). Subsection (a) addresses the efficacy of the proposed healing arts screening procedures. Efficacy is the first factor to be considered in evaluating a proposed healing arts screening procedure. The greater the radiation dose to the individual being screened, the more compelling the case should be for ensuring that the efficacy of the procedure compensates for the risk to the individual and for other detrimental factors. The Department considers the consensus positions taken by appropriate National medical organizations, relevant scientific and medical literature and information from appropriate Federal agencies. The Department does not determine efficacy but weighs the merit of these sources of information to support or deny approval of the procedure. Guidance for scientific and technical personnel to perform the evaluations is available through the National Council on Radiation Protection and Measurements Commentary No. 13 "An Introduction to Efficacy in Diagnostic Radiology and Nuclear Medicine (Justification of Medical Radiation Exposure)."

New subsection (a) also introduces a requirement for the Department to consult the Department of Health (DOH) in reviewing the efficacy of procedures that exceed a certain level of exposure to the screened population. The new requirement to seek assistance from the DOH in reviewing the efficacy of healing arts screening in such cases recognizes that actions taken by the Department may set defacto public health policy. The Department

already collaborates with the DOH in other areas of overlapping concern such as the issuance of potassium iodide during certain reactor emergencies.

A level of 100 mrem to the screened population was set to trigger consultation with the DOH. The Department sets standards for exposure to large populations of the general public from the activities it regulates based upon a limit of 100 mrem per year to the hypothetical maximally exposed individual. The expectation is that the majority of individuals will not receive the maximum exposure. There is also a performance based companion requirement, ALARA (as low as reasonably achievable), that controls operational implementation of this limit. An exposure of 100 mrem is below the threshold of producing an inevitable effect. It represents a risk for an individual that is potential or proportional rather than certain. For an individual or a small group of individuals, the Department routinely assumes the responsibility of weighing the risk versus the benefit of permitting those members of the general public to receive exposures at the level of 100 mrem. When higher exposures are involved, particularly across large groups, the potential for adverse health effects within the community approaches a certainty. Memoranda of Understanding are established as necessary to coordinate interdepartmental activities.

The existing paragraphs become part of subsection (b). Subsection (b)(5) is expanded to require a comparison with any alternate method to the proposed X-ray screening exam, even if it is a different type of X-ray exam. Previously, comparisons were restricted to nonradiation alternatives. Subsection (b)(6) is clarified to explain what is meant by measurement of patient exposure. Subsection (b)(7) addresses new technology by not requiring film for diagnostic imaging. Subsection (b)(8) also addresses new technology in which exposure parameters may be set by machine rather than manually. Subsection (b)(9) requires information on the qualifications of all individuals who will be operating the X-ray systems, not just one individual. Subsection (b)(11) now requires information on the qualifications of individuals interpreting the screening test results (note: the antiquated reference to radiographs is removed). Subsection (b)(12) is reworded to better show the intent of "implied consent" and what that entails. Subsection (b)(13) once again replaces antiquated references to radiographs. Subsection (b)(15) is a new requirement to specify relevant information regarding the frequency and duration of the entire screening program. Subsection (b) was originally patterned after the Suggested State Regulations for Radiation Control which includes the provisions of subsection (b)(15).

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

Subsection (b)(3), (6) and (9) is changed in like manner to their corresponding § 221.13(a)(5), (8) and (11). Subsection (b)(11) is new. It is intended to provide assurance of safeguards comparable to subsection (a).

§ 221.25. Beam quality.

Subsection (a) Table II has been updated. The values are the same as the current FDA hardware standards in 21 CFR 1020.30 Table 1. Footnotes of explanation have been added. Interpolation or extrapolation may be used between values in Table II. There is a column for specified intraoral dental systems manufactured after December 1, 1980. For those specified dental systems, the minimum half value layer below 71 kVp is 1.5 mmAl equivalent regardless of filtration. The FDA also prints leading zeros on decimals in the table to avoid misinterpretation.

§ 221.29. Kilovoltage (kV) accuracy.

The accuracy requirement for kilovoltage has been split into two specifications, one for variable kV units and one for fixed. The original precision of 10% was retained for variable units but the allowable error for units in which the kV can not be changed was relaxed to 20% because fixed kV units do not rely on kV for fine control of penetration and contrast.

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

The spelling of fluoroscopic is corrected in subsection (d).

§ 221.38a. Entrance exposure rate.

To emphasize the importance of output checks, subsection (c) is reworded to require that output measurements must be made at least annually, not just annually and they must be done in a manner sufficient to show compliance with the standards in this section.

§ 221.61. Radiation therapy simulation systems.

The current manner in which section numbers are referenced here is unnecessarily confusing. The references to the applicable sections have been restated in a clearer manner. The existing references also only apply to fluoroscopic based simulators. There is similar confusion in the way the applicable requirements for CT based simulators are addressed in existing § 221.202(h). A new subsection (b) has been created and the CT simulator references in § 221.202(h) have been clarified and moved to this section.

§§ 221.73, 221.74 and 221.75.

The references to radiological physicist has been deleted under the expanded definition of qualified expert in § 215.2.

§ 221.202. Equipment requirements.

Subsection (f) relating to beam quality is deleted as redundant to the requirements of § 221.25. Subsection (h) has been moved to new § 221.61(b) as previously discussed.

§ 221.204. Radiation measurements and performance evaluations.

The spelling of the abbreviation MSAD has been corrected from MSDAD.

§ 221.205. Operating procedures.

Subsection (a)(3), specifying the distance to the tomographic plane, is unnecessary and deleted.

Appendix A. Determination of competence

The existing wording is deleted and restated to be more adaptable and less proscriptive. As discussed previously, the continuing education requirement of paragraph (6) was moved to § 221.11(b).

Chapter 223. Veterinary medicine.

§ 223.21. In vitro testing.

Reserved references have been corrected to point to the regulations of the NRC that replace them in incorporation by reference.

§ 223.22. Sealed sources.

Reserved references have been corrected to point to the regulations of the NRC that replace them in incorporation by reference.

Chapter 224. Medical use of radioactive material.

§ 224.10. Incorporation by reference.

Subsection (b) references were updated to correspond to their counterparts in the new 10 CFR Part 35.

§ 224.21. Supervision.

This section is reserved. The requirements for supervision are incorporated by reference to 10 CFR Part 35 and the requirements of paragraphs (1) and (2) have been moved to new § 215.24(b) and (c).

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

This section has been updated because of incorporation by reference of the new requirements of 10 CFR 35.65 and includes transmission sources. Notwithstanding, a more restrictive limit is set for radium because it is more hazardous and the NRC did not consider radium use in deriving new 10 CFR 35.65.

§ 224.23. Decay-in-storage.

The spelling of half-life is corrected.

Chapter 225. Radiation safety requirements for industrial radiographic operations.

§ 225.1. Purpose and scope.

Section 225.2a (relating to incorporation by reference) is no longer reserved. The reference to it in subsection (b) is corrected.

§ 225.4a. Radiation safety program.

This section currently requires that the Department approve of radiation safety programs for industrial radiography before operations can be conducted. New subsection (b) clarifies that any change to a registrant's radiation safety program also requires prior Departmental approval.

§ 225.71. Definitions.

"Temporary job site" is a term usually associated with radiography utilizing radioactive sources. It is replaced by a new definition "field radiography" that better describes the type of radiography conducted with radiation-producing machines in Subchapter B. A new definition "safety device" is also defined for use in Subchapter B.

§ 225.73. Training of personnel.

In subsection (b), the new definition of "field radiography" replaces "temporary job site" radiography. The reference to 10 CFR 34 Subpart D (relating to radiation safety requirements) is replaced by Appendix A since the requirements of subchapter B relate to radiography with radiation-producing machines rather than radioactive materials and § 225.1(b) established the intent to minimize the effect of incorporation by reference of 10 CFR Part 34 on Subchapter B.

§ 225.82. Operating requirements.

Subsection (a) describes personnel requirements for field radiography. The list of individuals who may be called upon to assist the radiographer is increased by the addition of radiographer trainee.

§ 225.83. Records required at field radiography sites.

The new definition of field radiography is used in place of temporary job site in the heading and text of this section.

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

The intent of subsection (d) is to assure the X-ray systems continue to meet the performance standards relating to leakage radiation. Subsection (d) was reworded to clarify this. References to other manufacturer hardware standards in 10 CFR 20.1301 and 21 CFR 1020.40 were removed. Those standards are enforced under subsection (a).

§ 225.102. Shielded room X-ray radiography.

Existing subsection (b) is deleted and existing subsection (c) is renumbered. If the provisions of subsection (a) limiting radiation leakage from the room and existing subsection (c) requiring surveying before entry are followed, operator exposure can not reasonably be expected to exceed the threshold of 500 mrem per year that would require personnel monitoring.

A new subsection (c) is added that allows the use of an independent radiation monitoring system in lieu of a typical portable radiation survey meter to verify that the radiation-producing machine is off before entering the room.

Subsection (d) is new. Shielded room radiography is exempted from all other provisions of this chapter except §§ 225.4a and 225.84 (relating to radiation safety program; and operating and emergency procedures) because of its safe operating history.

§ 225.103. Field site radiography.

The new term field site radiography replaces temporary job site radiography in the section title.

Chapter 226. Licenses and radiation safety requirements for well logging.

§ 226.3a. Abandonment of a sealed source.

The general reference to incorporation by reference of 10 CFR Part 39 is replaced by specific references to sections of Part 39 for clarity.

Chapter 227. Radiation Safety Requirements for analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration systems.

§ 227.11a. Equipment requirements.

In subsection (a)(2), the reference to "devices" is changed to "safety devices" for consistency with the previous reference to safety devices in subsection (a).

§ 227.12a. Area requirements.

The reference to reserved § 219.51 is replaced by 10 CFR 20.1301, its equivalent from incorporation by reference of NRC regulations.

§ 227.13a. Operating requirements.

Subsection (d) is new. It provides for emergency instructions for operation of analytical equipment. Analytical X-ray equipment is capable of inflicting physical injury from radiation before an operator can react.

§ 227.14. Personnel requirements.

Subsection (a) is updated to require instruction in the new requirement for emergency procedures under subsection (a)(3) and the applicable regulations in general under subsection (a)(7).

Subsection (c) reference to § 219.31 (relating to occupational dose limits for adults) is actually reserved and misprinted. It is replaced with the equivalent reference to 10 CFR 20.1201 under incorporation by reference of NRC regulations.

Chapter 228. Radiation Safety Requirements for Particle Accelerators.

§ 228.2. Definitions.

The definition of "accelerator" is expanded to indicate that "particle accelerator" has the same meaning. (The term is used in § 228.37 referencing § 217.144.)

The definition of "filter" as used in the context of the application of radiation has also been modified for consistency with a similar definition used in § 221.2.

The new term "particle accelerator" is cross referenced to accelerator.

The term "Qualified expert" is deleted as the term has been consolidated under the definitions of § 215.2 discussed previously.

§ 228.11a. Licensee responsibilities.

Subsection (a) requirements also apply to persons possessing an accelerator, not just operators.

Subsection (d) is deleted since it is redundant to the requirements of § 215.28 (relating to improper use of a monitoring device).

§ 228.12. Information and maintenance record and associated information.

The reference to registrant is deleted, as accelerators cannot be registered, only licensed. The length of time records must be kept by the licensee for inspections by the Department is increased from 4 to 5 years.

§ 228.21a. Notification and license requirements.

Subsection (a)(1) is clarified to describe how an application for license is to be filed with the Department.

Subsection (g) requiring written permission of the Department to transfer an accelerator license is new. It is consistent with similar existing requirements in § 216.2(e) and 10 CFR 30.34(b) dealing with the transfer of radiation-producing machine registrations and radioactive material licenses respectively.

§ 228.23a. Expiration and termination of a license.

Subsection (d)(1) is expanded to clarify that if an accelerator licensee does not intend to renew their license, they must not only stop use of it after the deadline but transfer or dispose of the accelerator. This is consistent with revised § 221.11a(a) prohibiting possession of an accelerator that does not meet the requirements of this article.

Subsection (d)(3) updates the reference to Department Form ER-BRP-314 to its new designation 2900-PM-RP0314.

§ 228.31a. Limitations.

Subsection (b)(2) is revised to delete reference to registration. Accelerators are no longer registered.

§ 228.32a. Shielding and safety design requirements.

Subsection (a) is revised to indicate the type of qualified expert required. The existing requirement to have a safety survey performed prior to first use and after changes is deleted because it is already addressed in § 228.38(a).

Subsection (b) reference to reserved § 219.51 is replaced by 10 CFR Part 20 Subpart D, the NRC equivalent regulation incorporated by reference.

§ 228.34a. Accelerator controls and interlock systems.

Subsection (b) references to reserved §§ 219.91 and 219.54 are replaced by 10 CFR Part 20 Subpart G and 10 CFR 20.1902 respectively, which are the NRC equivalent regulations incorporated by reference.

§ 228.35. Operating procedures.

In subsection (g)(4), the term "misadministration" no longer exists. It has been replaced by its successor, "medical reportable event for radiation-producing machine therapy." Existing subsection (g)(5) and (6) are deleted. Those requirements are covered in new § 215.24 (b) and (c) discussed previously. Existing subsection (g)(7) is renumbered as subsection (g)(5) and the requirement for continuing education is moved from Appendix A to subsection (g)(5), similar to the treatment of continuing education in Chapter 221 Appendix A (relating to determination of competence).

§ 228.37. Production of radioactive material.

Subsection (a) reference to reserved § 217.48 is replaced by its successor § 217.144 (relating to incidental radioactive material produced by a particle accelerator).

Subsection (b) reference to reserved §§ 217.51—217.57 is replaced by reference to Chapter 217 (relating to licensing of radioactive material). It should be noted that Chapter 217 in turn incorporates requirements of 10 CFR Part 30 (relating to rules of general applicability to domestic licensing of byproduct material).

§ 228.38. Radiation safety surveys.

Subsection (a) requirements are clarified to ensure that the initial survey requirements in this subsection, replace those deleted from existing § 228.32(a). The type of qualified expert required is also clarified.

Subsection (d) references to reserved §§ 219.31 and 219.51 are replaced by the NRC equivalent regulations incorporated by reference, 10 CFR 20.1201 and 21.1301 (relating to occupational dose limits for adults; and dose limits for individual members of the public).

§ 228.39. Records.

Reference to reserved §§ 219.201—219.211 is replaced by the NRC equivalent regulations incorporated by reference, 10 CFR Part 20, Subpart L (relating to records).

§ 228.41a. Warning devices.

Subsection (b) reference to reserved § 219.91 is replaced by 10 CFR 20.1601 (relating to control of access to high radiation areas), the NRC equivalent regulation incorporated by reference.

§ 228.43. Radiation surveys.

A subsection (c) reference to a qualified expert is clarified.

A subsection (d) reference to reserved Subchapter L of Chapter 219 is replaced by the NRC equivalent regulations incorporated by reference, 10 CFR Part 20, Subpart L (relating to records).

§ 228.44. Ventilation systems.

A subsection (a) reference to reserved § 219.34 is replaced by 10 CFR 20.1204 (relating to determination of internal exposure), the NRC equivalent regulation incorporated by reference.

A subsection (b) references to reserved §§ 219.51 and 219.52 are replaced by the NRC equivalent regulations incorporated by reference, 10 CFR 20.1301 (relating to dose limits for individual members of the public) and 10

CFR 20.1302 (relating to compliance with dose limits for individual members of the public) respectively.

§ 228.61. Leakage radiation to the patient area.

A subsection (a)(2) reference to registrant is deleted because accelerators are no longer registered, only licensed.

§ 228.75. Calibrations.

A references to the type of qualified expert in subsection (b) and subsection (c)(4) are clarified.

§ 228.76. Spot checks.

A reference to the type of qualified expert in paragraph (1) is clarified.

Appendix A. Determination of Competence.

The existing wording is deleted and restated to be more adaptable and less proscriptive. As discussed previously, the existing continuing education requirement of paragraph (6) was moved and added to new § 228.35 (g)(5).

§ 230.3. Incorporation by reference.

Subsection (b) references to 10 CFR 71.47 and 10 CFR 71.83 are deleted and reference to 10 CFR 71.61 is added as previously discussed under § 215.1(e)(13).

Chapter 240. Radon Certification.

§ 240.2. Scope.

New subsection (b) is added to clarify that this chapter is in addition to, and not in substitution for, other applicable provisions of this article. For example, individuals subject to this chapter who are required to have health and safety plans for their activities are subject to the standards for protection against radiation in Chapter 219. Individuals who use certain radium or radon sources are subject to the licensing provisions for radioactive material in Chapter 217.

F. *Benefits, Costs and Compliance*

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

Benefits

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

Compliance Costs

The majority of changes represent clarifications of requirements. For them, the underlying requirements have not actually changed so the there is no additional cost to comply. Implementing the more flexible requirements for personnel exposure to X-rays, quality assurance programs, leak testing of sealed sources, general licenses for sealed source devices, cabinet radiography and shielded room radiography operations will add no additional costs and generally reduce existing costs. The new cost for out of state X-ray providers who establish semipermanent operations in the Commonwealth is no more than fees charged by other states for the equivalent activities. The new codified category 3Q annual general license fee of $315 is identical to what the current uncodified fee is pursuant to the formula in Chapter 218 Appendix A footnote 3. However, the proposed regulations would permit extension of this fee to certain current category 3P licensees resulting in a fee decrease for about 70 licensees who currently pay $750. There is a new annual fee of $100 for registration of radiation-producing machine service providers. The net loss of income from switching some category 3P licenses to category 3Q is expected to be about equal to the increase in income from the new radiation-producing machine service provider registration fee.

Compliance Assistance Plan

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

Paperwork Requirements

Changes dealing with clarification of existing regulations add no additional paperwork beyond the original requirements. Regulations made more flexible may or may not result in a decrease in record-keeping requirements depending on what options the registrant or licensee avails themselves. Those persons providing radiation-producing machine services will be required to file a registration of activities form that has yet to be developed with the Department. Any paperwork for reporting the details of actual services being provided is already being filed with the Commonwealth through United States Food and Drug Administration (FDA) form 2579. The application form for new general license category 3Q has not been developed yet. However, it requires less supporting documentation than any current category and will constitute a reduction in paperwork over the current alternative licenses.

G. *Sunset Review*

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

H. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 20, 2003, the Department

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

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed amendments within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of these issues by the Department, the General Assembly and the Governor prior to final publication of the regulations.

I. *Public Comments*

Written Comments—Interested persons are invited to submit comments, suggestions or objections regarding the proposed rulemaking to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 15th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by September 29, 2003. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by September 29, 2003. The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulation will be considered.

Electronic Comments—Comments may be submitted electronically to the Board at RegComments@dep.state.pa.us and must also be received by the Board by September 29, 2003. A subject heading of the proposal and a return name and address must be included in each transmission. If an acknowledgement of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to ensure receipt.

KATHLEEN A. MCGINTY,
Chairperson

Fiscal Note: 7-387. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE V. RADIOLOGICAL HEALTH

CHAPTER 215. GENERAL PROVISIONS

§ 215.1. Purpose and scope.

* * * * *

(e) Title 10 Chapter I (Nuclear Regulatory Commission) Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71 and §§ 150.1, 150.2, 150.3, 150.11, **[150.20(a)(1), 150.20(a)(2) and 150.20(b)] 150.20** of the CFR is incorporated by reference with the exceptions set forth in paragraphs (1)—(13). Notwithstanding the requirements incorporated by reference, nothing in this article relieves or limits a person from complying with the laws of the Commonwealth, including the act and the Low-Level Radioactive Waste Disposal Act (35 P. S. §§ 7130.101—7130.905).

* * * * *

(4) Sections **[31.3,]** 31.4 and 31.14 are not incorporated.

* * * * *

(8) Sections 35.8, **[35.990] 35.4001** and **[35.991] 35.4002** are not incorporated.

* * * * *

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

* * * * *

(13) Sections 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, **[71.47,]** 71.51, 71.52, 71.53, 71.55, 71.59, **71.61,** 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.

* * * * *

§ 215.2. Definitions.

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

Qualified expert—

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

(ii) **[With reference to the calibration of radiation therapy equipment An] For radiation therapy calibrations, an** individual having, in addition to the qualifications in subparagraph (i), training and experience in the clinical applications of radiation physics to radiation therapy**[; 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].**

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

* * * * *

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

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

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

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

* * * * *

RIGHTS AND RESPONSIBILITIES OF THE DEPARTMENT

§ 215.12. Inspections **and investigations**.

(a) *Maintenance of records.* Licensees and registrants shall maintain records under this article and have these records available for inspection by the Department **at permanent sites or facilities of use identified in a license or registration issued under this article**.

* * * * *

(c) *Inspections* ***and investigations*** *by the Department.* **[(1)]** The Department, its employees and agents may conduct inspections **and investigations** of the facilities **and regulated activities** of registrants of radiation-producing machines and licensees of radioactive material **necessary to demonstrate compliance with the act or this article. [at the following frequencies:**

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

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

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

(d) *Additional inspections* ***and investigations***. The Department, its employees and agents may conduct additional follow-up inspections **and investigations** if violations of the act or regulations promulgated thereunder were noted at the time of the original inspection, or if a person presents information, or circumstances arise which give the Department reason to believe that the health and safety of a person is threatened or that the act or this article are being violated.

§ 215.14. Availability of records for public inspection.

The following Department records are not available for public inspection, unless the Department determines that disclosure is in the public interest and is necessary for the Department to carry out its duties under the act:

* * * * *

(2) A report of investigation **[or inspection]**, not pertaining to safety and health in industrial plants, which would disclose the institution, progress or results of an investigation undertaken by the Department.

* * * * *

PROHIBITIONS AND RESTRICTIONS

§ 215.24. Human use.

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

* * * * *

(b) Only auxiliary personnel who have met the applicable radiologic requirements of 49 Pa. Code, Part I, Subpart A (relating to professional and occupational affairs) may use radiation sources in the healing arts when employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices.

(c) Auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government may only use radiation sources in the healing arts in accordance with written job descriptions and employee qualifications.

(d) Subsections (b) and (c) notwithstanding human use of radiation sources is permitted by individuals enrolled in clinical training programs approved by the Department.

§ 215.28. **[Deliberate exposure] Improper use** of a monitoring device.

The deliberate exposure **of, failure to use, or improper use** of, an individual monitoring device or area monitoring device **[to falsely indicate the dose delivered to] by** an individual is prohibited.

EXEMPTIONS

§ 215.32. Exemption qualifications.

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

* * * * *

CHAPTER 216. REGISTRATION OF RADIATION-PRODUCING MACHINES **AND RADIATION-PRODUCING MACHINE SERVICE PROVIDERS**

§ 216.1. Purpose and scope.

(a) This chapter establishes requirements for the registration of radiation-producing machines **and radiation-**

producing machine service providers. A person who possesses a radiation-producing machine **or provides services described in this chapter** shall comply with this chapter.

(b) A person possessing an accelerator as defined in § 228.2 (relating to definitions) is exempt from the requirements of § 216.2 (relating to registration of radiation-producing machines). Accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators) and license fees are specified in § 218.11(d) (relating to registration, renewal of registration and license fees.).

§ 216.2. Registration **of radiation-producing machines.**

* * * * *

§ 216.2a. Registration of radiation-producing machine service providers.

After _____ (*Editor's Note*: The blank refers to the effective date of adoption of this rulemaking.)**, a person who engages in the business of assembling or installing radiation-producing machines or who offers to assemble or install radiation-producing machines or who is in the business of furnishing or offering to furnish radiation-producing machine servicing or services or who is in the business of selling, leasing or lending radiation-producing machines in this Commonwealth shall apply for registration of the activities with the Department prior to furnishing or offering to furnish those services.**

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

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

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

(4) A person who, on _____ (*Editor's Note*: The blank refers to the effective date of adoption of this rulemaking.)**, is currently in the business of providing radiation-producing machine services shall apply for registration by** _____ (*Editor's Note*: The blank refers to a date 60 days after the date of adoption of this rulemaking.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The date service was provided.

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

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

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

§ 216.3. Exemptions.

The following radiation-producing machines or equipment are exempt from registration:

* * * * *

(2) Radiation-**producing** machines while in transit **[or storage incidental thereto] in the possession of a transport carrier**.

* * * * *

(4) Accelerators are exempt from registration. Accelerators shall be licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). Accelerator service providers are not exempt from registration of services under § 216.2a (relating to registration of radiation-producing machine services).

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

* * * * *

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

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

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

* * * * *

§ 216.6. **[Assembly,]** Transfer and disposal obligations.

(a) A person, distributor, retailer or other agent who **[sells, leases, transfers, lends, assembles or installs], by selling, leasing, lending or gifting, transfers possession of** radiation-producing machines **or major X-ray system components** in this Commonwealth **that are not otherwise reported under 216.2b (relating to reporting and recordkeeping requirements for registered radiation-producing machine service providers),** shall notify the Department within **[90] 30** days of the following information:

* * * * *

(2) The manufacturer, model and serial number of a machine or component transferred**[, assembled or installed]**.

(3) The date of transfer **[or installation]** of a radiation-producing machine or **[equipment] major X-ray system component**.

* * * * *

[(c) A distributor, retailer or other agent who sells, leases, transfers, lends, assembles or installs radiation-producing machines or equipment in this Commonwealth shall register the activities with the Department on a form supplied by the Department.]

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

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

* * * * *

(3) Not operate within this Commonwealth on a temporary basis in excess of **[180] 60** calendar days per year.

* * * * *

(c) When a radiation-producing machine is brought into this Commonwealth for temporary use exceeding **[180] 60** days per year, a person possessing the machine shall register with the Department under § 216.2 (relating to registration **of radiation-producing machines**) within **[30] 15** days after the **[180th] 60th** day.

CHAPTER 217. LICENSING OF RADIOACTIVE MATERIAL

Subchapter B. GENERAL PROVISIONS FOR RADIOACTIVE MATERIAL

§ 217.136. Exempt concentrations.

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

* * * * *

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

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

Subchapter C. GENERAL LICENSES FOR RADIOACTIVE MATERIAL

§ 217.141. Incorporation by reference.

* * * * *

(b) Notwithstanding the requirements incorporated by reference, **[10 CFR 31.3,] 10 CFR** 31.4 and 31.14 (relating to **[certain devices and equipment;]** information collection requirements: OMB approval; and criminal penalties) are not incorporated by reference.

§ 217.143. Certain measuring, gauging or controlling devices.

In addition to the parts of 10 CFR 31.5 (relating to certain detecting measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere) incorporated by reference, general licensees subject to registration under 10 CFR 31.5(c)(13)(i) or possessing general licensed devices containing **[370] 37** MBq (**[10] 1** mCi) or more of accelerator-produced material, as determined on the date of manufacture, or 3.7 MBq (0.1 mCi) or more of radium-226 shall also comply with the following:

* * * * *

Subchapter G. LICENSING OF SOURCE MATERIAL

§ 217.171. Incorporation by reference.

* * * * *

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

Subchapter J. RECIPROCITY

§ 217.201. Incorporation by reference.

Except as provided in this subchapter, the requirements of 10 CFR 150.1, 150.2, 150.3, 10 CFR 150.11 and **[10 CFR 150.20(a)(1) (2) and (b)] 150.20 [(relating to recognition of Agreement State licenses)]** are incorporated by reference.

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

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

* * * * *

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

(a) Subject to this article, a person who holds a specific license from **the NRC or** a **[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**, except for areas of exclusive Federal jurisdiction,** for a period not in excess of 180 days in a calendar year if:

* * * * *

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

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

* * * * *

(b) Notwithstanding the provisions of subsection (a), a person who holds a specific license issued by **the NRC or** 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:

* * * * *

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

* * * * *

(e) Implementation of the requirements of this section regarding byproduct, source and special nuclear material is subject to § 217.133 (relating to persons possessing a license for source, byproduct or special nuclear material in quantities not sufficient to form a critical mass on the date the Commonwealth becomes an agreement state as published in the *Federal Register*).

CHAPTER 218. FEES

GENERAL

§ 218.1. Purpose and scope.

(a) This chapter establishes fees for registration and licensing and provides for their payment. **For the purpose of this chapter, radiation-producing machines under the same administrative control in a single building are registered or licensed as a single facility. Radiation-producing machines under the same administrative control at the same address or in a contiguous group of buildings may be registered or licensed as a single facility if the Department determines that it is appropriate.**

(b) Except as otherwise specifically provided, this chapter applies to a person who:

(1) Is required to register or renew registration for radiation-producing machines **or radiation-producing machine service providers** under Chapter 216 (relating to registration of radiation-producing machines **and radiation-producing machine service providers)**.

* * * * *

PAYMENT OF FEES

§ 218.11. Registration, renewal of registration and license fees.

(a) Annual registration fees for radiation-producing machines, other than accelerators, are the sum of an annual administrative fee and an annual fee for each **X-ray** tube **or radiation generating device** as follows:

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

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

* * * * *

(d) Particle accelerators are licensed under Chapter 228 (relating to radiation safety requirements for particle accelerators). **[Fees] Annual fees** are as follows:

(i) Accelerators, below 50 MeV, other than for ion implantation—$1,500 for the first accelerator at the **[site] facility** plus $500 for each additional unit **[of the same general type]** at that **[site] facility**.

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

(iii) Accelerators above 50 MeV—full cost of staff time to review license applications and conduct inspections as needed. (Hourly rate is **$50 per hour) [given in Appendix A)]**. **For the purpose of anticipating costs and compliance with subsections (e) and (f), a minimum annual fee of $1,500 for the first accelerator at the facility plus $500 for each additional unit is established. Additional invoices shall be issued by the Department at regular intervals at least quarterly when net costs are incurred above the minimum annual fee.**

(e) An initial application for a license or reciprocity shall be accompanied by a check payable to the Department in accordance with the fee schedules in subsections (c) and (d). Thereafter, the Department will issue an annual fee invoice in accordance with the appropriate fee schedule at least 2 months prior to the license expiration. Fees are payable by the last day of the license expiration month as shown on the license fee invoice. **This provision is not applicable to full cost recovery licenses specified in Appendix A.**

* * * * *

(h) A radiation-producing machine service provider shall pay an annual registration fee of $100.

APPENDIX A

Fees for Radioactive Material Licenses

Fee Category	*Description*	[Proposed Pa] Annual Fee ($)[1, 2, 3, 4, 7]
1C	**[SNM] Special Nuclear Material** Sealed Source Gauges **[(XRF)] (X-Ray Fluorescence)**	875
1D	**[SNM] Special Nuclear Material**—Other	2,475
2B	Source Material as Shielding	450
2C	Source Material—Other (not 11e2)	8,650
3A1	**[MFR & Distr.] Manufacturing & Distribution** Commercial Broad Scope**—10 CFR** 30, 33	19,875
3A2	**[MFR & Distr.] Manufacturing & Distribution** Commercial Broad Scope—NARM Only	4,000
3B1	**[MFR & Distr.] Manufacturing & Distribution** Commercial Specific **[Lic.] License—10 CFR** 30	4,650
3B2	**[MFR & Distr.] Manufacturing & Distribution** Commercial Specific **[Lic.] License**—NARM Only	2,000
3C1	**[MFR & Distr.] Manufacturing & Distribution** Pharmaceuticals**—10 CFR** 32.72—32.74	11,650
3C2	**[MFR & Distr.] Manufacturing & Distribution** Pharmaceuticals—NARM Only	4,000
3D1	Pharmaceuticals—Distribution Only—**10 CFR** 32.7x	2,825
3D2	Pharmaceuticals—Distribution Only—NARM Only	2,000
3E	Irradiator—Shielded Source	2,575
3F	Irradiator—Unshielded $<$ 10kCi	4,300
3G	Irradiator—Unshielded $\geq$ 10kCi	10,750
3I	**[Distr.] Distribution** As Exempt—No Review of Device	3,525
3J	**[Distr.] Distribution**—SSD Devices to Part 31 GLs	1,550
3K	**[Distr.] Distribution—**No Review-Exempt Sealed Source	1,300
3L1	**[R & D] Research & Development** Broad Scope	8,300
3L2	**[R & D] Research & Development** Broad Scope—NARM Only	2,000
3M1	**[R & D] Research & Development**	3,650
3M2	**[R & D] Research & Development—**NARM Only	750
3N	Services **[Not Leak Test, Waste Disp. Calib.] other than Leak Testing, Waste Disposal or Calibration**	3,875
3O	Radiography	10,850
3P1	Other Byproduct **Material**	1,900
3P2	NARM Licenses not covered elsewhere	750
3Q	**Generally licensed devices under § 217.143 (relating to certain measuring, gauging or controlling devices)**	**315**
4A	Waste Storage, Processing**[,]** or Disposal	FullCost *
4B	Waste Packaging or Repackaging	8,175
4C	Waste Receipt of Prepackaged for Disposal	6,125
5A	Well Logging & Non Field Flood Tracers	7,500
5B	Well Logging Field Flood Tracer Studies	FullCost *
6A	Nuclear Laundry	14,250
7A	Human Use—Teletherapy	11,275
7B1	Human Use—Broad Scope (except Teletherapy)	19,975
7B2	Human Use—Broad Scope (except Teletherapy)—NARM Only	2,000

Fee Category	*Description*	[Proposed Pa] Annual Fee ($)[1, 2, 3, 4, 7]
7C1	Human Use—Specific **License** (except Teletherapy)	4,300
7C2	Human Use—Specific License (except Teletherapy)-NARM Only	750
8A1	**[Civil Defense] Specifically licensed sources used in static eliminators, nonexempt smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses or in temporary (2 years or less) storage**	875
8A2	Specifically licensed NARM sources used in static eliminators, **[non-exempt] nonexempt** smoke detectors, fixed gauges, dew pointers, calibration sources, civil defense uses**[,]** or in **temporary (2 years or less)** storage.	200
14	Decontamination, Decommissioning, **Reclamation or Site** Restoration**[, Special]**	FullCost *
16A	Reciprocity (180 days/year)	900
16B	Reciprocity—NARM (180 days/year)	300
SB1[5]	Small Business—Category 1	2,100
SB2[6]	Small Business—Category 2	400
[PF	**Professional Fees (Hourly Rate) for full cost items**	**$50 perhour]**

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

[2]All fees for NARM licenses will be effective upon publication of the final rules in the *Pennsylvania Bulletin*. The fees for NRC licenses that are transferred to the Commonwealth will be effective on the next license anniversary date. NARM licenses will be changed to the corresponding category of **[by-product] byproduct** material license on the next license anniversary date after achievement of Agreement State status and fees adjusted at that time. The NARM license categories will cease to exist one year after Agreement State status is achieved.

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

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

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

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

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

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

CHAPTER 219. STANDARDS FOR PROTECTION AGAINST RADIATION

Subchapter A. GENERAL PROVISIONS

GENERAL PROVISIONS

§ 219.3. Definitions.

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

Medical reportable event for radiation-producing machine therapy—The administration to a human being, except for an administration resulting from a direct intervention of a patient that could not have been reasonably prevented by the licensee or registrant, that results in one of the following:

* * * * *

(iii) A total dose delivered to the treatment site identi-

fied in a written directive for therapy that **is outside the prescribed dose range or** differs from the total prescribed dose by more than 20%, or for a fractionated dose, when the weekly administered dose differs from the weekly prescribed dose by more than 30%.

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

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

* * * * *

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

§ 219.8. Requirement for a Radiation Safety Committee.

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

Subchapter E. TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

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

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

* * * * *

(2) Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals **specified in the Sealed Source and Device Registry** approved by the Department **[under §§ 217.81—217.93 (Reserved)],** a **[licensing]** state or the NRC**[, except that the maximum interval between leak tests may not exceed 3 years]**.

(3) Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals **specified in the Sealed Source and Device Registry** approved by the Department **[under §§ 217.81—217.93 (Reserved), an agreement state],** a **[licensing]** state or the NRC**[, except that the maximum interval between leak tests may not exceed 3 years]**.

* * * * *

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

* * * * *

(6) Sealed sources, **[except teletherapy and brachytherapy sources,]** which are stored, are not being used, and are identified as in storage. The licensee shall, however, test each of these sealed sources for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer. **[The maximum interval between tests for leakage or contamination may not exceed 3 years.]**

* * * * *

Subchapter M. REPORTS

§ 219.229. Other medical reports.

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

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

§ 220.2. Posting of notices to workers.

* * * * *

(c) Department Form **[ER-BRP-3] 2900-FM-RP0003**, "Notice to Employees," shall be posted by a licensee or registrant as required by this article.

* * * * *

CHAPTER 221. X-RAYS IN THE HEALING ARTS

GENERAL PROVISIONS

§ 221.2. Definitions.

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

* * * * *

Filter—**[aterial] Material placed in the useful beam to [absorb the less penetrating radiation.] modify the spectral energy distribution and flux of the transmitted radiation and preferentially absorb selected radiation**.

Filtration—**[Material placed in the useful beam to absorb the less penetrating radiation.] The amount of material placed in the useful beam to modify the radiation's characteristics, typically expressed in terms of millimeters of aluminum or copper equivalent.**

* * * * *

Half-value layer (HVL)—

(i) The thickness of specified material which attenuates the exposure rate by 1/2 when introduced into the path of a given beam of radiation. **In this definition, the contribution of all scattered radiation, other**

than any which might be present initially in the beam concerned, is deemed to be excluded.

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

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

* * * * *

[*Qualified expert*—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. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the preceding qualifications, 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 Medical Physics; or those having equivalent qualifications.]

* * * * *

ADMINISTRATIVE CONTROLS

§ 221.11. Registrant responsibilities.

(a) The registrant is responsible for directing the operation of X-ray systems under his administrative control and shall **[do the following:**

(1) Assure] assure that the requirements of this article are met in the operation of the X-ray systems.

[(2) 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 operate X-ray systems for diagnostic or therapeutic purposes when employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices.

(3) 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 operate X-ray systems for diagnostic or therapeutic purposes in accordance with written job descriptions and employe qualifications.]

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

* * * * *

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

* * * * *

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

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

* * * * *

(l) The registrant shall have a quality assurance program. This quality assurance program shall be **documented and be** in accordance with guidelines established by the Department or by another appropriate organization recognized by the Department. **At a minimum, the quality assurance program shall address repeat rate; image recording, processing and viewing; and maintenance and modifications to the quality assurance program. Records shall be maintained by the registrant for inspection by the Department for 3 years**. The Department's guidelines and a list of recognized organizations will be maintained and made available on the Department's website and on request.

* * * * *

§ 221.13. Information to be submitted by persons **[proposing] requesting approval** to conduct healing arts screening.

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

(b) A person requesting that the Department approve a healing arts screening program shall submit in writing the following information **[and evaluation] for evaluation by the Department**. If information submitted to

the Department becomes invalid or outdated, the registrant shall immediately notify the Department.

* * * * *

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

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

(7) A description of the diagnostic **[film] X-ray** quality control program.

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

(9) The qualifications of **[an individual] all individuals** who will be operating the X-ray systems.

* * * * *

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

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

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

* * * * *

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

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

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

(11) The provisions for independent institutional review.

* * * * *

DIAGNOSTIC INSTALLATIONS GENERAL REQUIREMENTS

§ 221.25. Beam quality.

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

* * * * *

(*Editor's Note*: The existing Table II which appears at 25 Pa. Code page 221-18, serial page (249290) is deleted and replaced by the following Table II displayed in normal font for clarity.)

Table II

Design operating range (Kilovolts peak)	*Measured potential (Kilovolts peak)*	*Minimum half-value layer (millimeters of aluminum)*	
		*Specified dental systems**	*All other X-ray systems*
Below 51	30	1.5	0.3
	40	1.5	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5

Design operating range (Kilovolts peak)	*Measured potential (Kilovolts peak)*	*Minimum half-value layer (millimeters of aluminum)*	
		*Specified dental systems**	*All other X-ray systems*
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

Note: Half value layers for kilovoltages not listed in Table II may be determined by interpolation or extrapolation.
*** Dental systems manufactured after December 1, 1980 designed for use with intra-oral image receptors.**

(b) Beryllium window tubes shall have a minimum of **[.5] 0.5** millimeter aluminum equivalent filtration permanently installed in the useful beam.

* * * * *

§ 221.29. Kilovoltage (kV) accuracy.

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

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

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

* * * * *

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

* * * * *

§ 221.38a. Entrance exposure rate.

* * * * *

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

* * * * *

OTHER SYSTEMS

§ 221.61. Radiation therapy simulation systems.

[Radiation therapy simulation systems shall comply with §§ 221.35a—221.43a. Radiation therapy simulation systems are exempt from §§ 221.36a, 221.38a, 221.39a and 221.41a if the systems that do not meet the requirements in § 221.41a (relating to fluoroscopic timer) are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.]

(a) Fluoroscopic systems used solely for radiation therapy simulations shall comply with §§ 221.35a, 221.37a, 221.40a and 221.41a. The requirements in § 221.41a (relating to fluoroscopic timer) may also be satisfied if a means is provided to indicate the cumulative time that an individual patient has been exposed to X-rays. In this case, procedures shall require that the timer be reset between examinations.

(b) CT units used solely for therapy simulations shall comply with §§ 221.202(f)(1), (7) and (8) and 221.203.

THERAPEUTIC X-RAY SYSTEMS WITH ENERGIES LESS THAN 1 MEV

§ 221.73. Surveys.

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

* * * * *

§ 221.74. Calibration.

* * * * *

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

* * * * *

§ 221.75. Spot checks.

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

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

* * * * *

COMPUTED TOMOGRAPHY X-RAY SYSTEMS

§ 221.202. Equipment requirements.

* * * * *

(f) **[** ***Beam quality*****. The HVL shall be at least 3.2 millimeters aluminum at 120 kVp.**

(g)] *Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.*

* * * * *

[(h) ***Exemption of CT units used solely for therapy simulations*****. CT units used solely for therapy simulations are exempt from this section and §§ 221.203—221.205.]**

§ 221.204. Radiation measurements and performance evaluations.

(a) *Radiation measurements.*

(1) The CTDI or **[MSDAD] MSAD** along the two axes specified in paragraph (2)(ii) shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry at the point of maximum surface exposure identified. The CT conditions of operation shall be reproducible and correspond to typical values used by the registrant. If the point of maximum surface exposure constantly changes due to system design, then measurements shall be taken at four different locations—top left, top right, bottom left, bottom right—1 centimeter from the outer surface of the phantom.

* * * * *

§ 221.205. Operating procedures.

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

* * * * *

(3) **[The distance in millimeters between the tomographic plane and the reference plane if the reference plane is utilized.**

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

* * * * *

APPENDIX A

DETERMINATION OF COMPETENCE

[The following are areas in which an individual shall have expertise for the competent operation of diagnostic X-ray equipment:

(1) ***Familiarization with equipment.***

(i) Identification of controls.

(ii) Function of each control.

(iii) How to use a technique chart.

(2) ***Radiation Protection.***

(i) Collimation.

(ii) Filtration.

(iii) Gonad shielding and other patient protection devices if used.

(iv) Restriction of X-ray tube radiation to image receptor.

(v) Personnel protection.

(vi) Grids.

(vii) Proper use of personnel dosimetry, if required.

(viii) Understanding units of radiation.

(3) ***Film Processing.***

(i) Film speed as related to patient exposure.

(ii) Film processing parameters.

(iii) Quality assurance program.

(iv) Identification of film artifacts and corrective actions, if necessary.

(v) Identification of adequate film exposure on the resultant radiograph, and corrective actions, if necessary.

(4) ***Procedures.***

(i) Knowledge of anatomy and physiology.

(ii) Knowledge of positioning and radiographic demonstration of the requested anatomy with corrective actions, if necessary.

(5) ***Emergency Procedures.*** **Termination of exposure in event of automatic timing device failure.**

(6) ***Continuing education.*** **Continuing education annually to include radiation protection.]**

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

(1) Basic properties of radiation.

(2) Units of measurement.

(3) Sources of radiation exposure.

(4) Methods of radiation protection.

(5) Biological effects of radiation exposure.

(6) X-ray equipment.

(7) Image recording and processing.

(8) Patient exposure and positioning.

(9) Procedures.

(10) Quality assurance.

(11) Regulations.

CHAPTER 223. VETERINARY MEDICINE

RADIOACTIVE MATERIAL

§ 223.21. In vitro testing.

A veterinarian who uses radioactive material for in vitro testing shall comply with **[§ 217.46 (Reserved)] 10 CFR 31.11 (relating to general license for use of by-product material for certain in vitro clinical or laboratory testing)** but is exempt from **[§§ 219.181—219.186 (Reserved)] 10 CFR Part 20 Subpart K (relating to waste disposal)**.

§ 223.22. Sealed sources.

A veterinarian who uses sealed sources for therapeutic treatment of animals shall comply with **[Chapter 224, Subchapters G—I (Reserved)] 10 CFR Part 35 Sub-**

parts F, G, H, and K but is exempt from **[§§ 224.408 and 224.409 (Reserved)] 10 CFR 35.632—35.645 and 35.2632—35.2645**.

CHAPTER 224. MEDICAL USE OF RADIOACTIVE MATERIAL

Subchapter A. GENERAL

§ 224.10. Incorporation by reference.

* * * * *

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 35.8, **[35.990] 35.4001** and **[35.991] 35.4002** (relating to information collection requirements: OMB approval; violations; and criminal penalties) are not incorporated by reference.

Subchapter B. OTHER REQUIREMENTS

§ 224.21. **[Supervision] (Reserved)**.

[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**, transmission** and reference sources.

Notwithstanding the incorporation by reference of 10 CFR **[Part 35] 35.65 (relating to authorization for calibration, transmission, and reference sources)**, a licensee authorized for medical use radioactive materials may **not** receive, possess **[and] or** use **[sealed sources of radioactive material up to 1,110 MBq (30 mCi) apiece] radium in total quantity of 3.7 MBq (100 µci) or more** for check, calibration, **transmission** and reference use **except as specifically authorized by the Department.**

§ 224.23. Decay-in-storage.

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

CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Subchapter A. GENERAL PROVISIONS

§ 225.1. Purpose and scope.

* * * * *

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

* * * * *

§ 225.4a. Radiation safety program.

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

(b) The registrant shall notify the Department of intended changes to the registrant's radiation safety program and obtain Departmental approval.

Subchapter B. RADIATION-PRODUCING MACHINES

GENERAL ADMINISTRATIVE REQUIREMENTS

§ 225.71. Definitions.

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

* * * * *

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

* * * * *

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

* * * * *

[*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.]

§ 225.73. Training of personnel.

* * * * *

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

GENERAL TECHNICAL REQUIREMENTS

§ 225.82. Operating requirements.

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

* * * * *

§ 225.83. Records required at **[temporary job] field radiography** sites.

Each registrant or licensee conducting radiographic operations at a **[temporary job] field radiography**

site shall maintain and have available for inspection by the Department at that job site, the following records or documents:

* * * * *

RADIATION-PRODUCING MACHINE REQUIREMENTS

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

* * * * *

(d) The registrant shall **[evaluate the cabinet X-ray system to assure compliance with 10 CFR 20.1301 and 21 CFR 1020.40 if the system is a certified cabinet X-ray system. Records of these evaluations shall be maintained for inspection by the Department while the system is in the possession of the registrant or until the evaluation is replaced by an update following modifications.] perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 (relating to dose limits for individual members of the public) and maintain records of these surveys for inspection by the Department for 3 years:**

(1) Upon installation of the equipment.

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

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

* * * * *

§ 225.102. Shielded room X-ray radiography.

* * * * *

(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)] * * *

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

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

§ 225.103. **[Temporary job] Field** site radiography.

* * * * *

CHAPTER 226. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

GENERAL

§ 226.3a. Abandonment of a sealed source.

In addition to incorporation by reference of 10 CFR **[Part 39 (relating to licenses and radiation safety requirements for well logging)] 39.15 and 39.77 (relating to agreement with well owner or operator; and notification of incidents and lost sources; abandonment procedures for irretrievable sources)**, the requirements of § 78.111 (relating to abandonment) shall also be met.

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

ANALYTICAL X-RAY EQUIPMENT

§ 227.11a. Equipment requirements.

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

* * * * *

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

* * * * *

§ 227.12a. Area requirements.

* * * * *

(c) The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in **[§ 219.51 (Reserved)] 10 CFR 20.1301 (relating to dose limits for individual members of the public)**. For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.

* * * * *

§ 227.13a. Operating requirements.

* * * * *

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

§ 227.14. Personnel requirements.

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

* * * * *

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

* * * * *

(c) Reported dose values may not be used for the purpose of determining compliance with **[§ 219.31 (relating to occupational dose limits for adults)] 10 CFR 20.1201 (relating to occupational dose limits for adults)** unless they are evaluated by a qualified expert.

* * * * *

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

GENERAL PROVISIONS

§ 228.2. Definitions.

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

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

* * * * *

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

* * * * *

***Particle accelerator*—See the definition of "accelerator."**

* * * * *

[*Qualified expert*—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. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the preceding qualifications, 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 Medical Physics; or those having equivalent qualifications.]

* * * * *

ADMINISTRATIVE CONTROLS

§ 228.11a. Licensee responsibilities.

(a) A person may not **possess,** operate or permit the operation of an accelerator unless the accelerator and installation meet the applicable requirements of this article.

* * * * *

[(d) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.]

§ 228.12. Information and maintenance record and associated information.

The licensee shall maintain records of surveys, calibrations, maintenance, machine malfunctions and modifications performed on the accelerators, including the names of persons who performed the services. The **[registrant or]** licensee shall keep these records for inspection by the Department for **[4] 5** years.

NOTIFICATION AND LICENSING PROCEDURES

§ 228.21a. Notification and license requirements.

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

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

* * * * *

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

§ 228.23a. Expiration and termination of a license.

* * * * *

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

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

* * * * *

(3) Submit a completed Department Form **[ER-BRP-314] 2900-PM-RP0314**, "Certificate of Disposition of Materials," describing the disposition of materials in paragraph (2).

* * * * *

GENERAL RADIATION SAFETY REQUIREMENTS

§ 228.31a. Limitations.

* * * * *

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

* * * * *

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

* * * * *

§ 228.32a. Shielding and safety design requirements.

(a) The licensee shall consult a qualified expert for **radiation protection concerning** the shielding design of **an** accelerator installation **[and shall have the expert perform a radiation safety survey prior to the first use of the accelerator and when changes are made in shielding operations, equipment or occupancy of adjacent areas].**

(b) An accelerator facility shall have primary and secondary protective barriers that are necessary to assure compliance with **[§ 219.51 (Reserved)] 10 CFR Part 20 Subpart D (relating to dose limits for individual members of the public)**.

§ 228.34a. Accelerator controls and interlock systems.

* * * * *

(b) Entrances into a target room or high radiation areas shall have interlocks that meet the requirements of **[§§ 219.91 and 219.154 (Reserved)] 10 CFR Part 20 Subpart G (relating to control of exposure from external sources in restricted areas) and 10 CFR 20.1902 (relating to posting requirements)**. If the radiation beam is interrupted by a door opening, it shall be possible to reinitiate the radiation exposure only by closing the door first and then by manual action at the control panel.

* * * * *

§ 228.35. Operating procedures.

* * * * *

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

* * * * *

(4) **[Misadministrations] A medical reportable event for radiation-producing machine therapy,** as defined in § **[215.2] 219.3** (relating to definitions), shall be reported as required under § 219.228 (relating to reports of medical reportable events for radiation-**[prodicing] producing** machine therapy **[misadministrations]**).

(5) **[Only auxiliary personnel who have met the applicable radiologic requirements of 49 Pa. Code Part I, Subpart A (relating to occupational affairs) when employed by a licensed practitioner of the healing arts at the location at which the licensed practitioner practices shall be permitted to operate accelerators for therapeutic purposes.**

(6) Only auxiliary personnel employed by a health care facility regulated by the Department of Health, the Department of Public Welfare or the Federal government shall be permitted to operate accelerator systems for therapeutic purposes in accordance with written job descriptions and employe qualifications.

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

§ 228.37. Production of radioactive material.

(a) A licensee who produces radioactive material incidental to the operation of an accelerator shall comply with the general license requirements of § **[217.48 (Reserved)] 217.144 (relating to incidental radioactive material produced by a particle accelerator)**.

(b) A licensee possessing radioactive material intentionally produced by bombarding nonradioactive material with the accelerator beam shall comply with the specific license requirements of **[§§ 217.51—217.57 (Reserved)] Chapter 217 (relating to licensing of radioactive material)**.

§ 228.38. Radiation safety surveys.

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

* * * * *

(d) If the survey required by subsection (a) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by **[§ 219.31 or § 219.51 (Reserved)]**, 10 CFR 20.1201 (relating to occupational dose limits for adults) or 10 CFR 20.1301 (relating to dose limits for individual members of the public), the licensee shall do the following:

* * * * *

§ 228.39. Records.

In addition to the requirements of **[§§ 219.201—219.211 (Reserved)] 10 CFR Part 20, Subpart L (relating to records)**, the licensee shall maintain:

* * * * *

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL AND RESEARCH ACCELERATORS

§ 228.41a. Warning devices.

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(b) A high radiation area shall meet the requirements of **[§ 219.91 (Reserved)] 10 CFR 20.1601 (relating to control of access to high radiation areas).**

§ 228.43. Radiation surveys.

* * * * *

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

(d) Records of surveys shall be kept current and on file at an accelerator facility. Records of surveys shall be maintained as described in **[Chapter 219, Subchapter L (Reserved)] 10 CFR Part 20, Subpart L (relating to records).**

§ 228.44. Ventilation systems.

(a) A licensee shall control the concentration of radioactive material in air to meet the requirements of **[§ 219.34 (Reserved)] 10 CFR 20.1204 (relating to determination of internal exposure)**.

(b) A licensee may not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which does not meet the requirements of **[§ 219.51 (Reserved)] 10 CFR 20.1301 (relating to dose limits for individual members of the public)**. Every reasonable effort shall be made to maintain releases of radioactive material to uncontrolled areas as far below these limits as practicable. Compliance with this section shall be demonstrated as described in **[§ 219.52 (Reserved)] 10 CFR 20.1302 (relating to compliance with dose limits for individual members of the public)**.

RADIATION SAFETY REQUIREMENTS FOR ACCELERATORS USED IN THE HEALING ARTS

§ 228.61. Leakage radiation to the patient area.

(a) New equipment shall meet the following requirements:

* * * * *

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

* * * * *

§ 228.75. Calibrations.

* * * * *

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

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

* * * * *

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

* * * * *

§ 228.76. Spot checks.

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

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

* * * * *

APPENDIX A

DETERMINATION OF COMPETENCE

[The following are areas in which an individual shall have expertise for the competent operation of radiation therapy equipment, the administration of radiation therapy treatment and determination of treatment portals:

(1) *Familiarization with equipment.*

(i) Identification of controls.

(ii) Function of each control.

(2) *Radiation protection.*

(i) Personnel protection.

(ii) Use of shielding blocks.

(iii) Understanding of dose units.

(iv) Grids.

(3) *Film processing.*

(i) Ability to produce quality films for use by a physician.

(ii) Knowledge of portal film exposure factors.

(iii) Film processing parameters.

(4) *Procedures.*

(i) Knowledge of anatomy and physiology.

(ii) Knowledge of patient immobilization devices to allow treatment with minimal patient movement.

(iii) Ability to position patient to allow for treatment of desired area.

(5) *Emergency procedures.*

(i) Termination of treatment in event of machine primary and secondary and dose monitoring system failure.

(ii) Termination of treatment in the event of patient movement during treatment.

(6) *Continuing education.* Continuing education annually to include radiation protection.]

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

(1) Basic properties of radiation.

(2) Units of measurement.

(3) Sources of radiation exposure.

(4) Methods of radiation protection.

(5) Biological effects of radiation exposure.

(6) Medical accelerator operation.

(7) Treatment planning and execution.

(8) Patient positioning and protection.

(9) Operating and emergency procedures.

(10) Quality assurance.

(11) Regulations.

CHAPTER 230. PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

Subchapter A. SCOPE AND DEFINITIONS

§ 230.3. Incorporation by reference.

* * * * *

(b) Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, 71.13(c) and (d), 71.24, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, **[71.47,]** 71.51, 71.52, 71.53, 71.55, 71.59, **71.61,** 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.

CHAPTER 240. RADON CERTIFICATION

Subchapter A. GENERAL PROVISIONS

GENERAL

§ 240.2. Scope.

* * * * *

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

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